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Pharmaceutical Sector Inquiry

Final Report

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PHARMA SECTOR INQUIRY

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GLOSSARY

"Active" in an INN* means that an originator company* sells a product* belonging to that INN*, or has sold the product* in any given period since January 2000.

"API" stands for "active pharmaceutical ingredient".

"ATC" stands for Anatomical Therapeutic Chemical classification, i.e. an international standard for classifying medicines.

"BEUC" stands for the European Consumers' Association (Bureau Européen des Unions de Consommateurs).

"Biopharmaceutical" is defined as a biological medicinal product*, in particular when produced by using biotechnology.

"Biosimilar" is defined as a biological medicinal product* similar to a reference medicinal product* authorised in the Community.

"Blockbuster medicine" is defined as being one which achieves annual revenues of over US\$ 1 billion at global level.

"Community Pharmacies" refers to publicly accessible pharmacies as opposed to hospital pharmacies.

"Country codes" refer to the abbreviations found on the following website: http://www.iso.org/iso/country_codes/iso_3166_code_lists/english_country_names_and_code_elements.htm.

"CPME" stands for Standing Committee of European Doctors.

"Data exclusivity" refers to the period during which the data of the original marketing authorisation holder relating to (pre-) clinical testing is protected. Accordingly, in relation to marketing authorisation applications submitted after 30 October 2005 for the applications filed in the framework of national procedures or 20 November 2005 for applications filed in the framework of the centralised procedure, 'data exclusivity' refers to the eight-year protection period during which generic applicant may not refer to the information of the original marketing authorisation holder and 'marketing exclusivity' refers to the ten-year period after which generic products can be placed on the market. However, in relation to marketing authorisation applications submitted before the above mentioned dates, the wording 'data exclusivity' refers to the six or ten-year protection period granted to the original MA holder before generic applicants can file their applications for marketing authorisation.

"DCP" stands for Decentralised Procedure.

"DDD" is the assumed average maintenance dose per day for a drug used for its main indication in adults.

"Dispute" is understood as every exchange of views between two companies where, in particular, the actual or potential infringement, non-infringement or invalidity of one

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or several patents concerning a specific INN* or R&D pole* has been raised, which, however, did not (yet) end in litigation*.

"DTP" stands for the distribution form: direct to pharmacy.

"E75" stands for a group of INNs* selected by taking, in three Member States (France, Germany and the United Kingdom), the 75 top-selling INNs* that had faced loss of exclusivity* over the period 2000 – 2007. The list of the molecules in each of these three Member States were combined, producing a final list of 128 INNs*.

"EGA" stands for the European Generics Association.

"EFPIA" stands for European Federation of Pharmaceutical Industries and Associations.

"EMA" stands for European Medicines Agency.

"EPC" stands for the European Patent Convention.

"EPO" stands for the European Patent Office.

"EU27/EU27 Member States" refers to the countries that are members of the European Union:

AT = Austria	DE = Germany	NL = Netherlands
BE = Belgium	EL = Greece	PL = Poland
BG = Bulgaria	HU = Hungary	PT = Portugal
CZ = Czech Republic	IE = Ireland	RO = Romania
CY = Cyprus	IT = Italy	SK = Slovakia
DK = Denmark	LV = Latvia	SI = Slovenia
EE = Estonia	LT = Lithuania	ES = Spain
FI = Finland	LU = Luxembourg	SE = Sweden
FR = France	MT = Malta	UK = United Kingdom

For years prior to accession, EU27* stands for those Member States which were already Members of the EU.

"Generic" is defined as a medicinal product* which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as a reference (originator*) medicinal product* and whose bioequivalence with the reference medicinal product* has been demonstrated. If these conditions are met, a generic applicant for marketing authorisation is exempted from the requirement to prove safety and efficacy through pre-clinical tests and clinical trials, and the

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competent authority relies on the proof of safety and efficacy provided by the reference product*. The term "generic*" also includes biosimilars*, unless otherwise specified.¹

"Generic company" is defined as a company that sells generics*.

"INN" is the International Non-proprietary Name for pharmaceutical substances. A combination product and each of the related mono-products are viewed as separate INNs.

"Launch date" is the date a product* is first offered for sale on a market.

"Licensed generic" is defined as a generic* which may be marketed by another company than the originator company* under a licence granted by that originator company*.

"Litigation" / "Litigation procedure" refers to any type of court proceedings or other formal adversarial proceedings (excluding opposition procedures before any patent office). It comprises the litigation* through all instances in a given procedure.

"Loss of data exclusivity" refers to a situation where a pharmaceutical product is no longer subject to data protection.

"Loss of patent protection" refers to a situation where an invention no longer falls under the protection period provided by a patent (including SPC*).

"Loss of exclusivity" ("LoE") is defined as comprising two forms of protection: (1) protection through patents (possibly extended by the so-called Supplementary Protection Certificate "SPC"*) and (2) protection through marketing and data exclusivity*.

"MA" stands for Marketing Authorisation.

"Medicines for human use" refers to all medicines for human consumption.

"MRP" stands for Mutual Recognition Procedure.

¹ An association of biotech companies and an originator company voiced their concerns about the approach by which the Preliminary Report covered generic medicines and biosimilar medicines. They point out that both science and the EU regulatory framework make a difference between the two categories. However, the Preliminary Report did acknowledge throughout the text that there are specific differences between generic versions of molecule-based medicines and biosimilars. For instance, it was clearly explained that the production of biosimilars is more complex and costly due to the fact that the active ingredient is based on live tissue. The Preliminary Report also highlighted that there are special requirements for the approval of biosimilars by EMEA, and the EU legislative framework was reviewed. This distinction has been further reinforced in the Final Report. At the same time it should not be forgotten that biosimilar medicines, like generic versions of molecule-based medicines, are lower-priced versions of an originator medicine and their market entry can be affected by the deployment of the tool-box-instruments.

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"New Chemical Entity" (NCE) refers to a new chemical substance, duly authorised by the competent authority, that has not been previously available for therapeutic use in human beings.

"New Molecular Entity" (NME) refers to a new chemical or biological substance, duly authorised by the competent authority, that has not been previously available for therapeutic use in human beings.

"NPV" stands for Net Present Value.

"Originator" is defined as a novel drug that was under patent protection when launched onto the market.

"Originator company" is defined as a company that sells originators*.

"OTC medicines" refer to medicines that are sold over the counter, i.e. without prescription.

"Own generic" is defined as a generic* version of a particular originator* that is produced and/or marketed by the originator company* of that particular originator*.

"Patent settlement agreement" should be understood as any formal or informal agreement, such as a simple gentlemen's agreement, which settles an actual or potential patent issue, whether it was brought before a court or any other body or settled out of court without engaging in any formal adversarial procedure.

"PCT" stands for Patent Cooperation Treaty.

"Prescription medicines" refers to medicines that cannot be bought without a prescription by a physician.

"Product" refers to an actually marketed product* for which a marketing authorisation has been granted (e.g. different dosages, administration forms).

"R&D" stands for research and development.

"R&D pole" stands for R&D efforts directed towards a certain new product* or technology. An R&D pole* may cover R&D on one or several molecules and molecule combinations.

"RMP" stands for Reference Medicinal Product.

"RMS" stands for Reference Member State.

"SMPC" stands for Summary of Product Characteristics.

"SPC" stands for Supplementary Protection Certificate.

"T50" stands for a group of INNs* containing the 50 top-selling INNs* (whether protected or not) in each of three Member States (France, Germany and the United Kingdom), leading to the identification of a total of 90 INNs*.

PHARMA SECTOR INQUIRY – INTRODUCTION

A. INTRODUCTION

- (1) The pharmaceutical sector is essential for the health of Europe's citizens who need access to innovative, safe and affordable medicines. On average approximately € 430 was spent on medicines in 2007 for each European² and this amount will likely continue to increase as the population in Europe ages. Overall, in 2007, the market for prescription and non-prescription medicines for human use in the EU was worth over € 138 billion ex-factory and € 214 billion at retail prices. Put differently, the pharmaceutical market accounted for close to 2% of annual EU GDP.
- (2) This document contains the Final Report for the pharmaceutical sector inquiry launched by the European Commission on 15 January 2008. A preliminary version was presented to the general public on 28 November 2008 in Brussels. The document sets out the findings of the sector inquiry, summarises the comments received during the public consultation and makes policy recommendations where appropriate.
- (3) The sector inquiry dealt with the alleged obstacles to market entry for prescription medicines for human use. It focused on obstacles for generic products, i.e. products that can enter the market upon loss of exclusivity of the original product (i.e. upon patent expiry, possibly extended by SPC, or expiry of the exclusivity period pursuant to pharmaceutical law³). It also concerned obstacles for innovative products, i.e. obstacles to competition between originator companies. As it is a competition inquiry, it focused on the behaviour of companies. However it is acknowledged that behaviour of companies always takes place against the background of the regulatory environment.
- (4) The results of the sector inquiry suggest that the behaviour of originator companies contribute to the obstacles for generic and originator entry, whilst acknowledging that other factors e.g., the regulatory framework, might also play an important role.

The Wider Context

- (5) This report ties in with other Commission initiatives aimed at providing European patients with safe, effective and *affordable medicines* while at the same time creating a business environment that stimulates research, boosts valuable innovation and supports the competitiveness of the industry.⁴
- (6) The report is part of well-established Commission policies and initiatives relevant to the pharmaceutical sector including the Lisbon Strategy, the Commission's Industrial

² € 430 is an average amount. There are significant variations across Member States and citizens. Expenditure varies over the life cycle of a person.

³ For details on the marketing authorisation rules including the exclusivity provisions, see chapter B.2.2.

⁴ See, further to the above, the High Level Pharmaceutical Forum (http://ec.europa.eu/pharmaforum/docs/final_conclusions_en.pdf), as well as the ongoing market monitoring reviews.

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Property Rights Strategy⁵, the Communication on a Renewed Vision of the Pharmaceutical Sector⁶ and the Innovative Medicines Initiative⁷. It should also be viewed in parallel with the Commission's regulatory activities addressing, in particular, the safety, quality and efficacy of medicines⁸, the transparency of national pricing and reimbursement procedures⁹ and the protection of intellectual property rights¹⁰. Indeed, given the importance of the pharmaceutical industry for economic growth and employment, as well as its role for public health, the Commission is committed to pursuing policies that create an environment conducive to ensuring the viability of this sector.

- (7) The sector inquiry supports and complements these initiatives as it provides essential information about bottlenecks that delay or block innovation or access to affordable medicines.

The Key Role of Innovation

- (8) Innovation is of key importance for the pharmaceutical sector. Innovation in human medicines has enabled patients to benefit from treatments that were unimaginable a few decades ago. Moreover, the lack of adequate treatment for many diseases requires continuous innovative efforts in order to find new medicines. Without the very significant R&D efforts of originator companies and other stakeholders (e.g. universities) these benefits would not be possible.
- (9) Intellectual property rights are a key element in the promotion of innovation. The protection of intellectual property rights is important for all sectors of economic life and is paramount to Europe's competitiveness. However, it is particularly important for the pharmaceutical sector because of the necessity to address current and emerging health problems and the long life cycle of products (including long development periods). The pharmaceutical sector in the EU indeed has one of the highest investments in R&D in Europe and relies significantly on intellectual property rights to

⁵ Commission Communication of 16 July 2008 on an Industrial Property Rights Strategy for Europe, COM(2008)465 final.

⁶ See, in particular, Commission Communication of 10 December 2008 (COM (2008) 666 of 10.12.2008: Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector).

⁷ The Innovative Medicines Initiative is a Public-Private Partnership (PPP) between the pharmaceutical industry represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Communities represented by the European Commission. See: http://imi.europa.eu/index_en.html.

⁸ See, for instance, Regulation (EC) No 726/2004 and Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC.

⁹ Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems.

¹⁰ See footnotes 1 and 5.

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protect innovation. The exclusivity periods granted through patent law and other mechanisms (SPC, data exclusivity) provide incentives to originator companies to continue innovating.

- (10) The Commission, which is committed to the promotion of innovation through industrial property rights, including patents, as stated in the 2007 Patent Communication¹¹ and the above mentioned 2008 Industrial Property Rights Strategy Communication, underlines the need for high quality patents granted in efficient and affordable procedures and providing all stakeholders with the required legal certainty.

The Need to Keep Public Budgets under Control

- (11) At the same time, it is generally acknowledged that public budgets, including those dedicated to cover health expenditure, are under significant constraints. Competition, in particular competition provided by generic medicines, is essential to keep public budgets under control and to maintain widespread access to medicines to the benefit of consumers/patients.
- (12) In this context the Final Conclusions and Recommendations of the High Level Pharmaceutical Forum¹² welcomed the shared understanding among stakeholders that pricing and reimbursement policies need to ensure a.o. control of pharmaceutical expenditure for Member States. In this respect it was acknowledged that generic medicines provide an opportunity to obtain similar treatments at lower costs for patients and payers, while liberating budgets for financing new innovative medicines.¹³ As stated in the Communication on a Renewed Vision of the Pharmaceutical Sector¹⁴, "[m]any Member States recognise that generic medicines play an important role in helping to limit their healthcare expenditure in their reimbursement and prescribing practices. Competition with off-patent products enables sustainable treatment of more patients with less financial resources. The generated savings create financial headroom for innovative medicines. All actors should therefore ensure that generics can enter the market after expiry of patent and data exclusivity protections and compete effectively."
- (13) In particular generic medicines should reach the market without unnecessary or unjustified delay. Member States that want to fully benefit from the potential budget savings brought about by generic products also need to reflect about policies that facilitate speedy generic uptake in volume terms and effective price competition among generic producers.

¹¹ Commission Communication « Enhancing the patent system in Europe », COM(2007)165 final.

¹² http://ec.europa.eu/pharmaforum/docs/final_conclusions_en.pdf.

¹³ High Level Pharmaceutical Forum: Guiding principles for good practices implementing a pricing and reimbursement policy (http://ec.europa.eu/pharmaforum/docs/pricing_principles_en.pdf).

¹⁴ Commission Communication of 10 December 2008 (COM (2008) 666 of 10.12.2008: Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector).

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Scope of the Inquiry

- (14) Given the importance of a well-functioning pharmaceutical sector and the presence of certain indications that competition in the pharmaceutical market in the European Union might not be working well, the Commission launched a sector inquiry into pharmaceuticals on 15 January 2008.¹⁵ In particular, the inquiry sought to examine the reasons for observed delays in the entry of generic medicines to the market and the apparent decline in innovation as measured by the number of new medicines coming to the market. Sector inquiries allow the Commission to gather information for giving effect to Articles 81 and 82 of the EC Treaty.
- (15) Taking into account that sector inquiries are a tool under EC competition law¹⁶, the inquiry's main focus is company behaviour. The inquiry concentrates on those practices which companies may use to block or delay generic competition as well as to block or delay the development of competing originator products. The primary focus of the inquiry is thus the competitive relationship between originator and generic companies and amongst originator companies. To this end the Commission selected 43 originator companies and 27 generic companies for in depth analysis. They represent 80 % of the relevant turnover in the EU and are typically larger scale companies active in more than one Member State.¹⁷
- (16) As the industry is strongly regulated and the behaviour of the company needs to be assessed in the context of the existing regulatory framework, the sector inquiry also looked in broad terms at aspects of the regulatory framework, its implementation and alleged shortcomings reported by stakeholders. In this respect it concentrated on the legislation governing patents, marketing authorisations and pricing and reimbursement.
- (17) *Product scope:* The inquiry concerns prescription medicines for human use. Medicines sold over the counter (OTC), medicines for animal use and medical devices and health services are not subject to the inquiry. A sample of 219 substances was selected for the in-depth investigation. The selected molecules accounted for nearly 50% of the overall turnover of prescription medicines in the EU in 2007.

¹⁵ Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No 1/2003 (Case No COMP/D2/39.514).

¹⁶ Art. 17 (1) 1st paragraph of Council Regulation 1/2003 reads: "Where the trend of trade between Member States, the rigidity of prices or other circumstances suggest that competition may be restricted or distorted within the common market, the Commission may conduct its inquiry into a particular sector of the economy or into a particular type of agreements across various sectors. In the course of that inquiry, the Commission may request the undertakings or associations of undertakings concerned to supply the information necessary for giving effect to Articles 81 and 82 of the Treaty and may carry out any inspections necessary for that purpose."

¹⁷ For further details on the methodology see the Annexes to Chapter A, which also set out how the Commission services dealt with the issue that not all companies were able to provide complete information for all the years covered by the inquiry.

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- (18) *Geographic scope:* The geographic scope of the inquiry is the 27 Member States currently forming part of the European Union. For certain sections the analysis was limited to a more narrow selection of Member States. A comparison with other geographic regions was only possible to a limited extent. This also implies that the inquiry and its findings have mainly relevance for the EU and, as such, its findings cannot be extrapolated to other areas of the world with diverging regulatory regimes, e.g. on intellectual property rights.
- (19) *Time scope:* The period of inquiry is 2000 to 2007, but for certain sections updates up to June 2008 were requested. It has to be kept in mind that during this period a number of changes occurred, such as the enlargement of the European Union to 25 and later to 27 Member States. Moreover significant changes in the pharmaceutical regulatory framework entered into force in 2005, which had a.o. the objective to facilitate generic entry¹⁸, e.g. the introduction of the so called Bolar¹⁹ provision. Some of the new rules (namely the new harmonised rules on data and marketing exclusivity) will only take effect in practice in 2013 as the new periods of protection apply to originator products applied for and authorised after the coming into effect of these rules in 2005.²⁰
- (20) *Terminology:* In order to fully capture the competitive process from a commercial perspective, the report makes use of the industries' terminology and concepts to describe certain types of patents, products and related strategies. It is underlined that these terms and concepts are not defined in patent legislation. By using them in the context of the inquiry it is not intended to suggest that these terms and concepts should be relevant under patent law. With the same token no negative connotations, in particular with regard to terms like "primary"/"secondary" patents, "defensive patenting" and "patent clusters" or "patent thickets" is intended, as applications are to be evaluated on the basis on the statutory patentability criteria (i.e. novelty, inventive step and industrial applicability), and this is irrespective of the stage in which applications are made, the intent of applicants in applying for patent rights or how the patents are addressed in the company's internal strategy documents. The notion of "secondary patent" should therefore not be understood to mean that these patents are of a lower quality or value, but merely that – from a time perspective – they follow the primary patent. As regards defensive patenting, it is an inherent feature of a patent system to grant exclusive rights. The notion of "defensive patents" should therefore not be understood to mean that these patents are of a lower quality or value, but it tries to

¹⁸ See, for instance, Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC.

¹⁹ Article 10 (6) of Directive 2001/83/EC as amended by Directive 2004/27/EC: this provision was to be transposed by Member States by 31 October 2005. Prior to the introduction of the Bolar provision in the EU regulatory framework, pre-patent-expiry development was not regulated at EU level. Consequently, generic manufacturers carried out their product development and related testing in countries where the basic patent had already expired or where such protection did not exist, outside the EU or in European countries where a Bolar-type provision existed or in EU Member States where experimental work was in certain cases permitted (see Chapter B.2.2.1.)

²⁰ For further details, see Chapter B.2.2.

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capture a classification made in industry for this type of patents from a commercial perspective.

- (21) *Issues only partly covered or not covered:* In line with the opening decision the inquiry does not address in detail potential shortcomings in the distribution chain, which is currently subject to a market monitoring exercise.²¹ Nor does it address barriers to parallel trade in the pharmaceutical sector.²² Competition between generic companies, which broadly speaking takes place on the basis of price, was not in the focus of the sector inquiry, as any price fixing and/or market allocation agreements between competitors would be caught by Art. 81 EC and the inquiry was - under the present circumstances – not deemed to be the adequate tool to analyse potential shortcomings in this part of the market. However, national policies that have an impact on generic uptake and prices are analysed in the report. Finally, as the legal basis for launching a sector inquiry is EC competition law, the sector inquiry did not analyse which other important factors – apart from company behaviour – could have contributed to a decline in innovation as measured by less novel medicines reaching the market. Reasons given by the industry include increased scientific complexities, high attrition rates in late state development due to regulatory risk aversion and uncertainty about financial awards. The Commission is analysing these issues in the above-mentioned market monitoring exercise that is currently ongoing.²³
- (22) *Competition law guidance:* It is important to underline that – whilst the report primarily analyses company behaviour – it does not identify individual cases of wrongdoing or provide any guidance on the compatibility of the practices examined with the EC competition rules.²⁴ It provides the Commission however with relevant context and a factual basis for deciding whether and what further action is needed, including enforcement action.

²¹ See Commission Staff Working Document on 'Market Monitoring: State of Play and Envisaged Follow-Up', at: http://ec.europa.eu/economy_finance/publications/publication13688_en.pdf (see in particular Section 4 par. 5 on monitoring the retail sector); Commission Staff Working Document on 'The Single Market Review: one year on', at: http://ec.europa.eu/internal_market/strategy/docs/smr_oneyear_en.pdf (see in particular p. 11 par. 3 and the following box on market monitoring as part of the follow-up to the 2007 Single Market Review).

²² See on the application of competition law to parallel trade in the pharmaceutical sector the judgment of the ECJ of 16 September 2008 (Joined Cases C-468/06, C-469/06, C-470/06, C-471/06, C-472/06, C-473/06, C-474/06, C-475/06, C-476/06, C-477/06, C-478/06 Sot. Lélos kai Sia). See also pending Case C-501/06 P GlaxoSmithKline Services v Commission.

²³ Commission Staff Working Document on: 'The Single Market Review: one year on', at: http://ec.europa.eu/internal_market/strategy/docs/smr_oneyear_en.pdf (see in particular p. 11 par. 3 and the following box on market monitoring as part of the follow-up to the 2007 Single Market Review).

²⁴ For further details see Annex EC Competition law (Annexes to Chapter A).

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Issues under in Depth Investigation

- (23) As indicated above, the sector inquiry mainly focused on two issues: (1) Are there obstacles to market entry for generic companies caused by practices of originator companies? and (2) are there obstacles to market entry for originator companies caused by practices of competing originator companies? It also reports about alleged shortcomings in the implementation of the regulatory system by the respondents as well as certain ideas of how they could be addressed in the future.
- (24) With respect to the first issue (obstacles to generic entry), the investigation focused in particular on all patent and product life cycle strategies of originator companies and their implementation. Practically all originator companies subject to this inquiry have developed a tool-box – a term used by the industry – of instruments and measures for how to prepare for and react to generic entry. Issues that are addressed in more detail in this report include:
- patenting activities of originators,
 - contacts, disputes and litigations between originator and generic companies,
 - opposition procedures and appeals before patent offices,
 - patent settlements and other agreements between originator and generic companies,
 - interventions of originator companies before national authorities deciding on marketing authorisation, pricing and reimbursement of generic products,
 - promotional activities, and
 - second generation products.
- (25) A separate section shows how these issues are interlinked and may be used by companies in cumulative ways. The report also contains an empirical analysis of the conditions under which generic entry can be expected to occur and what its economic effects are.
- (26) As to be expected, generic entry appears to focus on products with a high turnover (including so-called blockbusters, which generate an annual turnover of more than US\$ 1 billion at global level). On the other hand, the revenues from these products are often the backbone of many originator companies, which they aim to defend. Delays in the market entry of such high turnover products thus need to be looked at with particular interest.
- (27) With respect to the second issue (relationship between originator companies), the sector inquiry investigated in particular the patent strategies of companies, contacts, disputes and litigation between originator companies, opposition procedures before patent offices and (settlement) agreements between them.

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Steps of the Inquiry

- (28) Following the launch of the inquiry²⁵ the Commission services carried out upfront inspections²⁶ and gathered data and other information on the basis of requests for information from a wide range of stakeholders, most prominently from the selected originator and generic companies.
- (29) The Commission also consulted widely with stakeholders such as industry associations, representatives of consumers and patients, insurance companies, associations of doctors, pharmacists and hospitals, the European Patent Office (EPO) and national patent offices, national competition authorities, and other national authorities.
- (30) Overall the Commission received very good cooperation from all stakeholders. In this light, it is probably fair to say that the sector inquiry is one of the most thorough investigations of the European pharmaceutical sector, in particular as regards commercial practices of originator companies.
- (31) In November 2008 – outside the scope of the Sector Inquiry, but inspired by its preliminary findings – the Commission carried out additional surprise inspections at several companies in different Member States. At the time of the publication of this report these investigations are ongoing.
- (32) The Commission presented its Preliminary Report on the pharmaceutical sector inquiry²⁷ on 28 November 2008. It reached the preliminary conclusion that behaviour and practices of the originator industry contributed to generic delay as well as to the difficulties in innovation while pointing to the existence of other possible factors, such as regulation in the sector.
- (33) In the framework of the public consultation on the report, more than 70 submissions from interested parties were received.²⁸ Stakeholder responses in summary are:
- (34) *Consumer representatives, the generic industry and the health insurers sector* underline the uniqueness of the report and submit that the findings confirm their concerns that generic entry is not occurring as quickly as it should and that less novel medicines reach the market addressing unmet patients' needs. They called for urgent action to remedy the problems highlighted in the preliminary report.

²⁵ Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No 1/2003 (Case No COMP/D2/39.514).

²⁶ The inspections brought to light documents that could not have been gathered otherwise (e.g. through information requests), e.g. on the implementation of certain strategies in individual cases. They contained very valuable information for the purpose of the inquiry as evidenced by the quotes used in this report.

²⁷ Pharmaceutical Sector Inquiry, Preliminary Report, DG Competition Staff Working Paper, 28.11.2008.

²⁸ The non-confidential versions of these responses are available at: http://ec.europa.eu/competition/consultations/2009_pharma/index.html.

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- (35) *Originator industry* representatives, partly supported by representatives of law firms and patent attorneys, by numbers the largest amount of submissions, argue that the Preliminary Report does not provide evidence that companies' practices hinder innovation, which leads to a decline in innovation. They also suggest that delays to generic entry cannot be attributed to the behaviour of originator companies, but consider factors related to the regulatory framework to be most important for delays. They finally suggest that the Commission should investigate other shortcomings in the market, e.g. the alleged lack of competition between generic companies.
- (36) The *European Patent Office* provided input on the functioning of the European patent system and draws attention to the line between IP law and competition law as drawn by the ECJ. In particular, it argued against a scrutiny of the intent of applicants in applying for patent rights for purposes of competition law.
- (37) Despite the differences in views on some of the findings set out in the Preliminary Report, there was broad consensus among stakeholders on the need to establish a Community patent and for a unified specialised patent litigation system in Europe.
- (38) All comments were carefully considered and changes were incorporated in the Final Report to the extent appropriate. The Final Report, which now consists of the Commission Communication and this technical annex, summarises the main findings and contains the main conclusions. The communication was adopted by the Commission on 8 July 2009. In the light of the findings, the Commission intends to take action where deemed appropriate.

PHARMA SECTOR INQUIRY – MARKET CHARACTERISTICS AND STRUCTURE OF THE PHARMACEUTICAL SECTOR

B. MARKET CHARACTERISTICS AND STRUCTURE OF THE PHARMACEUTICAL SECTOR

- (39) The structure of the pharmaceutical sector is unique. It is characterised by a great variety of stakeholders, significant involvement of the State and a high degree of regulation aimed at achieving different objectives. These objectives range from supporting innovation to ensuring a high degree of public health and keeping public expenditure under control. The sector itself is R&D-driven and continued innovation is only possible when the protection of intellectual property rights (primarily patents) is adequately ensured.
- (40) Before presenting the main findings of the sector inquiry (Chapter C of this report), a general overview of the sector is given. The first section describes the main market features, namely the role of the most important stakeholders and the life cycle of a pharmaceutical product. The subsequent section describes the main regulatory framework governing patents, marketing authorisations and pricing/reimbursement mechanisms. This is done in order to facilitate the understanding of the subsequent parts of the report.

1. Main Market Features

- (41) Total health spending (public and private) varies widely across EU Member States mainly because of the differences in the national health systems. It ranges from approximately 6% of GDP in Poland to around 11% in France and is significantly lower than in the USA (15%).²⁹
- (42) During the past decades, health care spending has increased, despite continuous efforts to contain costs. Pharmaceuticals have been a key factor driving the growth in health care expenditures. Since 1995, spending on pharmaceuticals has increased faster than total health spending in OECD countries. In 2006 pharmaceutical spending accounted for 17% of health spending in the OECD. Today, pharmaceutical spending is the third largest component in health care spending after hospitals and ambulatory care.³⁰
- (43) In 2007, the total size of the pharmaceutical market in the EU was € 138 billion³¹ on an ex-factory basis, which is almost one third of the global turnover (see figure below for a breakdown per Member State). It includes prescription and non-prescription medicines for human use. The breakdown per Member States (see figure below)

²⁹ See the paper "Some key features of growth and cross-country differences in health-care spending" presented on 17.9.2008 at the joint conference by the EU and the OECD, p. 9.
<http://ec.europa.eu/social/main.jsp?catId=443&langId=en&eventsId=106&furtherEvents=yes>

³⁰ See the paper "Some key features of growth and cross-country differences in health-care spending" presented at the joint conference by the EU and the OECD, pp. 5-7.
<http://ec.europa.eu/social/main.jsp?catId=443&langId=en&eventsId=106&furtherEvents=yes>

³¹ Including hospital and retail sales.

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indicates that the five biggest national markets (France, Germany, Italy, United Kingdom and Spain) account for 73% of the total EU market (ex-factory). As indicated above, at retail level, the total size of the market for the same period was € 214 billion³². Therefore, the pharmaceutical market accounted for close to 2% of annual EU GDP. This corresponds to an annual amount of approximately € 430 for every European citizen.³³

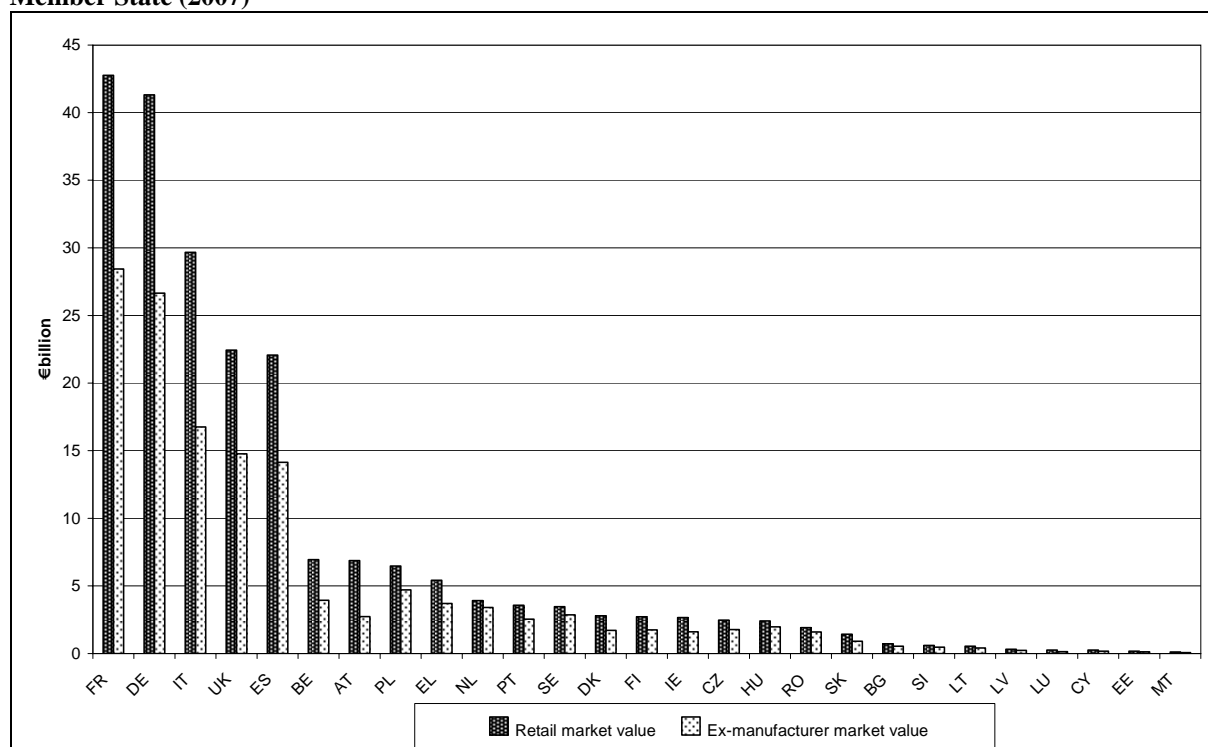
- (44) Concerning pharmaceuticals available only upon prescription, the turnover on an ex-factory level generated in the EU in 2007 amounts to € 122 billion. Thereof, the originator and generic companies included in the sector inquiry account for a turnover of € 98 billion, which is 81% of the EU market. The 219 molecules selected for the analysis in the sector inquiry account for € 57 billion, i.e. 47% of the overall turnover of prescription medicines in the EU in 2007.

³² Including hospital and retail sales and prescription and non-prescription medicines.

³³ The significant difference between the value of the pharmaceutical market in retail compared to ex-factory prices point at possible efficiency gains to be made by improving the efficiency of the distribution chain. The distribution chain for pharmaceuticals is not in the focus of the sector inquiry, but these issues are followed in the context of the Retail Market Monitoring by DG MARKT.

PHARMA SECTOR INQUIRY – MARKET CHARACTERISTICS AND STRUCTURE OF THE PHARMACEUTICAL SECTOR

Figure 1: Annual sales of prescription and non-prescription medicines (ex-factory and retail prices) per Member State (2007)³⁴



Source: Pharmaceutical Sector Inquiry (based on IMS data)³⁵

Note: Figures for Cyprus and Malta are based on EFPIA (2006).

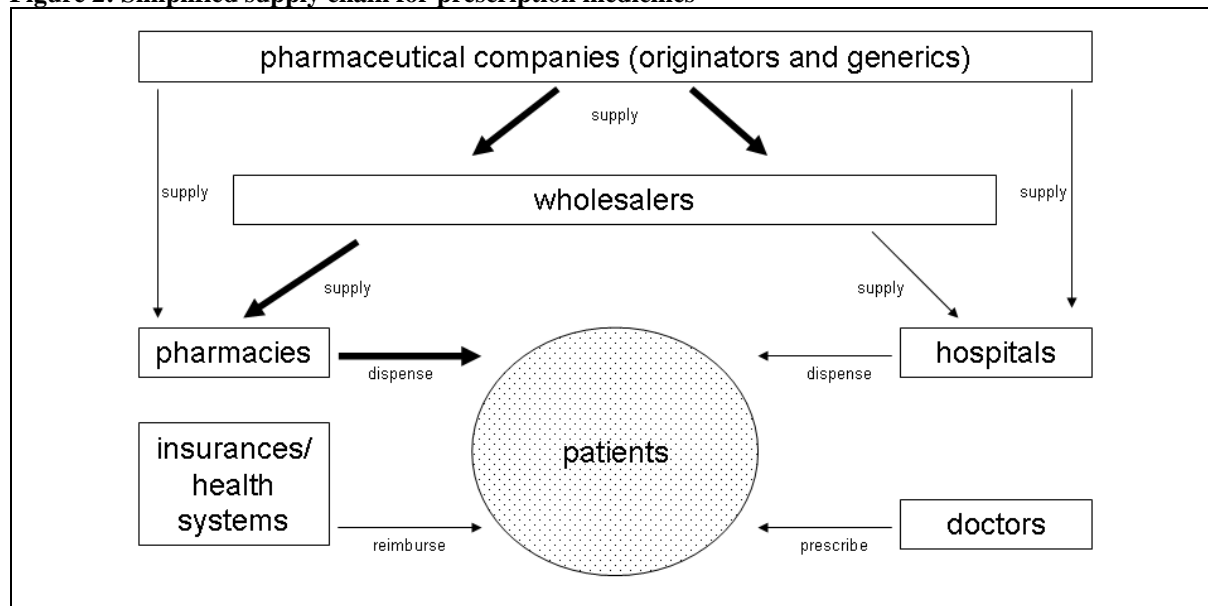
(45) Figure 2 shows the simplified supply chain for a prescription medicine from production by pharmaceutical companies to consumption by patients. While differences exist between Member States, the basic features are identical throughout Europe. The main supply channel (indicated by bold arrows) runs from the pharmaceutical company through wholesalers and pharmacies to the patients (retail sale). In general, medicines are prescribed by medical doctors and reimbursed by the insurance or health system.

³⁴ Please note that unless otherwise stated, the turnover figures reported in Chapter B are expressed at ex-factory level.

³⁵ Data and other information from IMS Health (IMS), a provider of pharmaceutical data services, which are cited or used in this Report (including in empirical analyses performed by the Commission) were obtained by the Commission pursuant to Article 18 of Council Regulation 1/2003. IMS has not acted as an advisor, expert, or consultant in connection with this report or, more generally, in connection with the inquiry. Further references to IMS in this report should be understood in the same way.

PHARMA SECTOR INQUIRY – MARKET CHARACTERISTICS AND STRUCTURE OF THE PHARMACEUTICAL SECTOR

Figure 2: Simplified supply chain for prescription medicines



Source: Pharmaceutical Sector Inquiry

Note: In certain national health systems, the patients do not pay for the medicines they receive. Instead, the insurances/health systems reimburse doctors, hospitals and pharmacies directly.

- (46) Apart from the retail chain described (pharmaceutical companies, wholesalers, pharmacies, patients), medicines can also be dispensed to patients by hospitals. As far as distribution is concerned a distinction must be made between sales to hospitals and sales to pharmacies via wholesalers (retail distribution). Hospitals more often buy directly from pharmaceutical companies, e.g. following a tender process, but they also buy part of their requirements via wholesalers. According to the data provided by the respondent companies, in the EU, the retail segment was the main source of income for most pharmaceutical companies. In 2007, the turnover from prescription medicines obtained through the retail channel was approximately three times the turnover generated through the hospital channel.

1.1. Main Structure

1.1.1. The Supply Side

- (47) On the supply side, the sector is characterised primarily by two types of companies. The first type consists of R&D-based companies (subsequently called "originator companies"), which can range from very large multinationals to SMEs concentrating on certain niche products. These companies carry out research into new pharmaceuticals, develop them from the laboratory to marketing authorisation and sell them on the market. Their products are largely patent-protected.
- (48) The second type of company is generally referred to as a "generic company". They produce and sell pharmaceutical products which have lost their exclusivity status (for a definition see box below). These generic products contain the same active pharmaceutical ingredients (APIs) and can therefore be used for the same treatments. However, the products are generally sold at a much lower price than the original product, which helps contain public health budgets.

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Box: Loss of exclusivity

The term "Loss of exclusivity" (LoE) as used in this report comprises two forms of protection: (1) protection through patents (possibly extended by the so-called Supplementary Protection Certificate, "SPC"), and (2) protection through marketing and data exclusivity. The different types of protection will be explained in more detail in subsequent chapters.

- (49) Both types of companies sometimes buy active pharmaceutical ingredients (APIs) from specialised companies (upstream activity) unless they produce the APIs themselves. Generic and originator companies both have to deal with a variety of government agencies, including patent offices, in Europe most prominently the European Patent Office (EPO), and marketing authorisation offices, be it at national or European level.³⁶
- (50) The subsequent sections focus on the activities of originator and generic companies surrounding prescription medicines for human use (as opposed to non-prescription, also referred to as over the counter (OTC) products, veterinary products or medical devices).

1.1.2. Originator Companies

- (51) Originator companies are active in R&D, manufacturing and marketing patented medicines. Their business model is based on research into, and the development of, new chemical entities (NCEs) and the incremental improvement of others already on the market.³⁷
- (52) In addition to the development of NCEs, some 60% of the respondent originator companies are active or intend to become involved in research into and production of biopharmaceuticals in the immediate future.
- (53) The main focus of activity reported by originator companies is on reaching unmet medical needs by bringing new prescription medicines to the market. For most of the originator companies, activities performed in-house range from the discovery of new compounds to life cycle management before or after patent expiry. In between, they are involved in research and development, promotion and sales of their pharmaceutical products. They carry out this wide range of activities alone or in collaboration with other companies or entities of various types such as universities and research institutes. The collaboration can take a number of forms, including joint-research and licensing agreements, co-development and co-marketing agreements, co-promotion and joint

³⁶ Traditionally the business models of originator and generic companies were considered mutually exclusive, although in recent times a trend can be observed whereby originator companies are acquiring generic companies and generic companies are becoming active in research.

³⁷ Pharmaceutical companies are among the higher investors in R&D in the EU. For information on R&D investment levels, please see 'The 2008 EU Industrial R&D Investment Scoreboard' available at http://iri.jrc.ec.europa.eu/research/scoreboard_2008.htm

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ventures.³⁸ At least large originator companies have their own sales and marketing networks.

- (54) Most of the originator companies consulted as part of the inquiry have a world-wide presence, with different departments located in different regions. These are real multinational companies acting in a global environment. Typically, strategic business decisions with regard to R&D projects are made at a global level while marketing and distribution decisions are rather taken at local level.
- (55) In addition to large originator companies there are numerous SMEs, which typically lack the resources required to conduct all necessary steps from basic research to the marketing and distribution of the finished product. SMEs in the pharmaceutical sector, therefore, tend to specialise in innovation in a well-defined and narrow field (niche), for example focusing on specific indications or pharmaceutical formulations. These SMEs either decide to out-license or sell their innovations to larger companies who have the resources to conduct clinical trials and the necessary marketing. Large pharmaceutical companies are increasingly in-licensing new products.³⁹ Currently 25% of the molecules in clinical development have been acquired from other companies, including SMEs. This is confirmed by the findings of the sector inquiry and shows the importance of SMEs for maintaining the innovative character of the pharmaceutical sector.⁴⁰
- (56) A further category of originator companies are biopharmaceutical companies.⁴¹ The business structure and size of the average biopharmaceutical company is generally different from that of the respondent originator companies. Biopharmaceutical companies tend to be small and medium sized businesses. Most biotechnology companies are young companies developing their first products and depend on investor capital for survival. Nevertheless, as indicated above, biotechnology is a highly attractive sector for big originators and many of the originator companies report that they are already active or intend to become involved in biopharmaceuticals in the future. Biotechnology is one of the most research-intensive industries in the world. It has been submitted by one stakeholder during the public consultation that biopharmaceutical companies spend approximately 40% of their turnover on R&D.
- (57) While the sector inquiry gathered information on activity in the biopharmaceutical area, this is not the main focus of the report, as patents on many of these products generally have some years left before LoE.

³⁸ For a description of the most common types of agreements among originator companies, please see Chapter C.3.4.

³⁹ This is also confirmed by the OECD report "Patents, Innovation and Economic Performance" (2004), p. 96

⁴⁰ SMEs and large pharmaceutical companies are mutually depending on collaboration between each other.

⁴¹ The biotechnology industry emerged in the 1970s, based mainly on a new recombinant DNA technique. Recombinant DNA is a method of producing proteins such as human insulin and other therapies in cultured cells under controlled manufacturing conditions.

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- (58) Leaving competition from generic companies and parallel trade aside, competition between originator companies appears to take two main forms. First, direct competition between patented products of two or more originator companies prescribed for the same treatment can exist as long as there is a degree of substitutability between products in terms of belonging to the same therapeutic area (also referred to as "competition *in the market*"). Here, an important parameter for competition is the relative efficacy and absence of side-effects of a medicinal product. Moreover, marketing and promotional activities are said to play a significant role. Depending on the national pricing and reimbursement system there might also be a certain degree of competition on prices.
- (59) Secondly, and more importantly, there is – over a longer time – competition through innovation in order to bring a patented product with limited substitutability to the market. Such patented products are essential for generating profit because they give an originator company the opportunity to reap the benefits during the exclusivity period. The need to innovate translates into a competition to be the first to discover and patent new molecules suitable to be developed into pharmaceutical products which are eventually launched onto the market.
- (60) The respondent originator companies are also large employers. Globally they employed some 1,150,500 people of which 180,000 were working in R&D for prescription medicines in 2007. The originator respondent companies employed alone approximately 360,000 staff in the EU in 2007. Nearly 60,000 were working in R&D for prescription medicine. As regards biopharmaceutical companies, according to data provided in the course of the public consultation, in 2007, there were 1,744 biopharmaceutical companies in Europe, the vast majority of which were in 13 Member States. Altogether, they had 81,947 employees⁴².

1.1.2.1. The Largest Originator Companies

- (61) Analysis of the information provided by the companies consulted as part of the sector inquiry focuses on prescription medicines. This segment constitutes on average approximately 80% of the turnover of the originator companies consulted.
- (62) The table below provides a ranking of the ten originator companies (selected from the total number of companies covered by the sector inquiry) with the highest turnover in the EU27 in 2007 in prescription medicines. The table also provides the turnover obtained in the USA and at global level for the same period as well as the EU market share in relation to the global market.

⁴² Some of these employees are, of course, also part of the staff of the originator companies in the sample.

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Table 1: Largest originator companies in the EU by turnover in prescription medicines (2007)

Company	Rank	Turnover EU (€ thousand)	Turnover USA (€ thousand)	Turnover global (€ thousand)	Share EU/global
Sanofi-Aventis	1	11,064,138	9,474,424	28,051,716	39%
Glaxo-Smith-Kline	2	8,189,486	13,513,760	28,032,381	29%
Pfizer*	3	8,004,675	15,589,595	32,433,183	25%
Hoffmann LaRoche	4	6,981,780	9,009,986	22,391,735	31%
Astra-Zeneca	5	6,260,463	8,400,802	19,819,190	31%
Novartis	6	5,463,289	6,473,219	17,530,229	31%
Wyeth*	7	3,332,506	6,159,070	11,590,479	29%
Johnson & Johnson	8	3,309,067	11,385,274	18,027,103	18%
Eli Lilly	9	3,201,487	7,016,469	12,869,539	25%
Abbott	10	2,845,826	5,695,479	10,878,652	26%
Total		58,652,717	92,718,078	201,696,207	29%

Source: Pharmaceutical Sector Inquiry

* On 26 January 2009 Pfizer and Wyeth⁴³ announced the conclusion of a merger agreement creating the largest pharmaceutical company in the world. The Swiss-based company Hoffmann LaRoche has also announced the takeover of the complete American biotech company Genentech.⁴⁴ These transactions will slightly modify the above ranking.

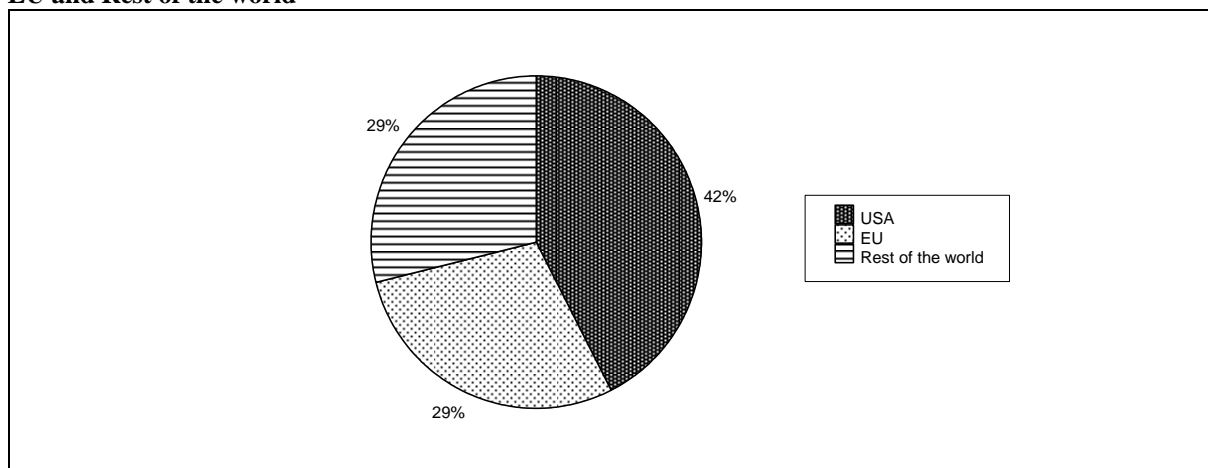
(63) For all ten companies, the EU market is highly relevant with a combined total turnover of nearly € 59 billion. Nevertheless, the total turnover for prescription medicines obtained in the USA is significantly higher than in Europe, despite half of the companies listed being European. In 2007 the ten leading pharmaceutical companies in Europe generated on average almost 30% of their total global turnover in the EU.

⁴³ Case COMP/M.5476.

⁴⁴ Roche's press release of 10 March 2009.

PHARMA SECTOR INQUIRY – MARKET CHARACTERISTICS AND STRUCTURE OF THE PHARMACEUTICAL SECTOR

Figure 3: Distribution of turnover for prescription medicines by originator companies in 2007 for USA, EU and Rest of the world



Source: Pharmaceutical Sector Inquiry

- (64) A similar picture emerges when a larger sample of originator companies examined is used to calculate annual turnover figures. In 2007, and considering the figures on a regional basis, the USA was the area where the highest amount of pharmaceutical sales of prescription medicines by originator companies was achieved. This was followed, some way behind, by the EU and the rest of the world (each accounting for 29% of the aggregated global turnover).

1.1.2.2. The Best Selling Products

- (65) Top-selling products, so-called blockbusters are the backbone of large originator company strategies aimed at recouping R&D investments (also those of failed products) and earning a profit. This section provides an overview of the top selling products.
- (66) Table 2 below shows the top ten prescription medicines and their respective therapeutic use ranked by turnover in the EU in 2007, the annual turnover at a global level for the same products and the relationship between the global turnover for the product and the total company turnover (all products) in %.
- (67) Table 2 demonstrates that some blockbusters account for a very large share of total turnover of the companies concerned (up to 55%). On average the most important blockbusters in the above table generate 19% of the total global turnover of the originator companies concerned. In addition, a significant number of these and other blockbuster medicines will lose their exclusivity soon. According to the respondents' replies, 46% of INNs in the T50 list⁴⁵ will lose patent protection (including SPC or other extensions if applicable) between 2008 and 2012. Considering those INNs still covered by patent protection at the beginning of 2008, 76% of these will lose patent protection (including SPC or other extensions if applicable) before the end of 2012.

⁴⁵ Please see Annexes to Chapter A: Methodology for an explanation of this list.

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Indeed, this underlines the degree of dependence of certain companies on the success of their blockbuster medicines and the efforts to prolong the high revenue streams generated with these products. Some commentators during the sector inquiry have argued however that the business model focusing on blockbusters could be of decreasing importance partly in view of the emergence of new, more focused therapeutic approaches in medicines. As indicated further below, most originator companies reported that the future of the sector lies in biopharmaceuticals and personalised medicines.

- (68) Based on the data provided by the companies, blockbuster medicines offer profit margins of up to 80%. On average, approximately 30% of the turnover is reported as profit. This is a rather conservative estimate taking into account the fact that some companies did not report any data on profitability and others reported surprisingly low figures when compared to other blockbuster medicines. No convincing explanation was given for these low profitability rates. In any event it seems fair to conclude that the companies rely heavily on their blockbuster medicines and have significant economic incentives to extend the economic life of such medicines for as long as possible.
- (69) Finally, Table 2 shows that there are a significant number of players in the market: the ten blockbuster medicines belong to six different therapeutic classes and originate from ten different companies. Out of the top ten best selling medicines, three are biopharmaceuticals (Herceptin, Enbrel and Aranesp).

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Table 2: Top selling prescription medicines (blockbusters) in the EU27 (2007)⁴⁶

Company	Rank	Product name (INN)	Therapeutic class (ATC ⁴⁷ 1st level)	EU27 turnover (€ thousand)	Global turnover (€ thousand)	Product share of company turnover (global)
Pfizer	1	Lipitor (atorvastatin calcium)	cardiovascular system	1,917,151	9,252,101	30%
Glaxo Smith Kline	2	Seretide/Advair (fluticasone + salmeterol)	respiratory system	1,795,800	5,108,540	18%
Sanofi-Aventis	3	Clopidogrel (clopidogrel)	blood and blood forming organs	1,620,000	2,424,000	9%
Hoffmann-La Roche	4	Herceptin (trastuzumab)	antineoplastic and immunomodulating agents	1,345,193	2,954,041	13%
Nycomed	5	Pantoprazole (pantoprazole)	alimentary tract and metabolism	1,289,069	1,685,000	55%
Wyeth	6	Enbrel (etanercept)	antineoplastic and immunomodulating agents	1,159,947	1,492,201	13%
Eli Lilly	7	Zyprexa (olanzapine)	nervous system	1,059,341	3,473,927	27%
Novartis	8	Glivec (imatinib)	antineoplastic and immunomodulating agents	939,194	2,228,470	13%
Johnson & Johnson	9	Risperdal (risperidone)	nervous system	924,799	3,318,294	18%
Amgen	10	Aranesp (darbepoetin alfa)	blood and blood forming organs	920,145	2,636,994	25%
Total/Average				12,970,639	34,573,568	19%

Source: Pharmaceutical Sector Inquiry

1.1.2.3. Main Drivers of Cost for Originator Companies

(70) The sector inquiry also investigated what are the important cost factors for originator companies and where they are incurred.

⁴⁶ This table changed compared to the Preliminary Report as one company provided updated figures.

⁴⁷ The WHO's Anatomical Therapeutic Chemical (ATC) classification classifies medicines in different groups depending on their chemical, pharmacological and therapeutic properties and the organ or system they affect. According to the WHO, a new medicinal substance is only included in the ATC system after marketing authorisation in at least one country has been granted. The ATC classification is generally followed by the European Commission to define the relevant product markets in merger transactions.

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- (71) The sector inquiry confirmed that for large originator companies research is an international activity in the sense that it can be located wherever a suitable research environment exists. Once a potential compound has been identified, there seem to be some synergies for the development phase (pre-clinical and clinical trials), although certain trials need to be carried out nationally or regionally.
- (72) Between 2000 and 2007 the respondent originator companies spent on average 17% of their turnover generated at global level with prescription medicines on R&D for new or improved prescription medicines. In 2007 approximately 1.5% of global turnover was spent on pre-clinical research – research to identify potential new medicines, the remaining part mostly on clinical trials and tests (for further details on the R&D phase for new chemical entities see further below in this Chapter).
- (73) Contrary to R&D activities, marketing and promotion activities are typically of national or regional nature. Within this type of activities, convincing doctors that they should prescribe or use a specific product for any given therapeutic indication accounts for the most important share. This activity is generally referred to as "detailing activity", i.e. a sales representative of an originator company visits a doctor to discuss the characteristics of a specific medicine and convince him/her of the safety, efficacy and quality of the product. In the EU in 2007, detailing accounted for nearly half of all marketing expenditures, according to the respondents. This is not surprising as, unlike the USA, direct advertising of prescription medicines to consumers is forbidden in the EU by European legislation.⁴⁸ Other marketing and promotion activities include advertising in medical journals, funding clinical studies, financing of continuing medical education (CME), writing to doctors, supply of free samples or sponsoring conferences.
- (74) Considering only the prescription medicines segment, the figure below shows that on the global level, originator companies spent more money on marketing and promotion than on R&D (on average 23% of global turnover in the period 2000-2007).⁴⁹ However, during the last few years the increase in the R&D budget was higher than that for marketing. From 2000 to 2007 absolute R&D expenditures constantly increased (with the exception of 2003) from € 34 billion to € 49 billion (for the sample of companies that provided complete data). In the same time period, marketing and promotion expenditures rose from € 52 billion to € 57 billion.⁵⁰ Moreover, it should be

⁴⁸ Article 88 of Directive 2001/83/EC of 28.11.2004 on the Community code relating to medicinal products for human use as amended by Directive 2004/27/EC of the European Council and the Parliament of 31 March 2004 (OJ L311/67 p.67). On 10 December 2008 the Commission put forward a proposal for a Directive modifying Directive 2001/83/EC (COM/2008/0662 final and COM/2008/0663 final).

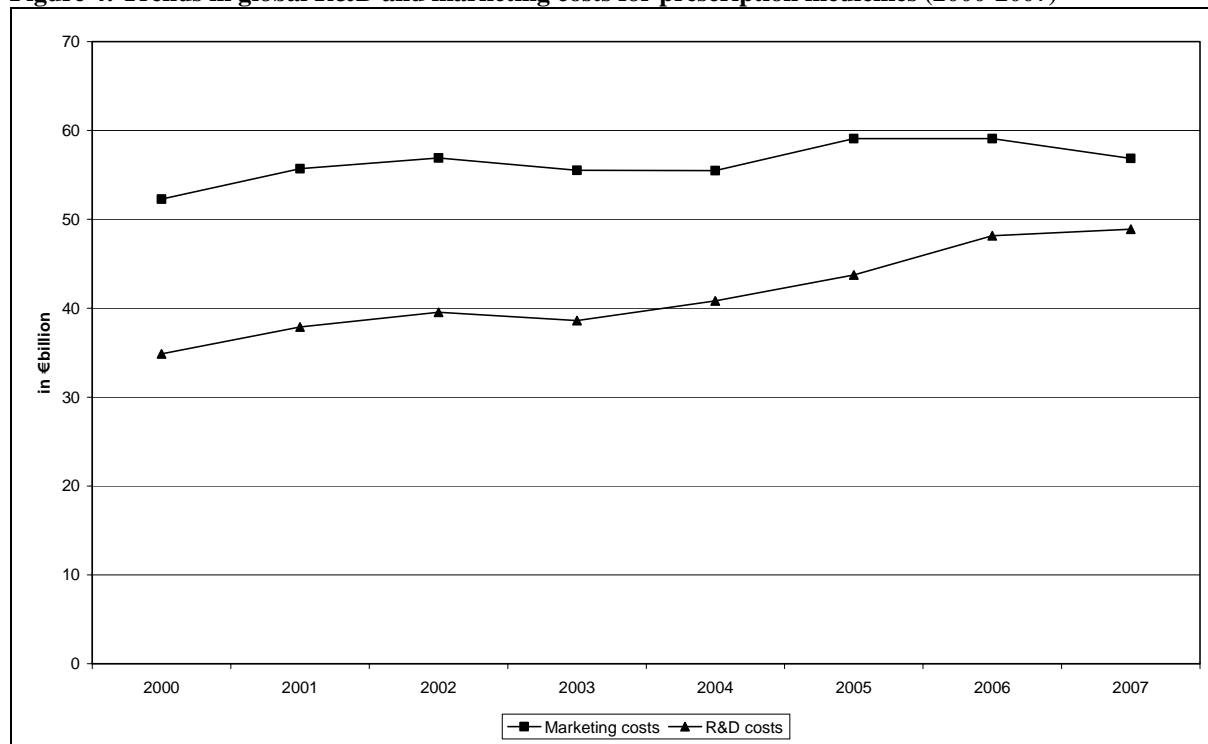
⁴⁹ In the EU between 2000 and 2007, companies reported to have spent on average between 20 and 25% of their turnover on marketing. For the development of marketing and promotion. The costs attributed to marketing and promotion are listed in the above paragraph and do not include regulatory costs required to commercialize a medicine (e.g. clinical trial clearance). For the development of marketing and promotion costs in the EU, see Chapter C.2.5.

⁵⁰ A decrease is observed from 2006 to 2007 from € 59 billion to € 57 billion.

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stressed that the difference between marketing and R&D expenditure is even greater, if non-prescription medicines are included.⁵¹

Figure 4: Trends in global R&D and marketing costs for prescription medicines (2000-2007)



Source: Pharmaceutical Sector Inquiry⁵²

- (75) As mentioned above, R&D is basically a global activity and, hence, a comparison between R&D and marketing expenditures at the global level, as shown in Figure 4, is warranted. Nevertheless, a regional breakdown of R&D is used to indicate the attractiveness of the EU for pharmaceutical research. The table below compares the total marketing costs to the total R&D costs for prescription medicines in the EU in 2007. It shows that also in the EU expenditure on marketing is significantly higher than on R&D.⁵³

⁵¹ It has been pointed out in one submission received in the public consultation that companies tend to include in the R&D budget many expenses that are in fact hidden marketing costs (e.g. expenses for symposia presenting positive study results, fees for ghost-written expert reports and articles etc.).

⁵² Based on an available sample size of 30 originator companies.

⁵³ The data provided by industry associations such as EFPIA shows different results as they include Switzerland and other European countries not members of the EU.

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Table 3: R&D and marketing costs for prescription medicines in the EU (2007)

Marketing (€thousand)	R&D (€thousand)
15,697,745	13,344,108

Source: Pharmaceutical Sector Inquiry⁵⁴

- (76) Based on the global figures reported by the originator companies, the number of employees in marketing and sales departments is twice the number of those working in R&D. In some companies, this ratio can reach even one employee in R&D to three in marketing. It should be highlighted, however, that efforts to reduce the marketing and sales workforces were reported by many originator companies for 2006 and 2007.
- (77) The sector inquiry also found that manufacturing activities can be located anywhere in the world and, generally speaking, are carried out in only a limited number of locations. As seen below, manufacturing involves significant costs for originator companies. However, the percentage of turnover used for manufacturing can vary widely from one company to another.⁵⁵ Table 4 shows that in general manufacturing, marketing and promotion as well as R&D are the three major cost factors in the pharmaceutical industry. Administration and distribution costs are significantly lower. Concerning the regional distribution of costs, it should be noted that manufacturing is located mostly outside the EU.

Table 4: Global share of cost factors of originator companies as a percentage of annual turnover (prescription medicines, 2007)⁵⁶

Marketing and promotion costs	Manufacturing costs	R&D costs	General administration and overhead costs	Distribution costs ⁵⁷	Other annual costs
21%	21%	18%	7%	1%	2%

Source: Pharmaceutical Sector Inquiry⁵⁸

- (78) Generally, the respondents stated that they do not face capacity constraints neither for production nor concerning their input facilities.⁵⁹ However, among those most affected by capacity constraints are the biopharmaceutical producers. The special nature of the substances required to develop biopharmaceuticals, such as living tissue, makes their

⁵⁴ Based on an available sample size of 31 originator companies.

⁵⁵ Especially, the production of biopharmaceuticals incurs costs above average.

⁵⁶ Percentages do not add up to 100% as the table provides an overview of annual cost categories in relation to annual turnover.

⁵⁷ Some companies were not able to provide a clear breakdown between marketing and promotion costs on the one hand and distribution costs on the other.

⁵⁸ Based on an available sample size of 32 originator companies (sample size was increased for the final report).

⁵⁹ In the pharmaceutical sector input facilities mainly refers to the supply of active ingredients.

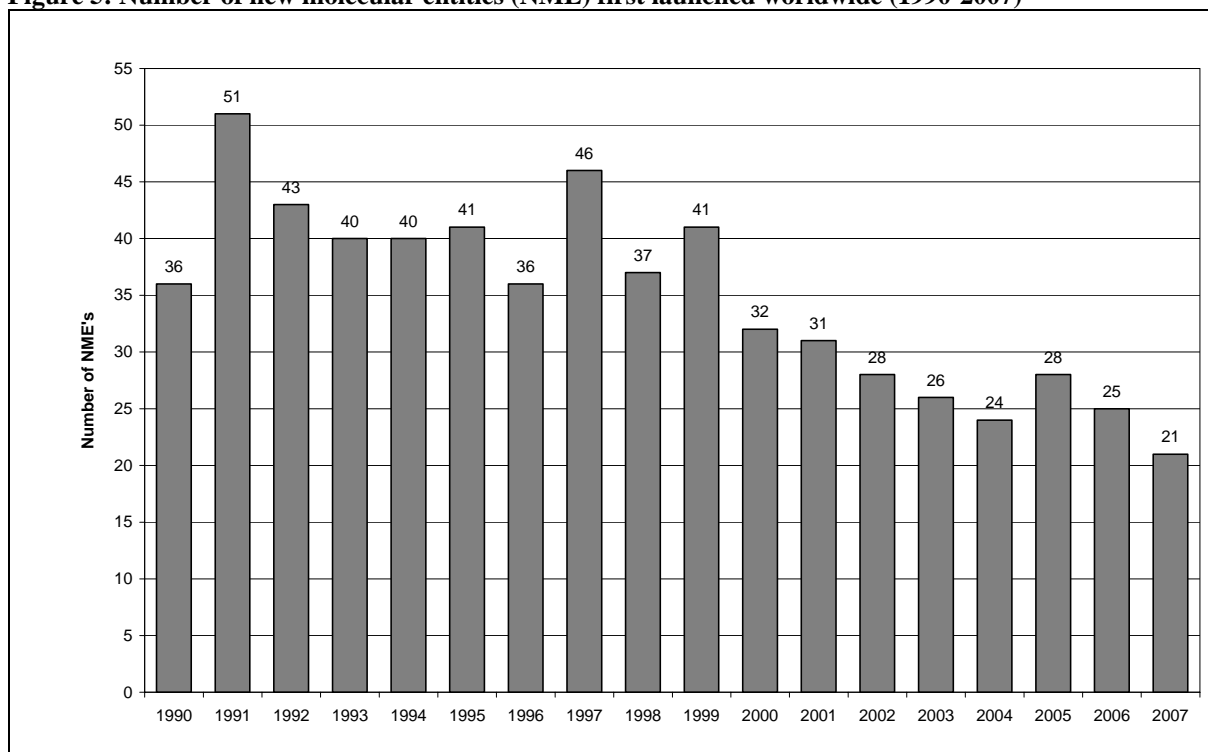
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supply more difficult than the supply of bulk chemicals as active ingredients for small molecule-based medicines.

1.1.2.4. Industry Trends

- (79) Many originator companies reported that they are currently undergoing a phase of transition. According to the respondent companies, the following trends are particularly noteworthy: (a) difficulties in refilling the pipeline with new products (in particular NCEs); (b) increasing requirements in terms of safety and efficacy for new medicines, resulting in higher R&D costs; (c) increasing control over prices and reimbursement levels, as well as on the prescribing practices of doctors by national health authorities; (d) a significant number of patent expiries for important blockbuster medicines; (e) new advances in genomics, proteomics and personalised medicines.
- (80) With respect to novel medicines, as shown in the graph below, the number of such medicines reaching the market has decreased over time. From 1995 to 1999 an average of 40 novel molecular entities were launched per year. From 2000 to 2007 the average was only 27.

Figure 5: Number of new molecular entities (NME) first launched worldwide (1990-2007)



Source: EFPIA and CMR International (Thomson Reuter)

- (81) EFPIA indicated in 2004 that previous years had seen a record low number of new chemical entities being approved by regulatory authorities.⁶⁰ As shown in Figure 5 this

⁶⁰ EFPIA Position Paper on Barriers to Innovation in the Development of New Medicines in Europe and Possible Solutions to Address these Barriers – November 2004.

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trend has not been reversed in the subsequent years.⁶¹ Possible reasons for this decline highlighted by EFPIA in the same document, in particular in Europe, are: the need to generate increasing amounts of data before and after the approval of a new medicine, the difficulty of conducting clinical research, the lack of predictability in the operating environment, the slow uptake of new medicines and lack of recognition of the value of incremental innovation, the public understanding and acceptance of science, and the need for support at early stage research. One submission in the context of the public consultation also points in addition to technological change and sensitivity to signals from buyers.⁶² A further contribution considers that mergers and acquisitions in the pharmaceutical sector can lead to decline of R&D.

- (82) In this context it is worth noting that the Commission has recently set up the Joint Technology Initiative on Innovative Medicines to overcome identified research bottlenecks in the development process of medicines.⁶³
- (83) In the changing environment, originator companies are re-engineering their business strategies and two main areas have emerged as future targets: patient-focused specialty/personalised medicines and biopharmaceuticals.
- (84) As indicated above, approximately 60% of the companies consulted declare that they are involved in, or intend to extend their activities to, biopharmaceutical-based medicines in the immediate future as they expect this field to grow faster than the traditional segment of the market. Companies report that the success rates for biopharmaceutical-based medicines are twice as high as those of chemical molecules in pre-clinical and clinical development. Companies also state that they have fewer side-effects, greater potency and better selectivity for specific diseases and patient groups.
- (85) It was also observed that a growing number of originator companies have acquired or are in the process of acquiring generic companies. They do so with a view to diversifying their product and risk portfolio as well as extending their geographical reach.
- (86) Acquisition is seen by companies as an alternative strategy to launching its own generic products or licensing them out. Of course, the acquisition of potential generic

⁶¹ According to one submission during the public consultation, this trend does not apply to biopharmaceuticals.

⁶² A number of submissions during the public consultation argue that there is no evidence of a marked decline of innovation. One submission states that the number of investigational new drugs (IND) submitted for approval in first-in-human studies, reached the record level of more than 700 in 2006, which is twice the amount that it was in 1996. It should be stressed however that the present report, as indicated in the introduction, has based its analysis on the number of new molecular entities coming to the market.

⁶³ Council Regulation (EC) No 73/2008 of 20 December 2007 setting up the joint undertaking for the implementation of the joint technology initiative on innovative medicines (OJ L 30, 4.2.2008, pp. 38-51). For further details please see section B.1.2.

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competitors could pursue the objective of avoiding or limiting generic competition. However, mergers are carefully scrutinised under EU or national merger control rules.

- (87) Furthermore, a trend to concentration among large originator companies or to the acquisition of biotech companies⁶⁴ has been observed in recent times. As indicated above, Pfizer is in the process of acquiring Wyeth. In addition, on 9 March 2009, Schering-Plough⁶⁵ announced a merger agreement with Merck in a stock and cash transaction to continue operating together under the name of Merck. The Swiss-based company Hoffman-La Roche has also announced the acquisition of the American biotech company Genentech which has become a wholly-owned member of the Roche Group.⁶⁶

1.1.3. Generic Companies

- (88) Generic companies active on the European market tend to be significantly smaller than originator companies. Many of them are SMEs, largely producing medicines for sale in their local markets. A number of generic companies have recently gained a global presence with a turnover exceeding € 1 billion per year, with more set to join them in the near future. The respondent generic companies employed in 2007 around 130,000 employees in the EU. These work primarily in areas such as development, production and sales.
- (89) The basic business model of generic companies is to develop an identical/equivalent medicine to an economically successful originator product and market it as soon as the originator product encounters loss of exclusivity. Occasionally they may even enter the market earlier, most notably in cases where the generic company believes patent(s) of originator companies are not to be valid or where the generic company believes it has found a way to produce the medicine without infringing any patent rights. As will be shown in Chapter C.2.4., patent settlement agreements between originator and generic companies or the launch of a generic product by the originator company itself can also lead to early generic entry.
- (90) Large generic companies are active with a significant range of products, and they are usually able to develop a generic version of any medicine that was previously patent protected.⁶⁷ Typically they will, however, concentrate on those originator products that have generated the most significant revenues (for details see Chapter B.1.3.).

⁶⁴ A new study by French research group Alcimed, on behalf of the European Biopharmaceutical Enterprises (EBE) published on 6 March 2009 suggests that a fifth of small European biopharmaceutical companies could be at risk of bankruptcy by the end of 2009 as a result of the global financial crisis.

⁶⁵ Case COMP/M.5502.

⁶⁶ Roche's press release of 10 March 2009.

⁶⁷ According to one submission received during the public consultation, however, some classes of medicines such as the cytostatic cancer agents or biosimilars require high levels of specialist manufacturing capabilities that might be not easily available to generic companies.

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- (91) Like their counterparts in the originator industry, generic companies are subject to strict regulations, in particular as regards marketing authorisation and national measures for pricing and reimbursement. Specifically, concerning marketing authorisation, generic medicines are subject to the same requirements of quality, safety and efficacy as all other medicinal products intended for the Community market. However, they do not need to provide detailed information from pre-clinical tests and clinical trials if they can prove that their product is equivalent to the product of the originator company, for which such tests and trials have already been carried out.
- (92) Since generic companies are able to provide cheaper versions of pharmaceutical products, they are an important pillar in cost containment measures of national health policies. Most Member States claim that they support the use of generic medicines in their territory in one way or another. Originator and generic companies also agree that generic competition creates and maintains incentives for innovation. Since generic competition limits the period during which originator companies can recoup their investments, originator companies are incentivised to constantly search for new medicines.
- (93) The sector inquiry also established that generic companies do not enter the market with all existing product versions (formulations), but at least initially opt for those most commonly sold. Several generic companies reported, however, that they are also involved in the development of new formulations, dosage forms and methods of delivery (so-called "line extensions" of existing products). These products are generally designed to capitalise on the profit-maximising potential of differentiating their product from the original product and from competing products of other generic companies. Such products are claimed to more likely receive rapid approval for marketing and have the potential for higher reimbursement rates.⁶⁸
- (94) Generic companies also pursue patent strategies to protect their products. Patent strategies are seen by generic companies as a tool to protect generic processes, products and formulations. The development of new formulations, dosages forms or methods of delivery entails also for generic companies early patenting activities.

⁶⁸ Conference Report – Integration for Innovation, R&D Leaders Forum, 1 – 3 March 2004.

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1.1.3.1. The Largest Generic Companies

(95) The table below shows the largest generic companies measured by turnover in the EU for prescription medicines.

Table 5: Largest generic companies in the EU by turnover in prescription medicines (2007)⁶⁹

Company	Rank	Turnover EU (€thousand)	Turnover USA (€thousand)	Turnover global (€thousand)
Teva	1	3,388,421	1,449,732	5,763,037
Sandoz†	2	2,041,182‡	1,318,915‡	5,406,935*
Ratiopharm	3	1,021,388	n/a	1,383,599
Stada	4	900,000-1,000,000	6,519	1,570,490*
Mylan	5	800,000-900,000 ¹	1,259,525	1,435,811 ²
Actavis	6	496,918	339,905	1,544,154*
Zentiva	7	341,379	0	511,646
Gedeon Richter	8	314,676	14,640	607,067
Pliva	9	282,191	104,670	564,772
Ranbaxy	10	237,432	286,579*	1,181,651*
Total		9,940,683	4,780,485	19,969,163

Source: Pharmaceutical Sector Inquiry

Notes:

* = global turnover for prescription medicines was not provided by the companies so the figures used refer to medicines in general.

† = these figures were originally calculated in US\$. The conventional foreign exchange rate used to translate Sandoz initial US\$ denominated figures into € was US\$ 1 = € 0.72966.

‡ = for prescription medicine only excluding the contribution from the Anti-Infective business and/or OTC activities in some markets.

¹= EU turnover of Merck Generics for prescription is between € 800 million and € 900 million for 2007 which includes, from the acquisition of Merck Generics Group by Mylan, the EU turnover for the fourth quarter publicly disclosed and amounting to € 272.3 million (US\$ 373.1 million).

²=Turnover (total sales), in thousand, globally but excluding Merck Generics.

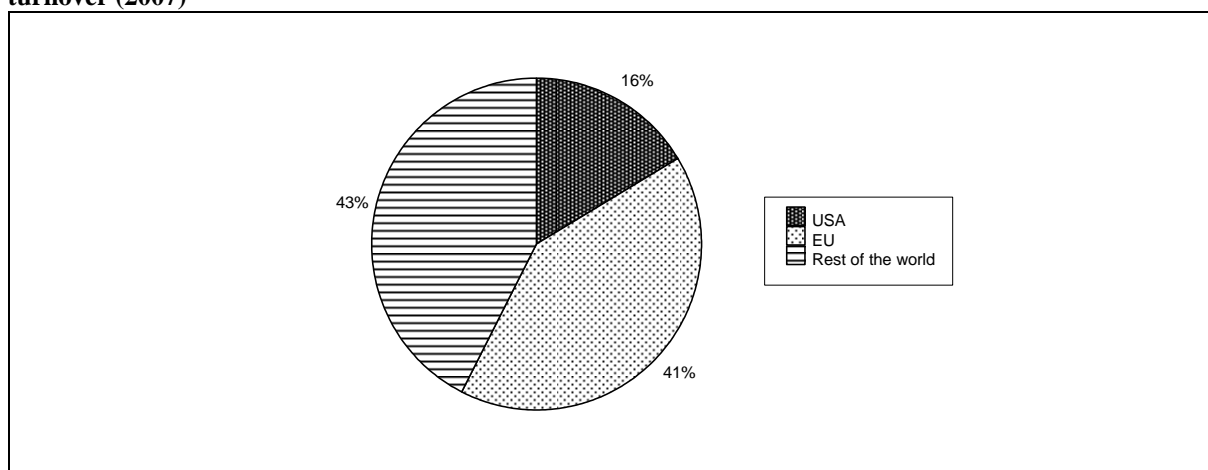
(96) As indicated in the figure below, the generic companies consulted in the sector inquiry generated a combined turnover in the EU in 2007 that was significantly higher than the turnover generated in the USA. This is not surprising as many of the companies are not multinationals and are Europe based. Their activities (in terms of turnover and number of employees) in the USA are therefore limited. However, as can be seen from table above, Mylan⁷⁰ and Ranbaxy had slightly higher revenues in the USA than in the EU.

⁶⁹ The generic landscape has changed substantially since the opening of the sector inquiry in particular in relation to the companies listed in Table 5. Teva and Barr Pharmaceuticals have merged (Case COMP M.5295, OJ C10 p.1 of 15 January 2009). Pliva had been acquired by Barr Pharmaceuticals in 2006. Zentiva has been acquired by the originator company Sanofi-Aventis (Case No COMP/M.5253). Ratiopharm is for sale and Ranbaxy has been acquired by the Japanese originator company Daiichi Sankyo (Case COMP/M.5247, OJ C20 p 11 of 27 January 2009).

⁷⁰ Mylan is an US-based generic company that acquired, Merck Generics Group, a large EU generic operator.

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Figure 6: Turnover of generic companies in the USA, EU and the rest of the world as a % of global turnover (2007)



Source: Pharmaceutical Sector Inquiry

- (97) As a whole, the generic products segment is currently growing faster than originator products segment. According to the submissions received, there are mainly two reasons for this. First, a large number of top-selling medicines are currently approaching patent expiry in both the USA and Europe. These are favourable conditions for generic companies to extend their pipelines in the world's largest generic markets. Secondly, in view of ever tightening health budgets, a growing number of countries on both sides of the Atlantic are promoting generic substitution as a cost-containment measure.

1.1.3.2. Best Selling Products

- (98) The table below shows the top five selling prescription medicines⁷¹ in the generic segment that accounted for a total turnover of € 1.2 billion in the EU in 2007. It is important to underline that top-selling generic products are typically sold by a number of generic companies. This means that depending on the regulatory framework there could be scope for direct competition between generic companies with a focus on price. As these products are (largely) identical, it could even be argued that there are certain similarities to a market for rather homogenous commodities.

⁷¹ The list of top five selling INNs is based on data for the top five products in terms of EU turnover provided by the respondent generic companies. The five INNs listed in this table account for 34 products by different generic companies.

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Table 6: Five top selling generic INNs in the EU27 (2007)

Rank	INN	Therapeutic class (ATC1 st level)	EU27 turnover (€thousand)	Global turnover (€thousand)
1	OMEPRAZOLE	alimentary tract and metabolism	557,011	871,072
2	SIMVASTATIN	cardiovascular system	391,457	565,629
3	FENTANYL	nervous system	108,738	296,663
4	METOPROLOL	cardiovascular system	98,464	212,107
5	ALENDRONIC ACID	musculo-skeletal system	80,025	83,952
	Total		1,235,694	2,029,424

Source: Pharmaceutical Sector Inquiry

1.1.3.3. Main Drivers of Cost for Generic Companies

- (99) The development of a generic product requires significantly lower expenditure than the development of a new product by an originator company. Generic producers therefore incur much lower costs for R&D activities. For the approval of a generic product, a company must simply prove that its medicine is equivalent to the original/originator product (reference product). There is no need to carry out and/or submit results of expensive pre-clinical and clinical trials, provided that the originator product is not protected by data exclusivity.⁷²
- (100) In the case of biosimilars, the R&D costs of generic companies increase significantly, as the companies must submit "comparability data" in the EU. In order to demonstrate that the safety and efficacy of the biosimilar medicine is comparable to the originator (reference) product, the results of certain pre-clinical tests or clinical trials are usually necessary, as specified in scientific guidelines adopted by the European Medicines Agency, EMA. These requirements along with the living nature of the substances from which biosimilars are produced (they are more scarce and difficult to handle and preserve), increase the development costs.

Table 7: Global share of cost factors among generic companies as a percentage of annual turnover (prescription medicines, 2007)⁷³

⁷² For an explanation of marketing authorisation procedures and data exclusivity periods, please see Chapter B.2.2.

⁷³ Percentages do not add up to 100% as the table provides an overview of annual cost categories in relation to turnover.

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Manufacturing Costs	Marketing and promotion costs	R&D costs	General administration and overhead costs	Distribution costs ⁷⁴	Other annual costs
51%	13%	7%	6%	3%	1%

Source: Pharmaceutical Sector Inquiry⁷⁵

- (101) The cost structure of generic companies is fundamentally different from originator companies. Manufacturing accounts on average for 51% of the annual turnover. It includes royalties and expenses for goods purchased. Marketing and promotion⁷⁶ as well as R&D expenses are significantly lower for generic than for originator companies. Moreover, marketing activities by generic companies differ from originator companies in countries where generic substitution at pharmacy level is an option. In those cases, the pharmacists are a particularly important target for marketing activities by generic companies.
- (102) In absolute terms the marketing and promotion efforts of generic and originator companies reach different dimensions: The ten largest originator companies in the EU spent over € 40 billion per year on global marketing and promotion activities. This is more than twice the global turnover of the ten largest generic companies in the EU.

1.1.3.4. Prices of Generic Products

- (103) Due to the different cost structure of generic companies, their products can be offered at substantially lower prices as compared to the pre-expiry prices of original products.⁷⁷ The ultimate price level of generic products depends on many factors including among others the degree of competition. Figure 7 can provide a proxy for the price effectiveness of the European generic sector by comparing it to its US counterpart. The comparison is based on a subsample of 50 generic medicines, taken from the E-75 data set, which had been on sale both in at least one EU-15 Member State and in the US for minimum twelve consecutive months. As subsequent generic medicines join gradually the EU and US price baskets over time, the 12-month moving averages were applied to smooth down the price effects related to step increases in a number of medicines included in the two baskets. In the period 2005 – 2007, on which Figure 7 was drawn, the EU price index was on average 15% below the US benchmark

⁷⁴ Some companies were not able to provide a clear breakdown between marketing and promotion costs on the one hand and distribution costs on the other.

⁷⁵ Based on an available sample size of 16 generic companies.

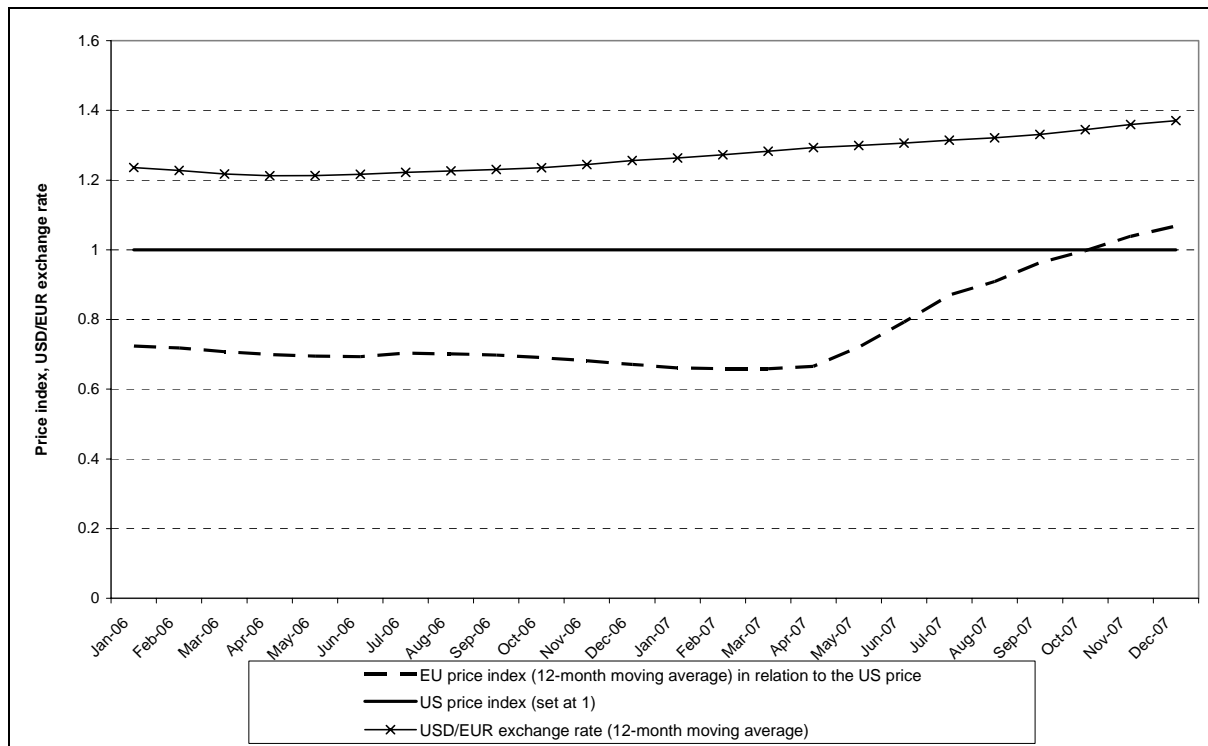
⁷⁶ According to one submission received during the public consultation, "the marketing costs of generics will be mitigated by their focus only on successful brands where the innovator has already established a successful product on the market".

⁷⁷ For the impact analysis of generic entry please see Section B.1.3.

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measured at the ex-factory level.⁷⁸ The gap was closing towards the end of that period, which can be partly explained with the depreciation of the US currency.

Figure 7: EU-US price comparison of generic medicines



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

1.1.3.5. Industry Trends

- (104) Generic companies see their future in the biosimilars segment. More than half of the respondents are, or will in the near future be, involved in the biosimilars market. Furthermore, generic companies considered that biosimilar products will achieve fundamental cost savings for national health care systems, as existing biopharmaceutical products are generally highly priced medicines. However, compared to chemical molecules, the savings expected are less prominent due to the high costs involved in the development of biosimilars. Some respondents stressed the need to develop an adequate regulatory framework; the possibility to use the INN name of the originator (reference) products was mentioned in particular. However, it should be noted that the EU has established a regulatory framework for biosimilars ahead of other regions in the world, allowing for the commercialisation of these products in the EU territory. Smaller-sized generic companies also raised the question of whether they will be able to tackle the financial burden associated with the R&D concerning biosimilar products.

⁷⁸ Before 2005, the number of generic medicines on the list E-75 fulfilling the criterion of sales for minimum twelve consecutive months drops by over a half. For this reason, the analysis was constrained to the years 2005 – 2007.

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- (105) The sector inquiry also revealed that certain generic companies aim to increase their economies of scale by acquiring other (often local) generic operators. A key motivation for these mergers is to extend the geographic reach of a company. The acquisition of Merck Generics by Mylan, or of Barr by Teva are examples of this ongoing concentration process. Furthermore, a developing trend in the pharmaceutical sector seems to be originator companies entering the generic business. As indicated above, Zentiva and Ranbaxy have been recently acquired by Sanofi-Aventis and Daiichi Sanyo respectively. In addition, Pfizer has recently decided to expand its generic medicines portfolio through licensing agreements with the Indian generic company Aurobindo Pharma Ltd.⁷⁹ These transactions point to substantial changes in the landscape of the generic sector.

1.1.4. The Distribution Chain

- (106) The distribution business for prescription medicines is highly sophisticated (this section covers only the retail channel; for dispensing via hospitals see below). This is in particular due to the need to ensure constant supply to retailers/pharmacists, as well as special needs such as cooling. Within the distribution chain, players include wholesalers, pharmacies and parallel traders (for a schematic overview see above in Figure 2).

1.1.4.1. Wholesalers

- (107) The wholesaler is the intermediary between the manufacturer and the pharmacy. In general terms the wholesale sector comprises so-called "full-line" wholesalers and "short-line" wholesalers.
- (108) Full-line wholesalers carry and distribute a range of products suitable to meet the needs of those with whom they conduct business (normally pharmacies). They are also able to deliver all medicines used in their geographical area within a short period of time. In addition, full-line wholesalers generally carry full stock-holding responsibility and usually hold a minimum stock level of two weeks' supplies.
- (109) In a number of Member States, in addition to the full-line wholesalers, short-line wholesalers exist. These companies supply a more restricted range of prescription medicines, focusing on the distribution of high-value and high-volume products. The number of medicines stocked by short-line wholesalers can vary substantially, with some holding a very small number of medicines for distribution to a specific group of pharmacies.
- (110) In the EU there is no obligation for manufacturers to distribute medicines via wholesalers. Forms of direct distribution include direct sales, sales through agents (for example in smaller EU Member States) and direct to pharmacy (DTP) distribution. The DTP system will be further described in Chapter C.2.5.

⁷⁹ Pfizer's press release of 3 March 2009.

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- (111) In EU Member States, the distribution system is subject to "public service obligations"⁸⁰ which require "the marketing authorisation holder of a medicinal product" and the "distributor" of a medicinal product actually placed on the market in a Member State to ensure appropriate and continued supplies within the limits of their responsibilities.⁸¹ According to Article 81 of the Directive, a "distributor" is to be interpreted only as an entity which supplies pharmacies and other authorised suppliers of medicinal products (this may, according to the Member State concerned, include pharmacies provided they engage in these resale-activities). The obligation of appropriate and continued supplies includes any type of product which must be delivered to meet the requirements of a specific geographical area in a very short time. The large majority of distributors are SMEs, but there are also some larger cross-border operators, such as Celesio, Alliance Boots and Phoenix.

1.1.4.2. Pharmacies

- (112) Retailers of prescription medicines are typically community pharmacies⁸². Further channels of supply include self-dispensing doctors, hospital pharmacies, and, for non-prescription products, pharmacy outlets, medicine stores, herbal shops and even supermarkets and petrol stations.⁸³ According to information received in the course of the sector inquiry, there are in total approximately 140,000 community pharmacies⁸⁴ in the EU, and approximately 21,000 hospital pharmacists⁸⁵ employed in pharmacies located inside hospitals mainly dispensing to in-patients.⁸⁶
- (113) Most pharmacies in the EU are SMEs or single-unit operators. The pharmacy sector is also highly regulated and some Member States (for example Germany, Italy, Spain and France) prohibit horizontal or vertical integration of pharmacies or ownership by non-pharmacists. Other Member States establish rules on the distance between pharmacies and number of inhabitants per pharmacy in order to control the distribution of

⁸⁰ Article 1.18 and 81 of Directive 2001/83/EC of 28.11.2004 on the Community code relating to medicinal products for human use as amended by Directive 2004/27/EC of the European Council and the Parliament of 31 March 2004 (OJ L311/67 p.67).

⁸¹ See in this respect the judgment of the ECJ of 16 September 2008 (Joined Cases C-468/06, C-469/06, C-470/06, C-471/06, C-472/06, C-473/06, C-474/06, C-475/06, C-476/06, C-477/06, C-478/06 *Sot. Lélos kai Sia*), which found that a pharmaceutical company is abusing its dominant position if it refuses to meet ordinary orders by wholesalers in order to prevent parallel exports.

⁸² Community pharmacies are pharmacies open to the public.

⁸³ Many EU countries however limit the sale of non-prescription products to pharmacies.

⁸⁴ The Pharmaceutical Group of the European Union (PGEU), representing community pharmacies.

⁸⁵ European Association of Hospital Pharmacists (EAHP).

⁸⁶ In some Member States pharmacies located in hospitals can also dispense to out-patients.

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pharmacies in their territory. This is for example the case in Spain, Austria, Italy and France.⁸⁷

- (114) In addition to dispensing medicines, pharmacists provide advice on non-prescription medicines (OTC medicines). With respect to prescription medicines, pharmacists are obliged to dispense the medicines prescribed by the doctor, and therefore do not determine the medicine that is given to the patient. However, in some Member States, the pharmacist is allowed or even required by law to either substitute an originator medicine with a cheaper generic version (if available), or prescriptions are issued on the basis of an active substance (INN) rather than a brand, in which case the pharmacist can or must select an appropriate generic product (if available) at the lowest price.
- (115) The remuneration system for wholesalers and pharmacies in most European countries is based on a margin, regulated by the individual Member State and sometimes combined with a fixed element. Pharmacies typically have one or two principal full-line wholesalers offering a several times daily delivery service. The discount structures offered by the wholesaler reward those pharmacies that place a substantial volume of purchases with it, although in some Member States discounts are prohibited.

1.1.4.3. Parallel Traders

- (116) Price differentials between Member States create the opportunity for arbitrage, i.e. the purchase of pharmaceutical products in low-price Member States and subsequent resale in high-price areas. It is from this price differential that parallel traders derive their profits.
- (117) According to information received in the course of the sector inquiry the turnover of parallel traders is approximately € 3.5 billion – € 5 billion in Europe, which is between 2% and 3% of the overall market. There are approximately 100 companies engaged in parallel trade in the EU employing in total between 10,000 and 15,000 people. With few exceptions, parallel traders fall within the definition of SMEs.
- (118) Some studies⁸⁸ indicate direct and indirect savings in importing Member States as a result of parallel trade. Other studies⁸⁹ contest these savings or at least the level of savings achieved and point to other effects of parallel trade. As parallel trade is not the object of this sector inquiry, no further details are provided in this report.

⁸⁷ The European Commission has currently a number of infringement proceedings open against the legislation on pharmacy ownership and establishment in Italy, Austria, Spain, France, Germany, Portugal and Bulgaria.

⁸⁸ For example, “The economic impact of parallel import of pharmaceuticals” (June 2006), University of Southern Denmark.

⁸⁹ “The Economic Impact of Pharmaceutical Parallel Trade: A Stakeholder Analysis” (January 2004), London School of Economics.

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1.1.5. The Demand Side

(119) The demand side of the pharmaceutical sector is rather unique. It is characterised by a complex interrelationship between amongst others patients, doctors, hospitals, insurance providers and reimbursement systems. For prescription medicines, the ultimate consumer (i.e. the patient) systematically differs from the decision maker (generally the prescribing doctor) and very often also from the bearer of the costs (generally the health system).⁹⁰ As a consequence, price sensitivity is rather limited for the decision makers and patients.

1.1.5.1. Doctors

(120) Unlike other markets, the patient is normally not in a position to choose directly which product he/she wishes to use. The relationship between patient and doctor is characterised by an information asymmetry where the patient generally must rely on the doctor's expertise. Doctors are therefore decisive for the choice of pharmaceutical products (type and volume). This explains why it is so important for originator companies to remain in constant contact with doctors. In addition to detailing (visiting of doctors by pharmaceutical companies), the respondent originator companies confirmed that medical journals and seminars are the main source of information for doctors on developments in relation to medicines.

(121) On average, the number of physicians (out-patient doctors) per 100,000 inhabitants in the EU has increased slightly during the last decade to over 300.⁹¹ Nevertheless, there are significant differences between Member States (and also on the regional level, e.g. between urban and rural regions) regarding the density of physicians.

(122) The relationship between pharmaceutical companies and doctors is the subject of controversy, given the potential for a conflict of interest between the business objectives of the industry and the duty of the doctor to prescribe the most appropriate medicines. EU legislation lays down some conditions to limit offers of hospitality by pharmaceutical companies at sales promotion events, and to regulate the main purpose of the event and conduct of the health professionals.⁹² In addition, EFPIA representing the pharmaceutical companies regularly updates its Code on the Promotion of Prescription-Only Medicines to, and Interactions with Healthcare Professionals⁹³ and

⁹⁰ The costs are mostly borne collectively by the citizens or the insured, financing with their contributions or taxes the public health systems.

⁹¹ WHO-HFA, 2007.

⁹² Article 94 of Directive 2001/83/EC of 28.11.2004 on the Community code relating to medicinal products for human use as amended by Directive 2004/27/EC of the European Council and the Parliament of 31 March 2004 (OJ L311/67 p.67).

⁹³ This EFPIA Code was adopted for the first time in January 1992. It sets out minimum standards, which member associations must adopt in their national codes. The current version was updated in October 2007.

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has concluded an agreement with the Standing Committee of European Doctors (CPME) in order to avoid/limit potential abuses in promotional activities.⁹⁴

1.1.5.2. Hospitals

- (123) In the EU both public and private providers operate in the hospital sector. Typically hospitals buy directly from manufacturers and prices may be determined, as well as providers selected, via public tenders. At times medicines are also supplied by wholesalers. Suppliers have generally more freedom to decide the price of their medicines than when selling to the retail segment. According to a submission received in the sector inquiry, competition between originator and generic companies in the hospital segment can be strong, especially because originator companies believe that outpatient doctors will continue to prescribe the product patients have received for treatment in hospital.

Box: Decision of the OFT in the Napp case⁹⁵

In April 2001, the UK Office of Fair Trading (OFT) imposed a penalty of £ 3.2 million on Napp Pharmaceuticals (Napp), a Cambridge-based pharmaceutical company, for abuse of its dominant position in the market for the supply of sustained-release morphine tablets and capsules in the United Kingdom. Sustained-release morphine is commonly used in the treatment of cancer-related pain and Napp was found to have supplied its sustained-release morphine product, MST, to patients in community pharmacies at excessively high prices while supplying hospitals at discount levels knowing that doctors are strongly influenced by the brands used in hospitals.

1.1.5.3. Patients

- (124) Patients are the ultimate consumers of medicines. Per European citizen, on average over € 430 is spent on pharmaceutical products per year, obviously with significant differences over time and patients, mainly through public or third party funding.
- (125) Since most prescription medicines are provided under public health (insurance) schemes, the overwhelming majority of European patients do not directly pay the price of the prescription medicines they receive. They may, however, make a direct contribution to the price, for example in the form of a "co-payment" representing a fraction of the full price, or other forms such as a flat fee contribution. In some new Member States (Poland and the Baltic States) co-payment can be up to 50% while the World Health Organisation (WHO) considers co-payments above 25% as a barrier to access to medicines.

⁹⁴ Joint Declaration of CPME and EFPIA on the Cooperation between the Medical Profession and the Pharmaceutical Industry – June 2005.

⁹⁵ http://www.offt.gov.uk/shared_offt/ca98_public_register/decisions/napp.pdf

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1.1.5.4. Social Security/Health Insurers

- (126) As just explained, patients do not pay directly the (full) costs of prescription medicines, and consequently health systems must organise the reimbursement to patients and/or distributors of relevant costs. This may be done through state agencies (for example, the National Health Service in the UK⁹⁶) or through relatively autonomous social insurers, as in Germany⁹⁷. However, there appears to be a trend for health insurers to directly negotiate prices and rebates with the manufacturers (see box in Chapter B.2.3.).
- (127) The level of reimbursement is often the subject of controversy between health insurers and pharmaceutical companies. High co-payments can discourage certain patients from buying the pharmaceutical products concerned. In order to find a solution to controversial reimbursement decisions, Member States tend to delegate the cost benefit assessment of medicines to independent experts such as the National Institute for Health and Clinical Excellence (NICE) in the UK and the Institute for Quality and Efficiency in Health Care (IQWiG) in Germany. These institutions assess medicinal products or treatments on two criteria: the effectiveness of a medicine in providing therapeutic benefits; and the effectiveness of a product or treatment in relation to its cost and alternative products, as a measure of the (relative) efficiency of the medicinal product or treatment.

⁹⁶ Typically such systems are financed on the basis of taxes. Such systems are also referred to as "Beveridgean" named after William Henry Beveridge (1879-1963) who was responsible in 1942 for the report Social Insurance and Allied Services (known as the Beveridge Report), which outlined the conceptual basis of the British Welfare State after the war. In this report, Beveridge also produced a blueprint for the tax-financed National Health Service.

⁹⁷ Typically, such systems are based on contributory social insurance schemes, which are mainly financed through contributions relative to the income earned from employment. Such schemes are also referred to as Bismarckian systems after the German chancellor Bismarck who introduced public health care based on contributions by employers and employees.

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Summary

The pharmaceutical sector is highly regulated and R&D driven. On the supply side, there are two types of companies. Originator companies are active in research, development, management of the regulatory process for new products including the clinical trials needed for marketing authorisation, manufacturing, marketing and supply of innovative medicines. Their products are usually subject to patent protection, which, on the one hand, provides a compensation for the often very high costs spent on innovation and, on the other hand, makes information on inventions public. The protection is limited in time, encouraging the company to bring the innovation to market as quickly as possible and ensuring that the company continues to innovate and bring forward future innovative products. The second category of companies, manufacturers of generic products, can enter the market with medicines that are equivalent to the original medicines, upon patent expiry of the pre-existing original products and when the data exclusivity period for the originator product expired. Their prices are typically much lower than those of the originator products. This helps containing public health budgets and ultimately benefits consumers. The market share of generic medicines varies significantly between Member States.

From 2000 – 2007 originator companies spent on average 17% of their turnover from prescription medicines on R&D worldwide (approximately 1.5% of turnover was spent on basic research to identify potential new medicines and 15.5% of turnover was spent on developing the identified potential medicines through trials into products sufficiently safe and efficacious to be marketed). Expenditure on marketing and promotional activities accounted for 23% of their turnover during the period. In the year 2007 manufacturing costs accounted for 21% of originator companies' total turnover. Originator companies rely, to a significant degree, on the acquisition of compounds from third parties. In 2007 about 35% of originator companies' molecules where marketing authorisation was pending had been acquired or in-licensed. Some of these third parties are small and medium sized enterprises, e.g. in the biotechnology sector. The largest cost block of generic companies in 2007 was manufacturing (51%), followed by marketing (13%) and R&D activities (7%), showing their different cost structure.

On the demand side, the pharmaceutical sector is unusual in that, for prescription medicines, the ultimate consumer (the patient) is not the decision maker. Decisions are generally made by the prescribing doctors, and in certain Member States, the pharmacist also plays a role. Yet, neither the patient, nor the prescriber or the dispenser directly bear most of the costs, as these are generally covered and/or reimbursed largely, or even wholly, by national health (insurance) schemes. The pharmaceutical sector is also unusual in that prices are most often the result of a regulated decision-making process, involving nevertheless negotiations between stakeholders. Where this is not the case, i.e. in countries with so-called free pricing, prices are dependent on the regulated reimbursement decisions. Because of this structure, doctors, pharmacists and patients are usually not very price sensitive for prescription medicines, although various mechanisms to control prescription medicine budgets do exist.

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1.2. Product Life Cycle

- (128) In general terms, the life cycle of an originator product can be divided into three distinct phases: the pre-launch period, where R&D as well as regulatory (governmental) approval take place; the marketing and sales period, during which the product benefits from exclusivity; and a later period when the LoE occurs and generic competition is possible.
- (129) In every phase, patent protection plays a crucial role in the business strategies of originator companies. Patent applications are already filed during basic research for a new medicine and can continue to be filed throughout its entire life cycle. As shown in the previous section, the period between launch and LoE is the period during which originator companies must aim to recover the investments made in R&D (including those made for failed projects) and indeed show an overall return.
- (130) In order to maximise the revenue streams from a given product (and in particular blockbuster medicines), originator companies put into place a variety of life cycle management strategies. These include not only patent and litigation strategies, but also other measures such as enhancing product loyalty or the introduction of product differentiation or OTC switches.
- (131) This section provides an overview of the main aspects of these three phases of the product life cycle and the business strategies applied. More details, in particular concerning patent and life cycle strategies, are provided in subsequent chapters.

1.2.1. Pre-Launch Period

- (132) Typically, R&D activities in the pharmaceutical industry produce a continuum of innovation which can be divided into two distinct categories. First, fundamental innovation, which leads to the discovery of new medicines containing novel pharmaceutically-active substances (NCEs). This type of innovation requires significant investment in research with no guarantee of commercial success. Secondly, incremental innovation results from the development of existing medicinal products. It may also include major innovations such as the novel use of existing products in new therapeutic areas, which may be of significant benefit to patients. Incremental innovation may also involve the development of a new formulation or mode of delivery, or the combination of previously disclosed active substances, or the use of a new salt or derivative of the original product.⁹⁸ In this section, the focus is on fundamental innovation in the above sense and the typical phases involved.

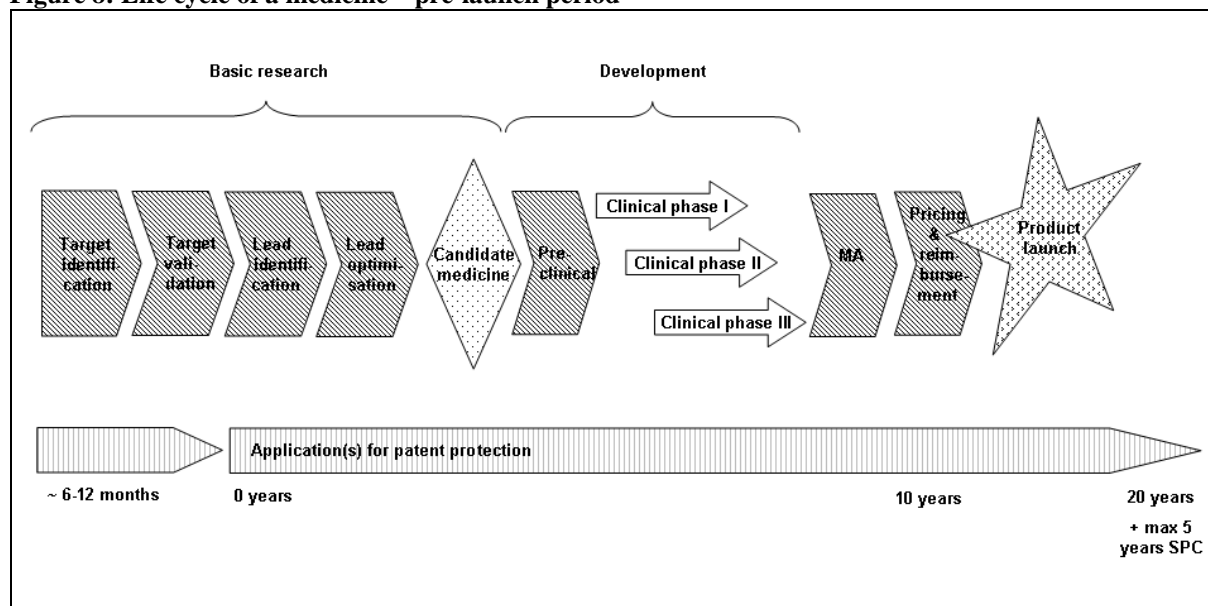
⁹⁸ During the public consultation it has been argued that incremental innovation takes place throughout the life cycle of a medicine and that incremental innovations constitute a parameter for competition between originator medicines in the same therapeutic class (see section C.2.6.).

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1.2.1.1. The Different R&D Phases

(133) The pre-launch period in the life cycle of a medicine comprises the initial discovery of a new molecule and its development as a new medicine up to marketing authorisation and any subsequent pricing and reimbursement decisions. Following their market launch, products continue to be monitored through the process of pharmacovigilance i.e. monitoring of possible adverse reactions and/or new side effects (also referred to as Phase IV studies). The figure below sets out these different steps along with average time frames and the corresponding patenting activity.

Figure 8: Life cycle of a medicine – pre-launch period



Source: Pharmaceutical Sector Inquiry

1.2.1.1.1. Basic Research

(134) The research process for a new medicine typically begins with scientists aiming to identify molecular targets (frequently enzymes or receptors) which are associated with the disease in question. This process is called target identification.

(135) Following target identification, scientists carry out tests to verify how the targets regulate the biological processes in the body and whether they are suitable as a target for a therapeutic agent. They also compare the performance of all potential targets for therapeutic action. This step is sometimes referred to as target validation.

(136) The next step is lead identification, whereby new molecules are actively sought which interact with the target(s) identified. This may involve mass screening of chemical libraries. This results in the identification of one or more molecules which show promise as potential treatments for the disease. Leads may also be derived from known treatments of disease, such as competitors' products or natural remedies. They may also result from a surprise discovery made in other pharmaceutical research programmes.

(137) Lead optimisation then aims to find molecules which have the greatest potential to be developed into a safe and effective medicine. The best compounds are studied for their

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therapeutic effects in both in vitro and animal studies. The resulting candidate medicines then progress to the development phase.

- (138) At some point during the lead identification/optimisation process, a company will begin to consider filing a patent application. Initially, these applications will be concerned with the active molecules themselves. The applications, and the resulting patents, are often referred to as "primary patents" because they relate to the first patents for the active molecules. Later during the development phase and, as the Sector Inquiry showed, not uncommonly after the product launch, further patent applications will be made for other aspects of these active molecules, such as different dosage forms (e.g. tablets, capsules or solutions for injection) or for particular pharmaceutical formulations (mixtures of active agents and other substances which promote the activity of the medicine by, for example, enhancing absorption in the body). Such patents, or their applications, are often referred to as "secondary patents".⁹⁹
- (139) To maintain its freedom to operate, it is essential for an originator company to ensure that its research options remain as open as possible, in particular with regard to further development of its own inventions. Filing for broad primary patents and using several secondary patents around an invention is therefore considered instrumental to achieving this goal. As will be shown in Chapter C.3.1., companies can however also develop patent strategies that are mainly aimed at foreclosing particular R&D of a competitor.

1.2.1.1.2. Development

- (140) The development phase assesses the safety (e.g. toxicity) and efficacy of the lead compounds mainly through laboratory (animal) testing. For the most promising candidates, human testing is undertaken at a later stage. Trials can generally be divided into two main stages: the pre-clinical stage (which involves laboratory and animal testing primarily aimed at ascertaining toxicity) and clinical trials where three distinct phases exist:

Phase I, which consists of studies on small groups of healthy human beings to determine safety and side-effects.

Phase II, which consists of studies on patients with the disease, who are often chronically or even terminally ill, to test the efficacy of the new medicine for the given indication. Parallel tests with placebo preparations, i.e. medicines devoid of the active compound, are often also carried out at this stage, to provide for a "control group". Also the development of novel pharmaceutical formulations and dosage forms may be necessary, which will result in the filing of further (secondary) patent applications.

⁹⁹ This terms "primary patents" and "secondary patents" are being used by the report, as they constitute part of the terminology employed by stakeholders in this sector and thus are key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying intentions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

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Phase III, which involves long-term trials comprising large patient groups (very often thousands of patients with the illness to be treated). New therapeutic applications for the candidate medicine can sometimes be found at this stage, which result in further (secondary) patent applications.

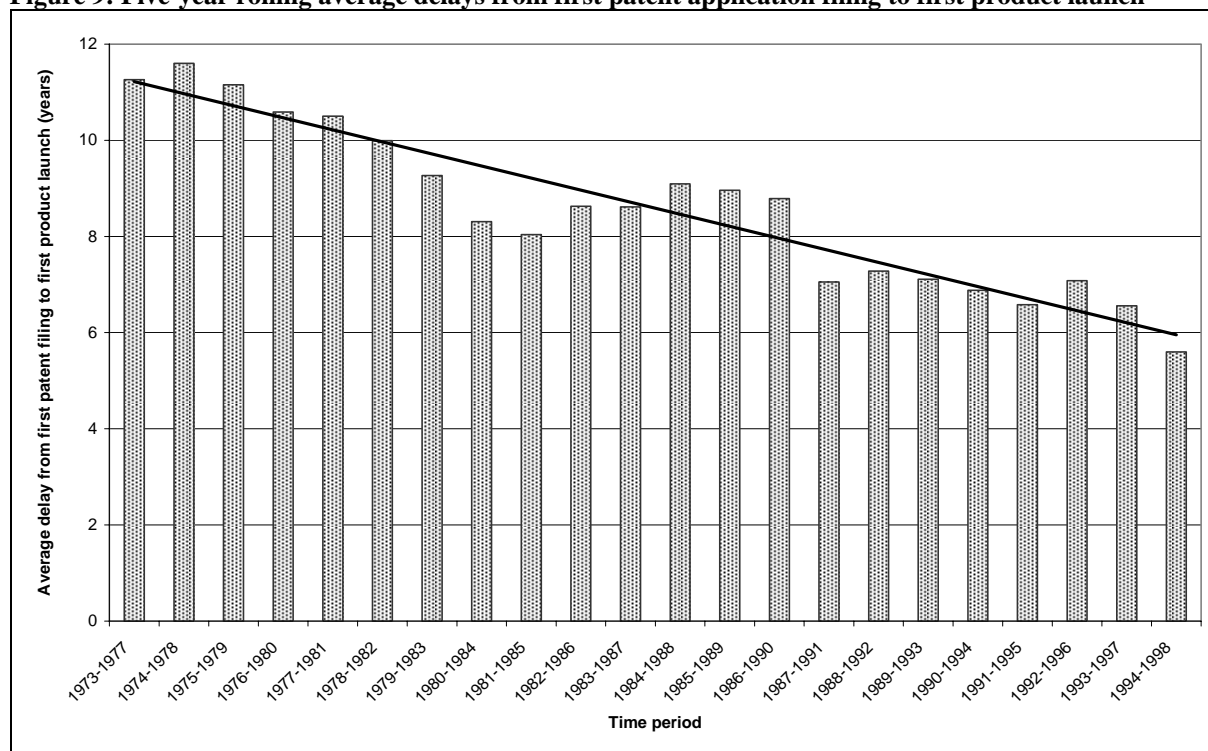
- (141) EU legislation provides harmonised measures aimed at guaranteeing good laboratory practice and the safety of animals and humans during pre-clinical and clinical testing.¹⁰⁰
- (142) The time between filing an application for the first compound patent to the launch of the product varies significantly, depending on the obstacles encountered. It can take between two to ten years for a potential medicine to go through the three clinical trial phases, with an average of five years.¹⁰¹ On the basis of a sample of the 20 best-selling molecules the time period between first patent application and launch on the market seems to vary between six and ten years.

¹⁰⁰ See (1) Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJL 121, 1.5.2001 p. 34-44). When submitting results, laboratories must certify that the tests were carried out in accordance with the principles of good laboratory practice. (2) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

¹⁰¹ "Pharmaceutical Pricing Policies in a Global Market", OECD 2008.

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Figure 9: Five-year rolling average delays from first patent application filing to first product launch



Source: Pharmaceutical Sector Inquiry

- (143) Using a wider sample of 141 INNs for which complete data was available,¹⁰² the average time taken from patent application filing to product launch was 8.6 years. Figure 9 shows the five-year rolling averages of delays from first patent application filing to first product launch and demonstrates a reduction in these delays from 1973 to 1998. Nevertheless, it is fair to say that the period between first patent filing and first product launch is quite significant. As a reaction to these delays, mechanisms were introduced by the legislature to provide additional patent-like protection in the form of SPCs and rules on data exclusivity. For further details on these mechanisms, see Chapters B.2.1. and B.2.2.

¹⁰² Data for combinations of INNs, as well as for INNs where the product launch was reported as having been prior to the filing of the first patent application, were excluded. The sample of 141 INNs nevertheless covers 77% of the INNs on the T-50 list and 69% of the INNs on the E-75 list. For an explanation of these lists, please see Annex on Methodology (Annexes to Chapter A).

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1.2.1.1.3. Marketing Authorisation

- (144) Medicines may only be placed on the EU market when they have a positive benefit-risk ratio as regards safety and efficacy and are of good quality. This is verified in the marketing authorisation process. Marketing authorisations are governed by EC law and can be granted either centrally by the Commission (after application to the European Medicines Agency, EMEA) or nationally. EU legislation also sets a time limit for taking marketing authorisation decisions. For further details reference is made to Chapter B.2.2., which summarises marketing authorisation procedures.

1.2.1.1.4. Pricing and Reimbursement

- (145) In many EU Member States a product can only be marketed after a decision on the price and reimbursement has been taken. The pricing decision determines the "commercial" terms of access to the market in a particular country. The aim of these policies is to ensure on the one hand that patients have access to the necessary medicines and, on the other hand, that health budgets remain under control in order to ensure sustainability of the health system. Obviously these policies are also decisive in giving incentives for further innovation.¹⁰³
- (146) Even in Member States in which prices are not officially fixed, indirect price controls exist through reimbursement decisions. If no reimbursement is offered for an expensive product facing competition, or it is subject to a very significant co-payment, a significant share of patients is likely to refrain from using the new medicines. When deciding on reimbursement, health insurers also rely on so-called "health technology assessments" aimed at assessing the added value of a new medicine over and above existing treatments as explained in Chapter B.1.1.
- (147) Pricing and reimbursement decisions must be taken within the time frame set by the Transparency Directive.¹⁰⁴ However, it has been submitted that in many Member States it would take longer than the 90 days stipulated in this Directive for each of these decisions. Once the pricing and reimbursement decisions have been taken, the product can be launched onto the market. For further details on the regulatory framework for pricing and reimbursement decisions, see Chapter B.2.3.

¹⁰³ It is interesting to note that the European Court of Justice in a recent judgment (Joined Cases C-468/06, C-469/06, C-470/06, C-471/06, C-472/06, C-473/06, C-474/06, C-475/06, C-476/06, C-477/06, C-478/06 *Sot. Lélos kai Sia*) has ruled that "*the control exercised by Member States over selling prices or the reimbursement of medicinal products does not entirely remove the prices of those products from the law of supply and demand*".

¹⁰⁴ Directive 89/105/EEC of the Council of 21 December 1988 relating to the transparency of measures regulating the process of medicinal products for human use and their inclusion in the scope of national insurance systems (OJ L 40, 11.2.1989, pp. 8-11).

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1.2.1.1.5. Pharmacovigilance

(148) Throughout the lifetime of products, pharmaceutical companies are subject to harmonised pharmacovigilance requirements¹⁰⁵ to monitor adverse reactions to a medicine and/or new side effects (also referred to as Phase IV studies). As already mentioned above, further R&D (incremental innovation) aimed at improving the medicine or finding new uses is frequently conducted by originator companies during this phase. New patent applications can be therefore submitted at this stage.

1.2.1.2. Costs

(149) The costs of bringing a new medicine to market are subject to wide debate and a variety of estimations. The originator industry claims that the cost of a new medicine from basic research to launch amounts to between US\$ 800 million and US\$ 1 billion,¹⁰⁶ (this figure includes the costs of failed projects). Some respondents have suggested, however, that the costs are closer to US\$ 450 million.¹⁰⁷ For biopharmaceuticals, the costs of R&D are generally reported to be higher than those of traditional pharmaceuticals.¹⁰⁸

(150) According to the submissions received by the respondent companies, pre-clinical and clinical trials are generally financed by the companies' own resources and the amount of financial support received from governments or other sources is not significant.¹⁰⁹

(151) However, it is worth noting that within the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 – 2013), it was recently decided that support would be provided to European R&D activity through the Innovative Medicines Initiative Joint Undertaking (IMI JU). In this public-private partnership, the European Commission and EFPIA have joined forces to overcome bottlenecks in the development of innovative medicines. The Commission is contributing € 1 billion to the project, half of the IMI

¹⁰⁵ Title IX of Directive 2001/83/EC and chapter 3 of Title II of Regulation (EC) No 726/2004.

¹⁰⁶ At current exchange rates this would be the equivalent to € 552 million and € 690 million. See <http://www.ecb.int/stats/exchange/eurofxref/html/index.en.html#data> (18 September 2008).

¹⁰⁷ At current exchange this would be the equivalent to € 310 million. See <http://www.ecb.int/stats/exchange/eurofxref/html/index.en.html#data> (18 September 2008).

¹⁰⁸ Of course, depending on the type of medicine under development costs can vary significantly.

¹⁰⁹ As regards basic research, one contribution received in the public consultation reports that, according to some studies, as much as 84% of all funds for basic research comes from public sources (Light, Donald. 2006, Basic research funds to discover important new drugs: who contributes, how much. Global Forum for health research). On the other hand, another contribution puts emphasis on the fact that "*The gigantic research investments by the innovative industry is paid for by today's medicines sales, not by public funding as is often wrongly assumed*". Please note that, as reported in Chapter B.1, on the basis of the information received from our company sample, approximately 1.5% of turnover was spent on pre-clinical research and the remaining part mostly on clinical trials and tests.

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JU budget. The other half will be provided by the pharmaceutical industry through EFPIA.¹¹⁰

- (152) On the basis of sector inquiry data, the development phase, in particular Phase III clinical trials, is the most expensive. In comparison, the costs associated with basic research are low. This is a positive aspect for the companies as the risk of failure decreases with every step in the R&D process. The table below provides an average break-down of R&D costs invested by the originator companies during the different stages, as reported by the companies.

Table 8: Distribution of costs in clinical and pre-clinical phases at global level (2007)

Costs	In % of total R&D
Pre-clinical (including basic research)	8%
Phase I	12%
Phase II	20%
Phase III	60%

Source: Pharmaceutical Sector Inquiry

- (153) In the course of the sector inquiry, companies were asked to indicate whether they carry out the R&D activities for new compounds themselves or whether the compounds that they currently have in their respective pipelines were acquired from third parties, e.g. through acquisition of the patent, through acquisition of the company owning the patent or through licensing agreements. The figures for the year 2007 are given in the following table:

Table 9: Percentages of molecules acquired or in-licensed by originator companies during pre-clinical research, clinical development or pending marketing authorisation (2007)

Phase	% of company's own molecules	% of molecules acquired or in-licensed
Pre-clinical research	88%	12%
Clinical development	75%	25%
MA pending	65%	35%

Source: Pharmaceutical Sector Inquiry

- (154) The table suggests that originator companies rely, to a significant degree, on the acquisition of compounds from third parties. It is also evident that the degree to which originator companies rely on inventions by third parties rises with increasing proximity to product launch. Obviously, the table only provides a snapshot and does not allow to conclude whether originator companies are today more or less successful in innovating than in the past.

¹¹⁰ Council Regulation (EC) No 73/2008 of 20 December 2007 setting up the joint undertaking for the implementation of the joint technology initiative on innovative medicines (OJ L 30, 4.2.2008, pp. 38-51).

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1.2.1.3. Selection Process

- (155) Originator companies are commercial operators. They therefore determine the areas in which they carry out R&D activities from a commercial perspective, taking into account the costs and expected returns.
- (156) In order to assist with this decision, all originator companies reported that they produce documents which they sometime refer to as target product profiles (TPPs). TPPs contain the indicators on which decisions concerning future product pipelines are based. The importance assigned to each indicator varies from company to company but the indicators listed below were reported to be of decisive influence for (almost) all companies:
- Therapeutic indication/area (ideally an unmet medical need);
 - Market size and growth potential (patient numbers, medical needs, pharmacoeconomic benefits);
 - Risk assessment and profitability (economic return);
 - Portfolio synergy (company experience, R&D and manufacturing facilities already available);
 - Competitive environment (differentiation);
 - Future regulatory environment (pricing-reimbursement); and
 - IP protection (patents owned by both the company and their competitors).
- (157) Taking into account these factors, the following therapeutic areas are currently the main targets of the originator companies questioned as part of the sector inquiry (presented in alphabetical order, no ranking whatsoever is implied):

Table 10: Main therapeutical areas in R&D

Alzheimer/mental health	Obesity
Cardiovascular	Oncology
Digestive conditions	Respiratory tract disease/asthma
Hepatitis	Rheumatoid arthritis
HIV/AIDS	Virus control/infections

Source: Pharmaceutical Sector Inquiry

- (158) The areas highlighted above include the therapeutic areas addressed by the main blockbusters for 2007 listed in Chapter B.1.1., for example cardiovascular system, respiratory system, nervous system, alimentary tract and metabolism.
- (159) However, this leaves insufficient incentives to invest in R&D for rare illnesses, illnesses affecting specific segments of the population such as children or pregnant

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women or illnesses less present in the USA and the EU.¹¹¹ Besides the collective financing of health care, market exclusivity and data protection have been used by the legislator as targeted incentives for companies to enter areas such as paediatric and orphan medicine.¹¹²

1.2.1.4. Success Rates

- (160) The attrition rate (percentage of failed projects) is very high at the basic research stage, but this rate decreases throughout the development process. Costs, however, follow the opposite trend, the last phase in clinical trials (Phase III) being the most expensive one.
- (161) According to industry figures, as few as 1 in 5,000 – 10,000 compounds tested are successfully launched.¹¹³ In the course of the sector inquiry it was not possible to verify this data, as many companies claimed that they were unable to provide the requested information.
- (162) The companies reported that the main reasons for discontinuing the development of a compound already under clinical trials are generally speaking of a scientific nature (often a lack of safety or efficacy). Once the project reaches the last phases of development, commercial reasons appear to play a less significant role in that decision. This is to be expected as commercial expectations are carefully considered by the companies at the outset.¹¹⁴

¹¹¹ In this context, it has been submitted during the public consultation that the G-FINDER, a survey of global investment into Research and Development of new products for neglected diseases reports that in 2007 public and philanthropic funders provided around 90% of global R&D funding for neglected diseases and that collectively, the private sector (pharmaceutical industry) contributed 9.1% being the third largest source of investment in this type of diseases (report published by the George Institute for International Health in February 2009).

¹¹² Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000 p. 1-5), Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, pp. 1-19).

¹¹³ EFPIA Submission to the European Commission in relation to the pharmaceutical sector inquiry, 13 June 2008 (p. 20).

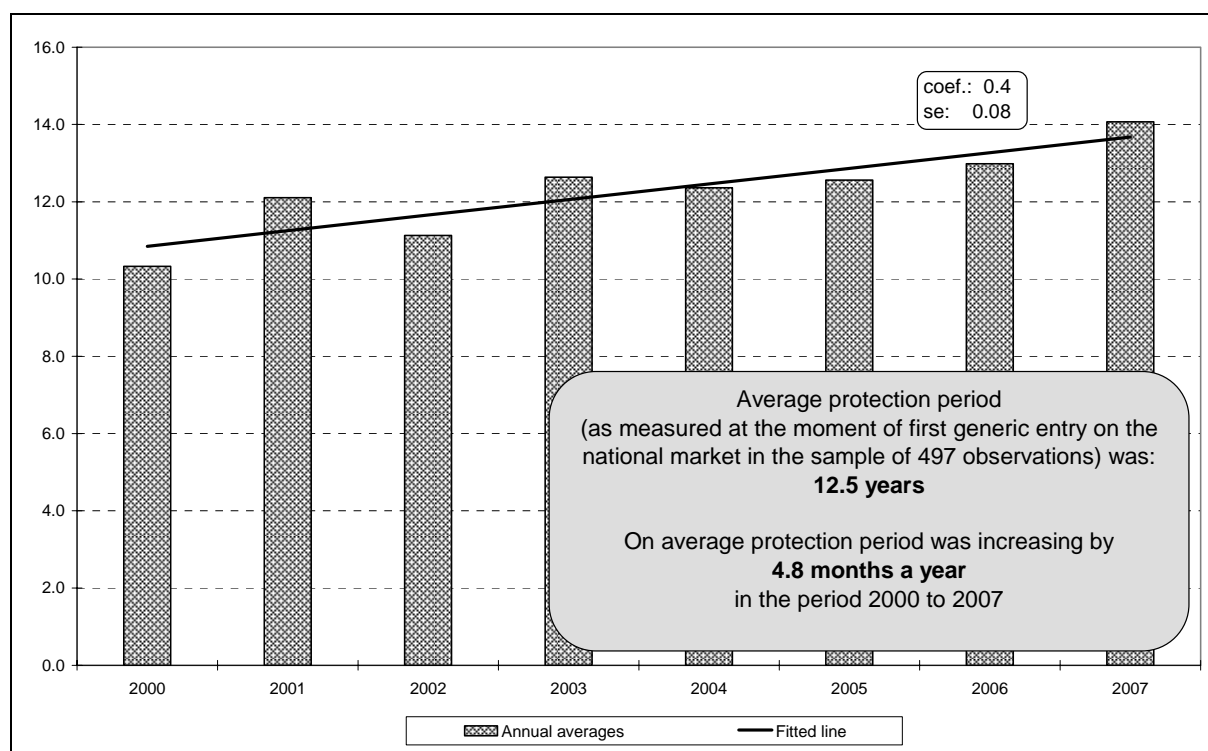
¹¹⁴ In this regard, it was submitted in the context of the public consultation that commercial considerations play a decisive role throughout clinical development, also at late stages, with a continuous assessment of commercial factors. This is in contradiction to information submitted by the originator companies investigated.

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1.2.2. Product Life Cycle during Patent Protection

- (163) As explained in previous sections, it is the time period between launch and LoE during which an originator company must generate sufficient revenues from a product to cover the R&D expenses and earn a profit. After patent expiry, generic companies will be able to enter the market, leading to falling prices and decreasing volumes for the originator company.
- (164) In this respect, it is interesting to note that the effective protection period counted from first launch to first generic entry increased by approximately 3.5 years in the period 2000 – 2007. Figure 10 shows that the average protection period moved from less than 10.5 years calculated for the medicines with first generic entry occurring in 2000 to fourteen years for the medicines with first generic entry in 2007. The fitted line, which is also displayed on Figure 10, shows the trend line calculated for all available observations. It has a clearly positive slope with the coefficient value of 0.4 that translates into an average increase in protection period of 4.8 months a year. These findings are based on 497 observations for which dates of first launch could be coupled with dates of first generic entry for individual medicines at the Member State level.

Figure 10: Evolution of the effective protection period counted from first launch to first generic product in the period 2000 – 2007



Source: Pharmaceutical Sector Inquiry

- (165) A significant number of blockbuster medicines will lose patent protection during the next few years. This fact, along with increasingly restrictive health care budgets throughout the EU, form the background against which originator companies aim to maximise their return on investment and reaping the benefits of prior R&D investments.

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- (166) In anticipation of the declining turnover following patent expiry, originator companies confirm employing strategies with broadly two aims: (1) extending the time of their market exclusivity without generic competition; and (2) maintaining or expanding the market that the product covers during its exclusivity period.¹¹⁵ These strategies are generally developed by life cycle management plans for specific products and markets. Most of the companies consulted report having life cycle management departments. Life cycle strategies can be considered as a tool-box for originator companies to use in order to maximise the return from their products. The use of the term "tool-box" in this report has been criticised by originator companies and their associations as giving it a "pejorative" meaning. However this term has not been invented for purposes of this report. Rather, it seems to be the term commonly used by originator companies themselves, as evidenced in the strategy documents collected during the inquiry.
- (167) In the subsequent parts of this report the most common life cycle management strategies will be described in detail. The main strategies that became apparent from the respondents are:
- Measures enhancing product loyalty (including criticising competitor's products); (Chapter C.2.5. and C.2.7.);
 - Reformulation and second-generation launch; (Chapter C.2.7.);
 - Putting into question the efficacy or quality of generic products; (Chapter C.2.5.);
 - Creation of patent clusters (in particular through secondary patents protecting a product)¹¹⁶; (Chapters C.1.2., C.2.7.);
 - Defensive patenting¹¹⁷ against other originators; (Chapter C.3.1.);
 - Litigation against originator companies; (Chapter C.3.2.);
 - Litigation against generic companies; (Chapter B.1.3.);
 - Settlements with generic companies; (Chapter C.2.3.);

¹¹⁵ Originator companies also develop life cycle management strategies to face competition from other originator companies. These strategies include conventional business practices which are not specific to the pharmaceutical sector, such as cost savings for example through optimising the manufacturing process or product improvements.

¹¹⁶ These terms are being used by the report, as they constitute part of the terminology employed by stakeholders in this sector and thus are key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying intentions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

¹¹⁷ This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying intentions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

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- Interventions at the level of marketing authorities and pricing and reimbursement bodies; (Chapter C.2.5.);
- Interventions at the level of doctors (e.g. marketing and promotion activities); (Chapter C.2.5.);
- Interventions at the level of other stakeholders (e.g. wholesalers and pharmacies); (Chapter C.2.5.);
- Pricing strategies; (Annex to Chapter B);
- Launch of a licensed or a company's own generic (Annex to Chapter B);
- Switch to OTC (Annex to Chapter B).

(168) The Annex to Chapter B outlines those strategies not generally described in the other parts of the report, i.e. pricing strategies, launch of an own generic version and the switch to OTC. These strategies were less frequently reported by the respondent companies.

1.2.3. Product Life Cycle after Patent Expiration

(169) As will be shown in Chapter B.1.3., the launch of a generic version of a product following LoE has a major impact on the sales price and the volume of the medicine sold.

(170) The latest market figures on the generic medicines industry in Europe from July 2007 show that generic penetration varies widely between Member States. This ranges from less than 20% by value in Belgium, Finland, France, Greece, Ireland, Italy and Spain, to between 20 and 40% in Austria, Denmark, Germany, the Netherlands, Portugal, Sweden, Hungary and the UK, and to over 40% in Poland.¹¹⁸ The level of generic penetration in the EU is influenced by the different public policy choices made by the Member States.¹¹⁹ Most importantly, generic penetration rates are higher in Member States, where the prescription of active substances (INNs) instead of brands is encouraged (for example in the UK).¹²⁰

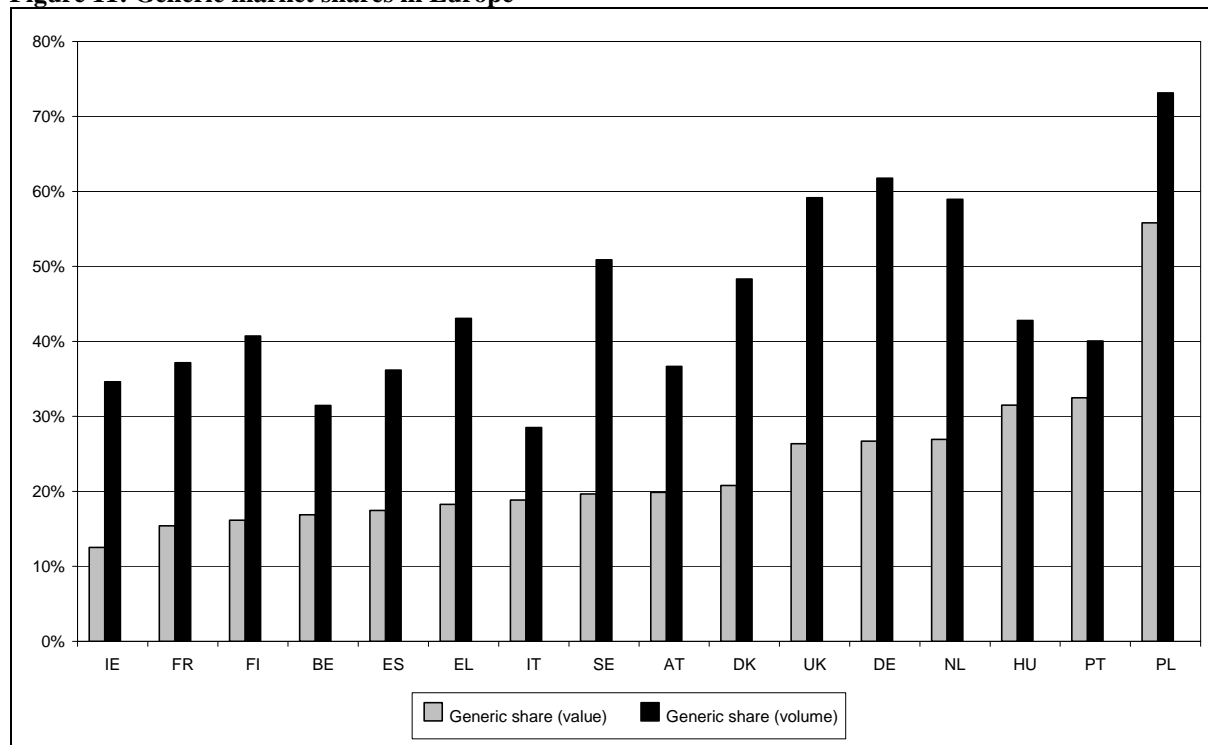
¹¹⁸ These figures relate to all INNs in the market (irrespective of whether and when they went off-patent). As a result, the penetration rates may differ from those reported in the section B.1.3. which relate to the market shares obtained by generic companies within one and two years following loss of exclusivity for a selection of INNs that lost exclusivity in the reference period 2000-2007 (the E75 list).

¹¹⁹ According to one submission received during the public consultation the high penetration rate of generics in Poland is explained by the low market access of innovative medicines during the period under investigation. This might be an additional factor to the Polish generic substitution policy at the pharmacy level.

¹²⁰ It has been reported during the public consultation that for example in France, general practitioners make more use of the possibility to prescribe active substances (INNs) than medical specialists. The same stakeholder argues that the use of the INN for prescriptions also increases the transparency, and therefore the security of the medicines for patients.

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Figure 11: Generic market shares in Europe



Source: Pharmaceutical Sector Inquiry (based on IMS data)¹²¹

Note: Generic market shares in Figure 11 may differ from findings by other sources, e.g. EGA, due to the fact that the definition of generic products may include different product categories in the various countries.¹²²

(171) However, despite the differences in generic market shares, all EU Member States nowadays encourage the penetration of generics medicines in an attempt to keep healthcare expenditure under control (for further details concerning policies encouraging generic penetration see Chapter B.2.3.).

¹²¹ The calculation of generic value and volume shares relates to the total prescription retail market and is based on IMS' definition of generic products. Generic market shares for the remaining eleven Member States were not available.

¹²² For instance with respect to Finland it has been submitted during the public consultation that the actual generic market penetration is higher in volume and value. This is mainly due to the fact that two companies (Orion and Leiras Finland) are active in both, generic and originator markets, but are counted by IMS as originators. Similarly, the figure indicating the value of the generic market in Portugal was questioned by one submission.

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Summary

There are three distinct phases to the life cycle of a new medicine: (1) R&D phase up to market launch; (2) the period between launch and loss of exclusivity (e.g. patent expiry); and (3) the period following the loss of exclusivity, when generic products can enter the market.

During the first phase, companies identify potential new medicines and take them through intensive pre-clinical and clinical trials. The originator companies surveyed rely to a large degree (i.e. for more than one third of all new medicines in the marketing approval phase) on innovations acquired from third parties.

During the second phase, originator companies market the medicines they have developed, with a view to recouping upfront investments and making a profit. Effective patent protection is vital to sustain this business model, which also ensures there are incentives for further innovation. In the period 2000 to 2007, the effective period counted from the first product launch of the originator product to the marketing of the first generic product increased from 10.5 years to more than fourteen years.

Following loss of exclusivity, generic medicines can enter the market. The share of generic medicines varies significantly between Member States. The generic share (value terms, volume terms) is the highest in Poland (56%, 73%), Hungary (32%, 43%), Portugal (32%, 40%) and lowest in Ireland (13%, 35%), France (15%, 37%) and Finland (16%, 41%).

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1.3. Impact of Generic Entry and Regulatory Factors Affecting Generic Competition

- (172) This section addresses the overall impact of generic entry on the medicines that faced loss of exclusivity (i.e. expiry of patent protection, SPC protection and data exclusivity) in the period 2000 – 2007.
- (173) The question of the impact of generic entry has two dimensions. First, there is the question of the extent of entry. What part of the sector that faces loss of exclusivity is exposed to subsequent generic entry? How quickly does it occur? How many generic entrants are typically observed?
- (174) Second, in those instances where generic entry occurs, what is the *effect*? In particular, to what extent are the prices of the product that went off-patent affected? How are the volumes of the originator company affected? Are there any effects on other products (e.g. possible substitutes for the product that went off-patent)? The combination of the extent of entry and the effect of entry when it occurs determines the aggregate impact of entry on the sector facing loss of exclusivity.
- (175) This section provides descriptive statistics on each of the two dimensions of generic entry. Further, where possible, it provides an analysis of the factors that may explain (in a statistical sense) the pattern of entry and the degree of competition by generics. It will do so principally on the basis of regression analysis¹²³
- (176) The analysis is based on two main sources. First, it draws on data collected from pharmaceutical companies in the course of the sector inquiry.¹²⁴ Second, the Commission has used data obtained from IMS Health.¹²⁵
- (177) Consequently, in this section the dates of loss of exclusivity are those as reported by the (originator) companies themselves and, when these were not available, those provided by IMS Health. The section analyses the impact of generic entry in relation to these given dates. For instance, it reports the "time to entry" (the number of months it takes for generic entry to occur after loss of exclusivity) as measured by the difference between the date of generic entry and the reported loss of exclusivity. The analysis does not identify any (additional) delays to generic entry that might arise from companies seeking to claim an extended exclusivity period in the context of life cycle strategies such as the ones described in Chapter C of this report. Nor should it be inferred that the measured time to entry is due to one factor in particular (e.g. the

¹²³ Regression analysis is the standard tool used by statisticians to find and evaluate relationships between variables (e.g. between the variable of interest and factors that may influence this variable). In particular, it allows analysing the relationship between two variables, while controlling for changes in other factors.

¹²⁴ Company data were gathered for the EU as a whole, except for price data, where the set of countries on which companies were requested to provide data was narrowed down to Denmark, France, Germany, Greece, Hungary, Italy, the Netherlands, Poland, Spain and the United Kingdom.

¹²⁵ For further details on the method see the Annexes to Chapter A.

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length of regulatory procedures, logistical constraints for the generic companies,¹²⁶ behaviour by companies or any other factor).

- (178) The analysis in this chapter is based mainly on the "E75" list of INNs on which the Commission requested information from the companies. This list was the result of initial selection, in three Member States (France, Germany and the United Kingdom), of the 75 top-selling INNs that faced loss of protection in the period from 2000 – 2007.¹²⁷ The top 75 molecules in each of the three countries were then combined into a single list of molecules (the "E75" list) with a view to obtaining a robust sample of INNs likely to be representative of the EU as a whole. The resulting list comprised 128 INNs for which the Commission subsequently requested information from the companies in each of the 27 EU Member States.¹²⁸
- (179) The analysis at Member State level was based on those INNs on the E75 list that were relevant to the Member State in question, i.e. those INNs that were effectively sold in that Member State and which faced loss of exclusivity in the period 2000 – 2007. For further details on the methodology, see the Annexes to Chapter A.

1.3.1. Extent of Generic Entry

- (180) This section consists of three subsections. Subsection 1.3.1.1 analyses the number of instances where generic entry occurred after the INN faced loss of exclusivity¹²⁹. Subsection 1.3.1.2 analyses the time lag between loss of exclusivity and generic entry if and when it occurs. Finally, Subsection 1.3.1.3 looks into the average number of generic entrants in the event of entry.

¹²⁶ For the effective launch of a generic product certain logistical operations need to be carried out, such as manufacturing, importing, storing and distribution. For a generic company it is important to ensure that these operations do not violate applicable patent law. In the course of the sector inquiry the generic industry maintained that an immediate launch (essentially, on day one) after LoE can nonetheless be achieved (e.g. by manufacturing in a country, in which patent protection already expired or never existed and importing/distributing the goods on day one), a fact that is confirmed by the findings of the inquiry.

¹²⁷ For this initial selection, IMS sales and expiry data were used for France, Germany and the United Kingdom. In each country, the top 75 INNs accounted, in value terms, for well over 90% of sales of all INNs that faced loss of exclusivity in the period 2000-2007 in the Member State concerned.

¹²⁸ For a more general analysis of the sample of INNs and products on which the main issues of this report were investigated, see Chapter C.1.1.

¹²⁹ Whenever this section refers to an INN losing exclusivity, it means the first time that one of the formulations sold under the INN loses exclusivity.

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1.3.1.1. Occurrence of Entry

(181) Table 11 shows, for the EU as a whole¹³⁰, the share of INNs in the sample that faced generic entry over the period 2000 – 2007. All shares are presented both as a head count (where within each country each INN is counted as one; left-hand column) and in value terms (where within each country weights are given to the INN in relation to their sales value in the year before loss of exclusivity; right-hand column).

Table 11: Share of INNs that faced generic entry following loss of exclusivity (EU average; sample: E75-list)¹³¹

	Entry share (head count)	Value share entry
Entire sample; entire period	66%	85%
Measured one year after loss of exclusivity (entire sample)	47%	70%
Measured one year after loss of exclusivity (INNs expired in 2000-2006)	46%	69%
Measured two years after loss of exclusivity (INNs expired in 2000-2005)	54%	80%

Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

(182) The first row in the table gives the occurrence of entry for the entire sample of 128 INNs on the E75-list, irrespective of when in the period the INN lost exclusivity or generic entry took place. As can be seen, the share of INNs in the overall sample that faced generic entry at any point in time over the period 2000 – 2007 is about 66% in number terms and about 85% in value terms.

(183) These shares may be somewhat difficult to interpret, however, in that not all INNs are in an equal position. For instance, if those INNs lost exclusivity early in the period 2000 – 2007, that left a long time for entry to occur within the period under investigation. By contrast, for INNs which lost exclusivity late in the period (e.g. in autumn of 2007), little time is left for entry to occur and – even if they were relatively quick – instances of generic entry might not be counted for these INNs. For this reason, the table also indicates the shares of INNs for which entry took place within one year, both for the entire sample (second row, mainly for comparison) and the sample which lost exclusivity up to 2006 (third row). It also indicates for this sample,

¹³⁰ All EU averages in this section are calculated taking into account the relative weight of the individual Member States (as measured by sales of the relevant INNs in the Member State concerned, either in the year prior to expiry (for establishing shares of generic entry, average time to entry and generic penetration) or in the year 2007 (for the indices that track the development of prices or volumes over longer time periods).

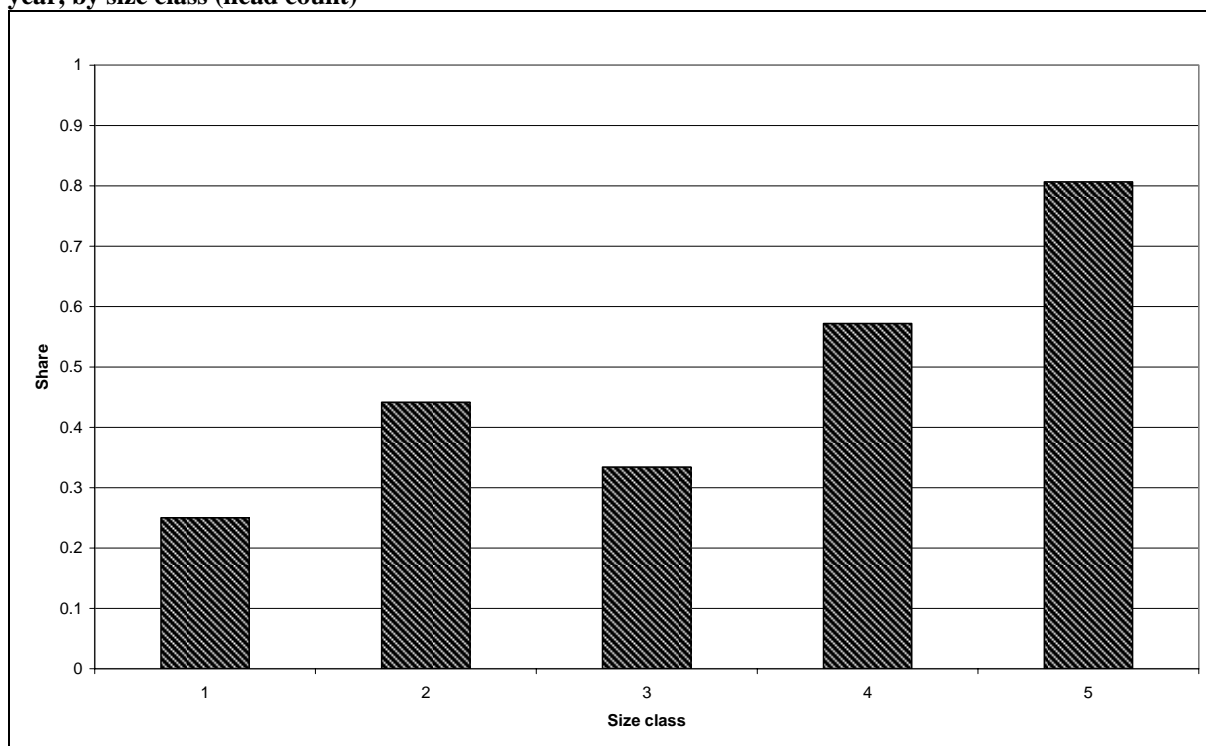
¹³¹ The shares differ slightly from those reported in the Preliminary Report following updates from the companies and correction of entry dates to reflect entry by independent generic companies (as opposed to the launch of own generics or the entry of licensed entrants). Further, in a relatively small number of cases, INNs are used for distinct medical indications and are accordingly part of several distinct ATC classes. Where the loss of exclusivity date and/or date of generic entry differed per ATC class, these cases have been treated separately (except for the headcount measures, to avoid double counting). See Annex on Methodology (Annexes to Chapter A) for further details.

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the shares of INNs for which entry took place within two years (for loss of exclusivity up to 2005).

- (184) The table shows that, focusing on patents which expired between 2000 and 2006 followed by entry within one year, the share of INNs that faced generic entry is about 46%. However, taking into account the importance of the INNs (in terms of sales), the entry share is higher, at 69%.
- (185) This last finding suggests that generic entry tends to concentrate especially on INNs with a high sales value. This pattern can also be seen to some extent in Figure 12 below, which sets out the share of generic entry for individual size classes. The set of INNs is split into five size classes, with class 1 containing the 20% of smallest INNs (in terms of their sales value in the year prior to expiry), class 2 the next smallest 20%, etc. Class 5 therefore contains the 20% of largest-selling INNs. On average, the share of generic entry appears higher for the larger size classes than for the smaller ones. This can be explained by higher incentives for the generics to enter. Obviously, from the perspective of consumer welfare, generic entry without delay for this category is most valuable.

Figure 12: Share of INNs which expired between 2000 and 2006, followed by generic entry within one year, by size class (head count)

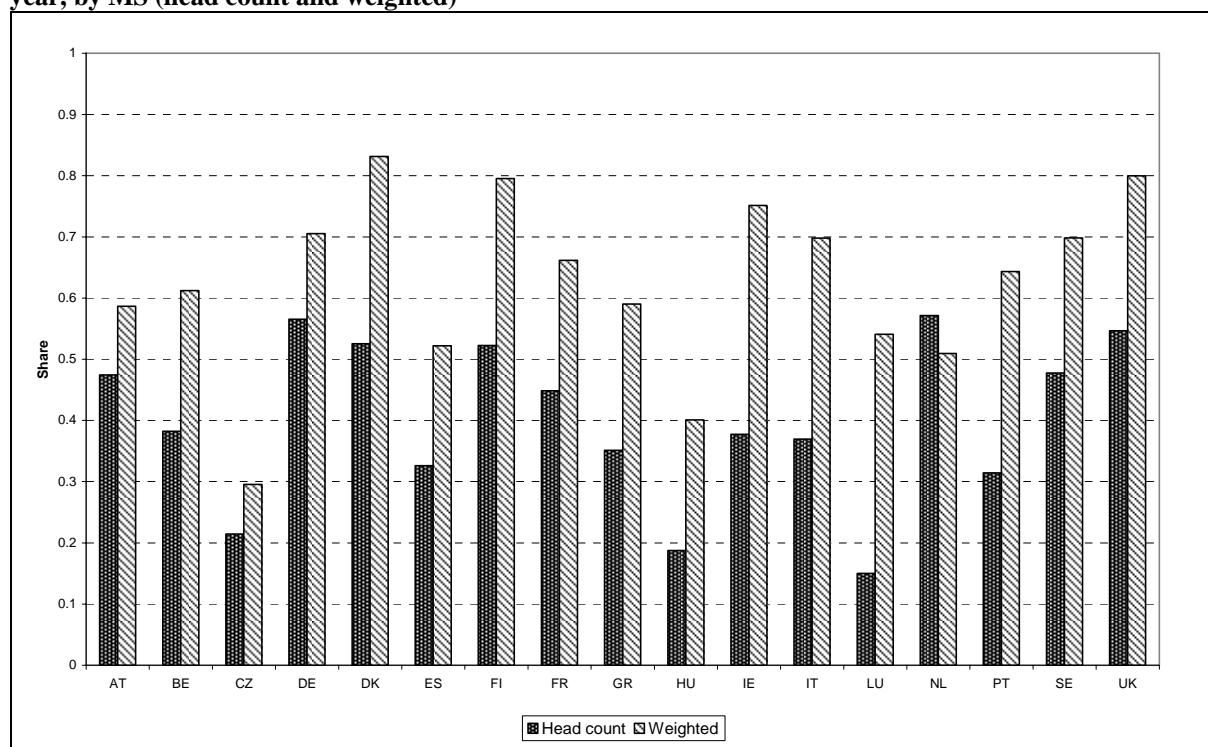


Source: Pharmaceutical Sector Inquiry (partially based on IMS data). Class 1 contains the 20% of the smallest INNs (in terms of sales value), class 2 the next smallest 20%, etc. Class 5 contains the 20% of largest-selling INNs.

- (186) The EU averages indicated above hide considerable variation between the EU Member States. Figure 13 provides an overview of the share of entry in a range of countries, both as a head count of INNs and with the INNs weighted by value. The figure shows that in the sample investigated, generic entry is most pervasive in Germany, Denmark, Finland, the Netherlands and the UK, with entry shares within the first year above 50% both in number and value terms.

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Figure 13: Share of INNs which expired between 2000 and 2006, followed by generic entry within one year, by MS (head count and weighted)¹³²



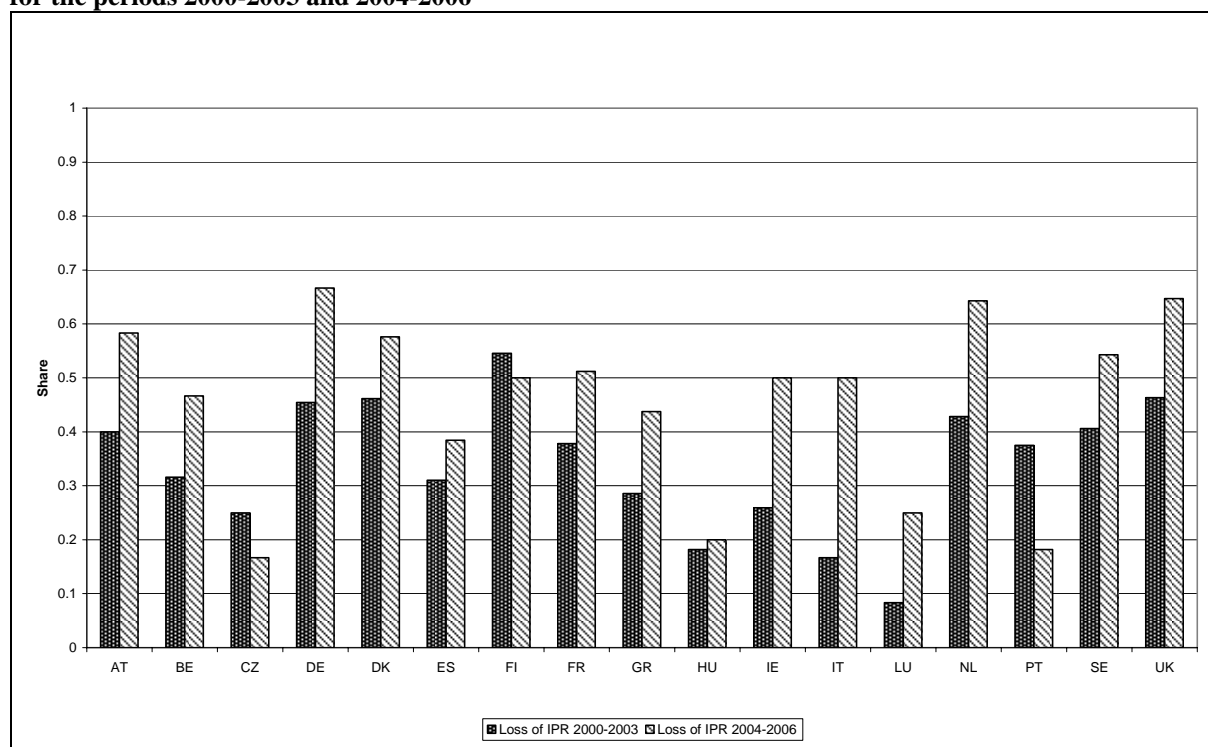
Source: Pharmaceutical Sector Inquiry (partially based on IMS data). Statistics for other countries not available (cf. Annex: Methodology)

(187) Another interesting aspect is whether the generic entry has changed over the period in question. Figure 14 presents the share of INNs that faced generic entry for a number of countries, drawing a distinction between INNs which experienced LoE in the period 2000 – 2003 and in the period 2004 – 2006.

¹³² The entry shares have changed to a limited extent in comparison with the Preliminary Report (cf. footnote 131 above). The change for Hungary and the Netherlands is somewhat more pronounced due to the relatively small samples.

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Figure 14: Share of INNs which expired followed by generic entry within one year, by MS (head count), for the periods 2000-2003 and 2004-2006



Source: Pharmaceutical Sector Inquiry (partially based on IMS data).

- (188) As can be seen in the above figure, the share of expiring INNs followed by generic entry within one year has in most countries increased somewhat over the period 2000 – 2007, although there are some exceptions.
- (189) Regression analysis can shed further light on some determinants of generic entry. The regression analysis confirms that the value of the market (measured per capita and in terms of the Member State's size of population) at the point of LoE is an important driver of generic entry, holding other factors constant.¹³³ Further, it also confirms that the occurrence of entry tends to increase over time. In other words, the probability of generic entry appears to be higher in later years than in earlier years, holding other factors constant.
- (190) Regression analysis has also been used to explore the relevance of characteristics of the regulatory environment. The results suggest that a number of regulatory variables play an important role. A first is whether pharmacists are required to dispense the cheapest available product from those covered by the doctor's prescription. In countries and time periods where compulsory generic substitution exists, generic entry in the first year appears to be more prevalent. Another relevant variable is whether or not generics are subject to a mandatory discount (in comparison to the pre-existing originator price) or price cap when they enter. The regression results suggest that such environments are less favourable to swift generic entry (entry within the first year). A

¹³³ See Annex to Chapter B.1.3.: Econometric Analysis for more detail.

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tentative explanation for this latter finding is that mandatory discounts or price caps may remove some of the advantage of first-movers into the market (the first generic entrant to enter the market has to give a mandatory discount, whereas otherwise it might be able to offer mild price reductions compared to the originator company until the point in time that other generic companies enter the market as well).

1.3.1.2. Time to Entry

- (191) One important dimension of the entry process is the speed with which it takes place. Table 12 provides an overview of the average gap between the time when the INN in question lost exclusivity and the first generic entry into that INN ("time to entry").¹³⁴ The average time to entry is presented both as a head count (within each country each INN in counted as one; left-hand column) and within each country weighting the INN in relation to their sales levels in the year before LoE (right-hand column).¹³⁵

Table 12: Average time to entry following loss of exclusivity (in months; EU average; sample: E75-list; expiries in 2000-2006); INNs facing entry¹³⁶

	Time to entry (head count)	Time to entry (with INNs weighted by value)
Time to entry (sample: E75)	12.9	7.9

Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

- (192) The average time to entry is about thirteen months in absolute terms, whereas it is more than seven months in weighted value terms.
- (193) The table suggests that it takes less time for high value products to be faced with generic entry. As mentioned earlier, this finding is not surprising considering that top selling INNs are normally also the most attractive to enter. The conclusion is further confirmed by the figure below setting out the time to entry for individual size classes. The set of INNs is split up into five size classes, where class 1 contains the 20% of smallest INNs (in terms of sales value in the year prior to expiry), class 2 the next smallest 20%, etc. By and large, the average time to entry appears to be smaller for the larger INNs (as measured by sales in the year prior to expiry). However, even for the top selling category it still took about four months on a weighted average basis before

¹³⁴ For the reasons that can lead to a delay, see paragraph (177).

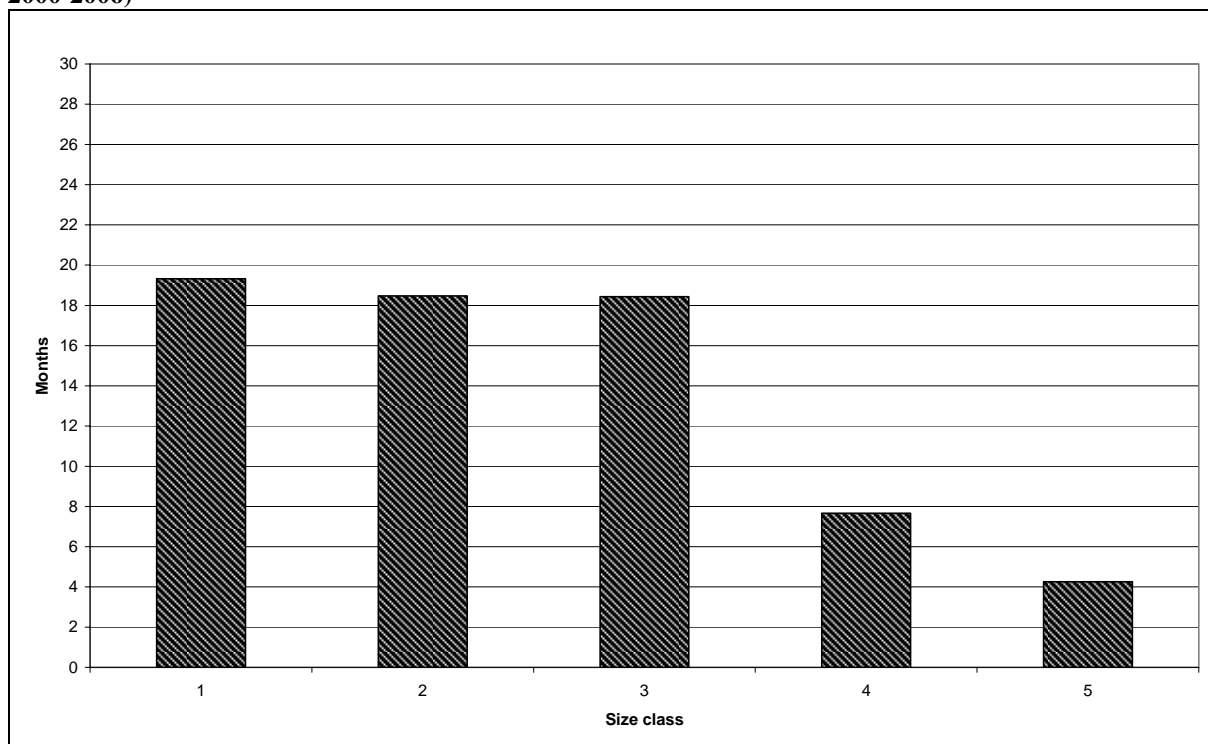
¹³⁵ The period of expiries is restricted to 2000 – 2006. When calculating the average time to entry on a collection of expiring INNs, one needs to bear in mind that not all INNs are in an equal position (See also Subsection 1.3.1.1). For instance, for all INNs that expired towards the end of the period 2000 – 2007 and for which entry can be observed, the time to entry is necessarily short. Taking these late observations into account would not give a representative estimate (a biased estimate) of the average time to entry of the sample of INNs under investigation.

¹³⁶ The entry shares have changed to a limited extent in comparison with the Preliminary Report, following data updates and a separate treatment of INNs belonging to several ATC classes (cf. footnote 131 above). Without distinguishing between ATC classes for given INNs (as was the case in the Preliminary Report), the weighted average delay was estimated at 7.2 months.

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entry took place. In individual cases in this category, the time to entry ranged from 0 months (no delay) to over 50 months.

Figure 15: Average time to entry following LoE, by size class (EU average); sample: E75-list; expiries in 2000-2006)

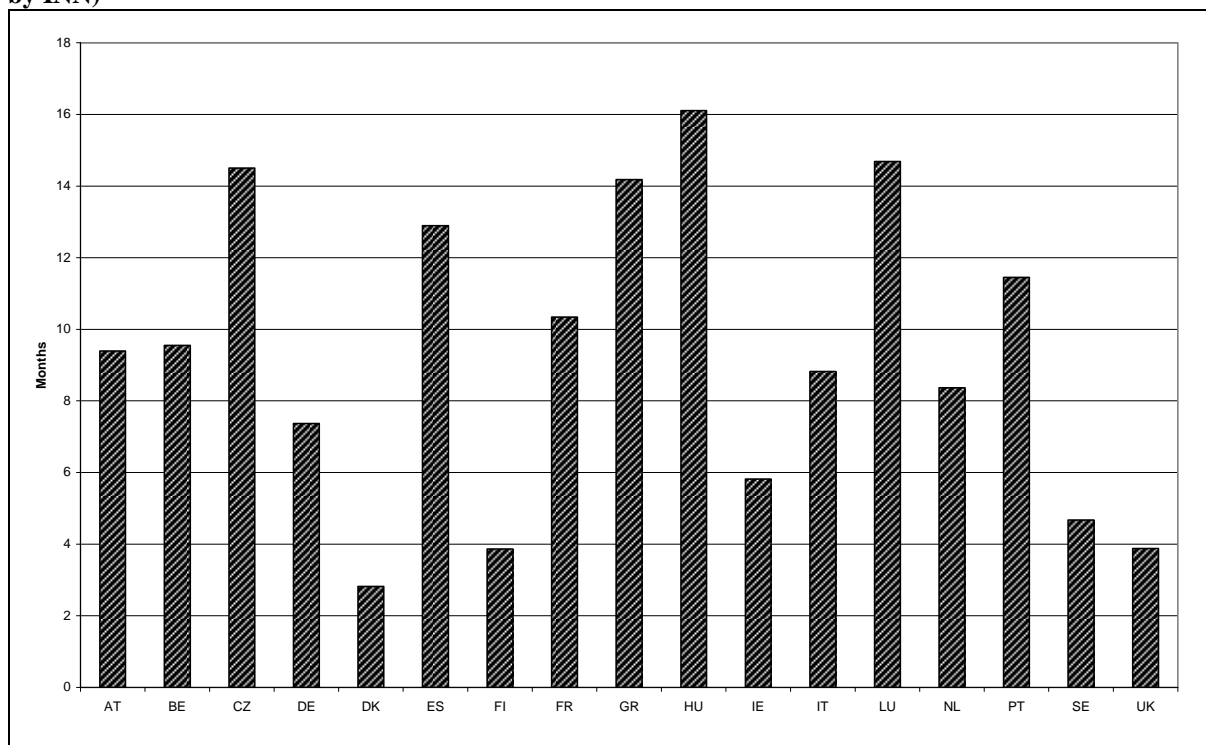


Source: Pharmaceutical Sector Inquiry (partially based on IMS data). Class 1 contains the 20% of smallest INNs (in terms of EU sales value), class 2 the next smallest 20%, etc. Class 5 contains the 20% largest selling INNs.

(194) There are equally considerable differences in time to entry between the EU Member States. Figure 16 shows the average time to entry in a range of countries. It is relatively short in Denmark, Finland, Ireland, Sweden and the UK but exceeds half a year, on average, in Austria, Belgium, the Czech Republic, Germany, Spain, France, Greece, Hungary, Italy, Luxemburg, the Netherlands and Portugal.

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Figure 16: Average time to entry following LoE, by country (sample: E75 list; LoE in 2000-2006; weighted by INN)



Source: Pharmaceutical Sector Inquiry (partially based on IMS data).

- (195) Over the period, there appears to be a gradual decline in the time to entry for expiring INNs. It is, however, difficult to provide meaningful descriptive statistics in this respect, given that the choice of time horizon (the time one allows for expiry to take place) heavily influences any resulting statistic.¹³⁷
- (196) Regression analysis confirms the above findings.¹³⁸ In particular, the value of the market per capita at the point of LoE is an important driver of the speed of generic entry, holding other factors constant.
- (197) Further, it also suggests that a number of regulatory variables play an important role. Notably, where compulsory generic substitution exists, speed of entry tends to be higher. The same appears to hold for the presence of policies encouraging doctors to prescribe an INN rather than a specific brand. Further, where generics are subject to a mandatory discount or price cap, the speed of entry appears to be lower.¹³⁹
- (198) During the public consultation it was submitted that for the purposes of measuring delays to generic entry companies, the expiry of patent protection (or SPC protection) cannot be compared with the expiry of data exclusivity. According to these

¹³⁷ See also Footnote 123.

¹³⁸ See Annex to Chapter B.1.3.: Econometric Analysis.

¹³⁹ See also discussion on the occurrence of entry in Section B.1.3.1.1.

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submissions, generic companies were, during the reference period 2000 – 2007, only able to submit abridged applications for marketing authorisation to the competent authorities after the expiry of the data exclusivity period for the originator product. As a result, in cases where the loss of exclusivity was based on expiry of the data exclusivity rather than patent expiry (or SPC expiry), the time period for obtaining regulatory approval would de facto extend the exclusivity period.¹⁴⁰ As indicated in the introduction to this section, the statistics in this section must be understood as relating to the concept of time to entry. This concept is not confined to delays to generic entry caused by the behaviour of originator companies, but also comprises other factors such as the time that generic companies need for standard regulatory procedures in the country concerned. It can further be noted that the impact of the cases where loss of data protection came after patent expiry (including SPC protection) appears to be rather limited for the average statistics reported in this section on time to entry.¹⁴¹

1.3.1.3. Number of Generic Entrants

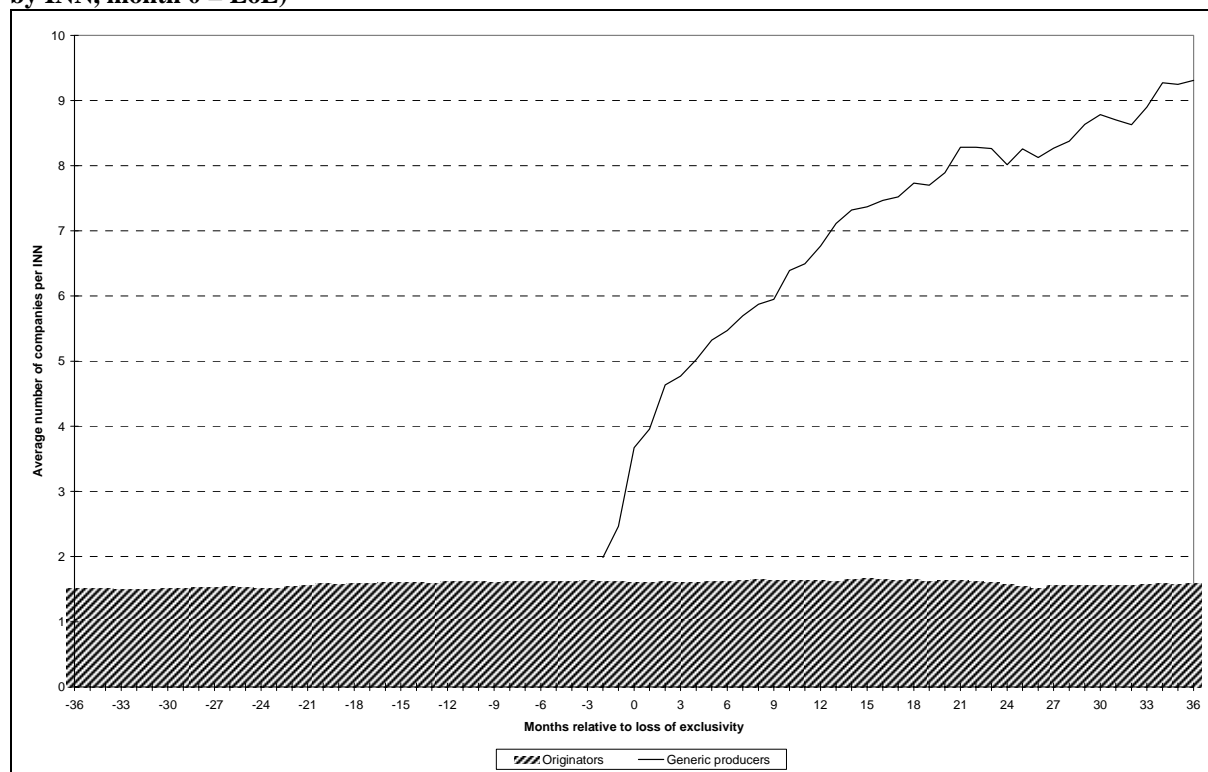
- (199) The third aspect of the extent of entry is the number of generic companies that enter if and when entry takes place. Figure 17 charts the trend in the number of companies active per INN over time.

¹⁴⁰ It was also submitted during the public consultation that prior to the introduction of the Bolar provision, the impossibility of generic companies to carry out tests on their future products during the patent protection period de facto extended the exclusivity period of originator products. However, the submissions from the generic companies indicate that the companies had found ways to carry out the necessary tests already prior to the introduction of the Bolar provision, e.g. in third countries not covered by the patent (for details see Chapter B.2.2.). Finally, it was also submitted that the issue of regulatory delays is further aggravated by the necessary procedures to obtain pricing and reimbursement decisions.

¹⁴¹ The number of instances (INNs and countries) in which loss of data protection came after patent expiry (including SPC protection) was 51, out of a total of 713 for which it was possible to make the comparison, amounting to about 7% of cases.

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Figure 17: Number of companies active per INN per MS (sample: E75 list; all instances of entry; weighted by INN, month 0 = LoE)



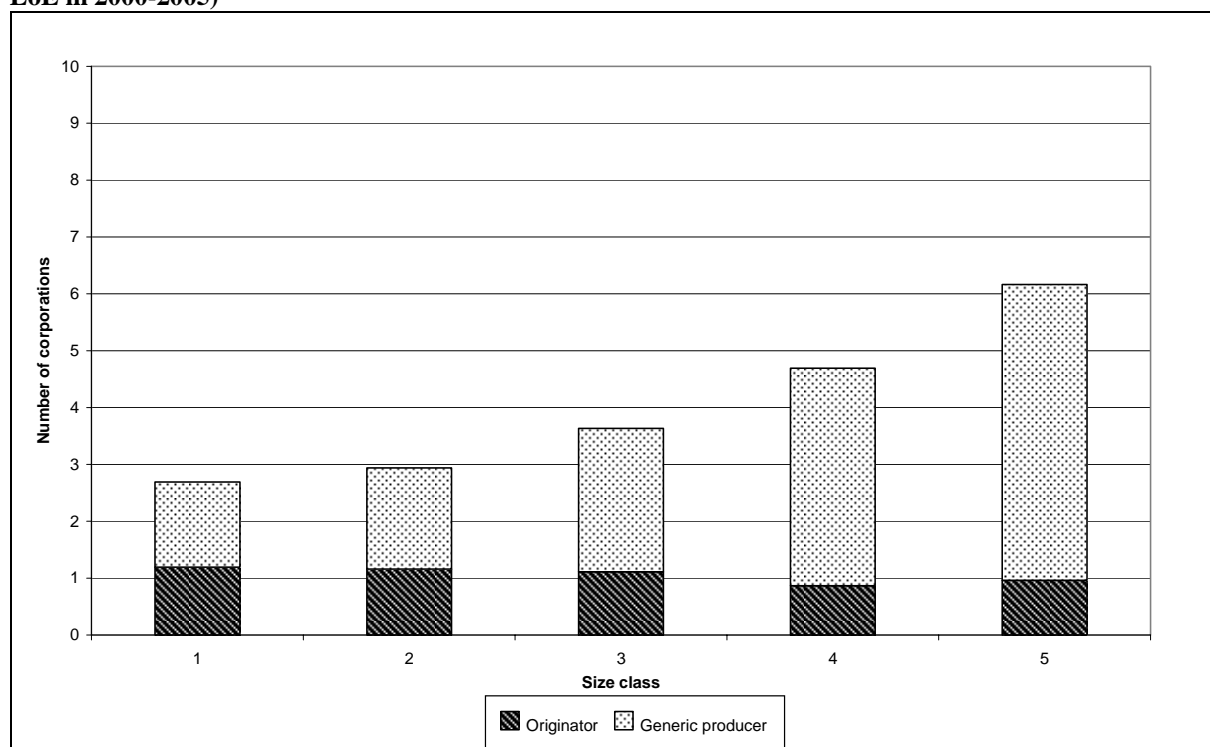
Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

- (200) Before entry, the average number of companies per INN per Member State remains stable at about 1.5, normally comprising the originator firm itself and/or the companies which have obtained a licence to produce and sell the INN concerned.¹⁴²
- (201) One thing which is clear from the figure above is that the LoE leads to a considerable increase in the number of companies selling products incorporating the INN concerned. On average, after one year following the LoE, about four to five generic companies appear to be present in the market. Within three years following the LoE the ratio of generic companies to originators is about 6:1.
- (202) As with the share of INNs that faces generic entry following LoE, the number of generic firms entering also increases as a function of the value of the market as measured by the sales of the INN in question. This is borne out by Figure 18.
- (203) There is also quite some variation when it comes to the number of companies active per INN across the various Member States. This is visible in Figure 19.

¹⁴² A small proportion of "other" companies can also be observed prior to the loss of exclusivity. These may relate to INNs for which the company status had not been fully established or recorded in the IMS dataset, but also to possible "early" entries by generic firms, i.e. entries before the date of loss of exclusivity.

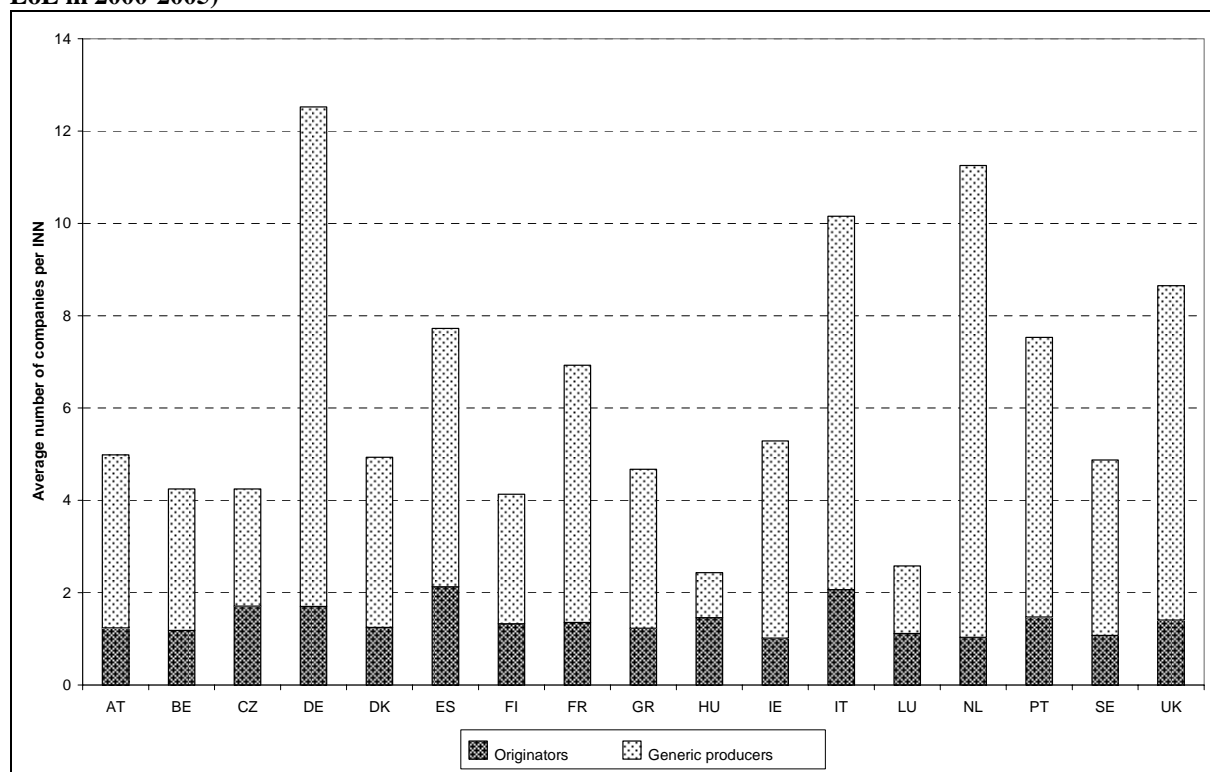
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Figure 18: Number of companies active per INN per MS within two years, per size class (sample: E75 list; LoE in 2000-2005)



Source: Pharmaceutical Sector Inquiry (partially based on IMS data). Class 1 contains the 20% of smallest INNs (in terms of EU sales value), class 2 the next smallest 20%, etc. Class 5 contains the 20% top selling INNs.

Figure 19: Number of companies active per INN per MS within two years, per size class (sample: E75 list; LoE in 2000-2005)



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

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- (204) It is striking to see that in the pharmaceuticals markets of Germany, the Netherlands, Portugal, Spain, the UK, France and Italy a high number of generic producers is present in the market. The generic segment of the pharmaceuticals market in these countries appears therefore rather fragmented.
- (205) The above findings are also borne out by regression analysis¹⁴³. Among other things, the value of the market per capita at the point of LoE and the size of the Member State's population are important drivers of the number of generic entrants, holding other factors constant.
- (206) Further, it also suggests that a number of regulatory variables play an important role. First, where compulsory generic substitution exists, the number of entrants tends to be higher. Second, where generics are subject to a mandatory discount or price cap, the number of entrants (measured after one or two years) appears to be lower.
- (207) Another interesting aspect is the number of formulations which generic companies enter with when they enter. The figure below plots the average number of formulations generic companies sell over time alongside, the same average for originator companies for the purpose of comparison¹⁴⁴.

¹⁴³ See Annex to Chapter B.1.3.: Econometric Analysis.

¹⁴⁴ In the calculation of this number, each single formulation (for instance, a tablet of a certain strength) is counted as one, regardless of whether or not it is sold under more than one brand name.

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Figure 20: Average number of products per company (sample: E75 list; all entries; month 0 = entry date)



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

- (208) Generic companies generally appear to enter with about 2 to 2.5 products (formulations) per INN (EU average). This is smaller than the number of products with which originator companies are typically active (about 3.5 to 4). There are two main explanations for this. First, if and when a generic company enters a certain INN, it makes sense to focus on the commercially most attractive formulations, and to leave aside formulations that sell less (e.g. niche products). Second, typically, while the INN loses exclusivity insofar as the first formulation loses exclusivity, there are still other formulations that remain exclusive and that only the originator firm or its licensees can sell.

1.3.2. Effects of Generic Entry

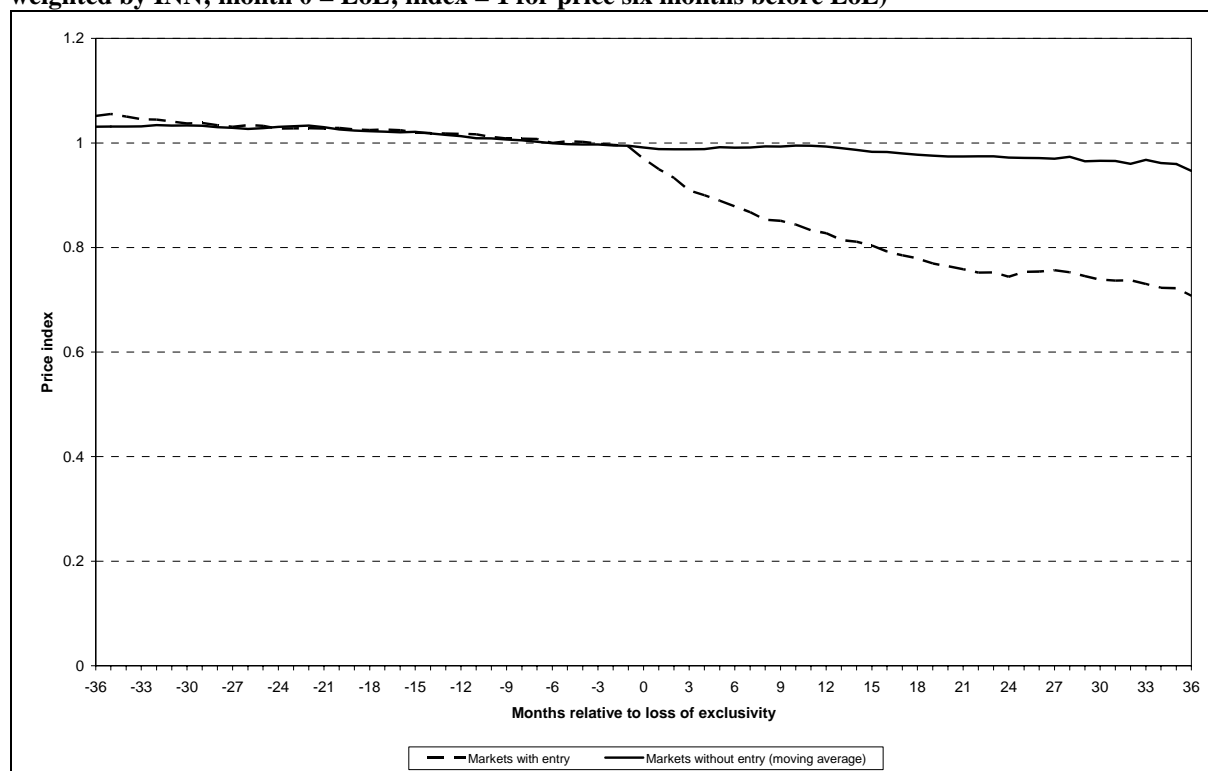
- (209) Generic entry into a pharmaceuticals market can have a profound effect as it changes the market from one in which only one firm could sell the product(s) concerned (possibly via licensees) into one where more sources of supply become available for the product. The most direct effect is likely to be on the average price level of the product(s) concerned and the sales volumes of the originator. But other products can also be affected, both products under the INN that remain patent-protected and products based on other INNs but competing with the product(s) that lost exclusivity.
- (210) This section first looks into the effects on prices for the INN concerned. It then turns to the effects on volumes, both the total volume of products sold and the volume sold by originators and generics respectively. Finally, it addresses, for a limited number of INNs, the effects of generic entry on possible substitute for the product that lost exclusivity.

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1.3.2.1. Effects on Prices

(211) The first measure considered is the average price of the products sold under the INN. This average price is constructed as an index, which is set at one shortly (six months) prior to the end of the exclusivity period. Figure 21 plots the development over time of the average price index separately for expiring INNs with generic entry and without generic entry.

Figure 21: Development of average price index for INNs with and without generic entry (sample: E75 list; weighted by INN; month 0 = LoE; index = 1 for price six months before LoE)

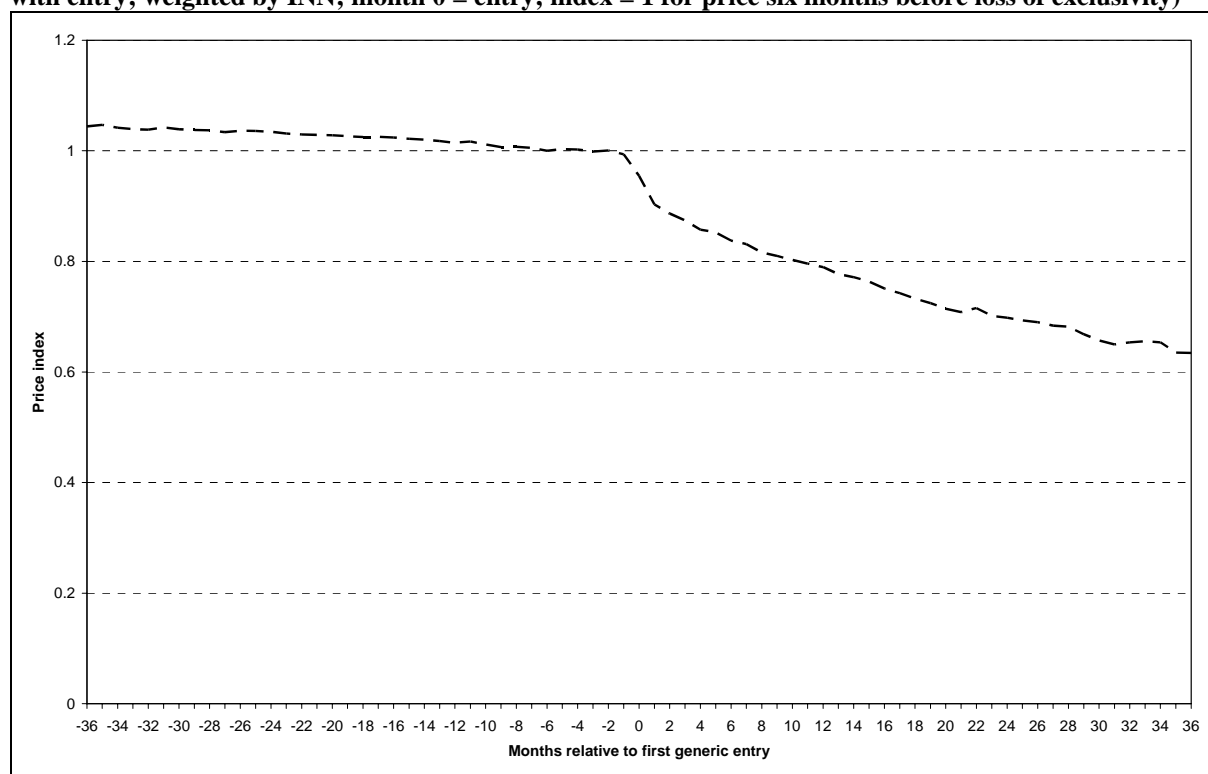


Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

- (212) Comparison of the two lines clearly shows that the average price index drops considerably on markets with generic entry, but not on markets without. In markets with entry, average prices dropped by almost 20% after the first year following LoE and about 25% after two years. In rare cases, for some medicines in some Member States, the decrease in the average price index was as high as 80-90%.
- (213) Of course, it must be borne in mind that entry will not take place immediately on LoE for every INN (as described in Chapter 1.3.1). The gradual drop in levels observed in Figure 21 is therefore the result of the combination of average price levels coming down quickly in those markets, where entry took place quickly and average price levels coming down later because entry took longer.
- (214) A different picture emerges when not the date at which the INNs lost exclusivity, but the date of first generic entry is taken as the reference point. The resulting price development is illustrated in Figure 22.

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Figure 22: Development of average price index for INNs with generic entry (sample: E75 list; all INNs with entry; weighted by INN; month 0 = entry; index = 1 for price six months before loss of exclusivity)



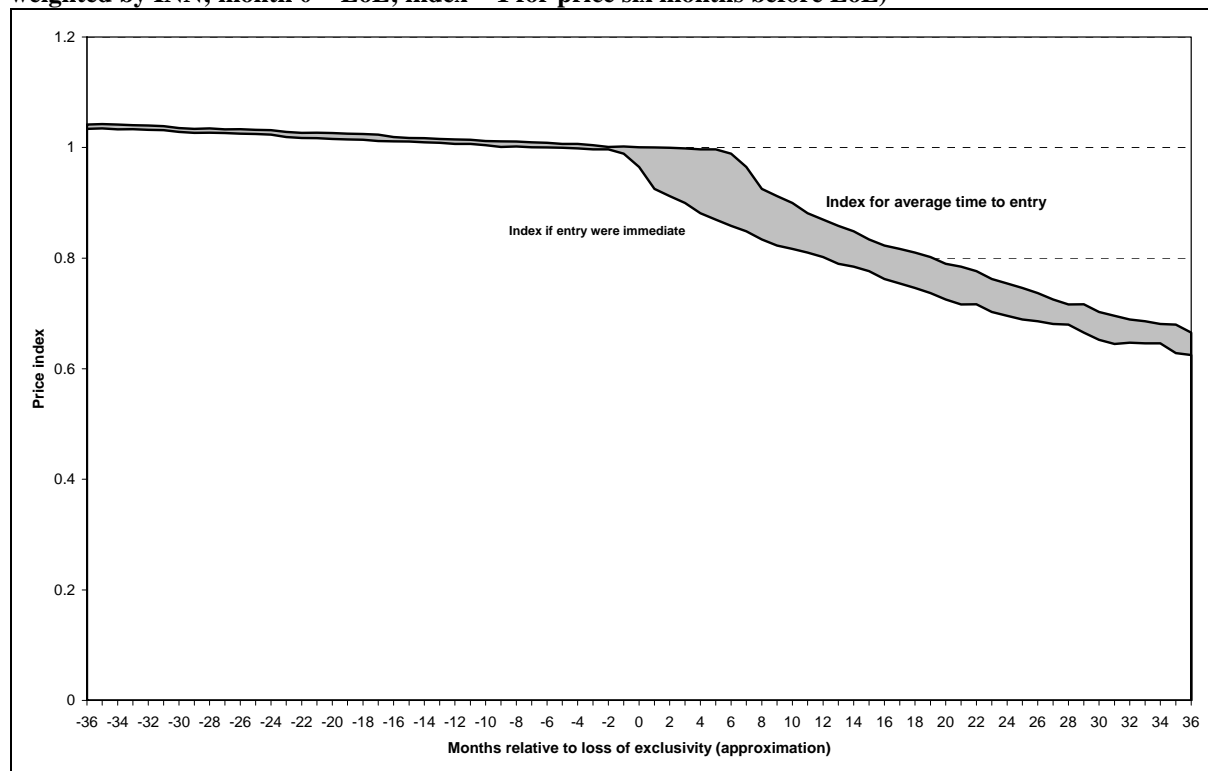
Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

- (215) Taking the date of entry as the reference point, the decreases in average prices emerge a little more clearly. The difference can be observed in the form of a somewhat sharper average price decrease in the month of entry, with the differences between the two graphs diminishing after one year.
- (216) Figure 22 can also be used to obtain an impression of the additional savings that might have accrued to health systems in the period 2000 – 2007 if entry following LoE had been immediate, rather than occurring with a delay.¹⁴⁵ In Subsection B.1.3.1.2. above, it was observed that the average time to entry in the sample of INNs under consideration exceeded seven months (weighted average). Figure 23 presents two lines, both depicting a development of the average price index following first generic entry. The two lines have identical shapes, the only difference is that the line on the left ("Index if entry were immediate") assumes that for all INNs in the sample the first generic company enters at the time the INN lost exclusivity, whereas the line on the right ("Index for average time to entry") assumes that all INNs faced first generic entry only after seven months following LoE.

¹⁴⁵ The sample is again restricted to INNs expiring in the period 2000 – 2006. See footnote 135.

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Figure 23: Development of average price indices if entry were immediate and for generic entry after seven months following LoE (approximation; sample: E75 list; expiries in 2000 – 2006; all INNs with entry; weighted by INN; month 0 = LoE; index = 1 for price six months before LoE)



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

- (217) At each month along the horizontal axis, the vertical difference between the two lines can be interpreted as (an approximation of) the difference between the price index that applied, in an average sense, in reality and the average price index that would have applied had entry taken place seven months earlier. By summing up these monthly differences over a longer period (see the grey area in Figure 23¹⁴⁶), one obtains an estimate of the total potential savings that could have been obtained had generic entry taken place earlier, evaluated at constant consumption volumes.¹⁴⁷ Taking the volumes in the year prior to expiry as a benchmark,¹⁴⁸ the cost of the average time to entry on

¹⁴⁶ Note that Figure 23 only displays a time window of 36 months before and 36 months after loss of exclusivity, of which only the period after loss of exclusivity matters for the purpose of calculating the costs of delayed generic entry. In reality, however, the relevant horizon extends beyond the 36 months following loss of exclusivity displayed in the Figure 23, as all INNs expiring up to December 2004 have a horizon exceeding 36 months. In the calculations for the period 2000 – 2007 presented subsequently in this section this aspect is taken into account.

¹⁴⁷ The comparison of price indices only allows for making meaningful statements about possible cost savings when these are evaluated at constant volumes. See also Subsection B.1.3.2.2. and B.1.3.2.3.

¹⁴⁸ The sales in the year before expiry have been approximated by taking 12 times the sales in the month of expiry.

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the E75 sample under consideration can, for the entire period 2000 – 2007, be roughly estimated at € 3 billion (at retail prices).¹⁴⁹

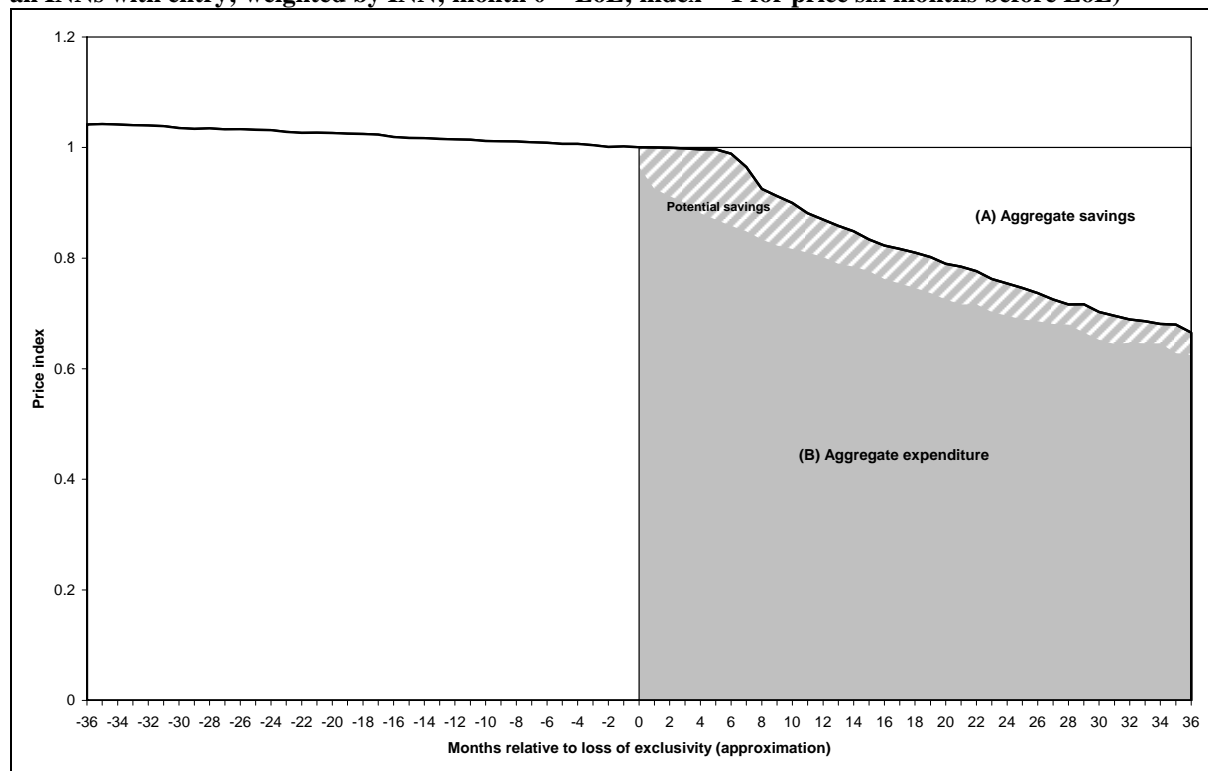
- (218) In the public consultation, a number of questions have been raised as to the way the figure has been calculated. It should be noted that the figure is a composite figure. It relates to an estimate of the missed savings of the list of 128 INNs under consideration (E75 list) in the Member States for which observations were available. Each of these INNs expired at different times during the period 2000-2007. All calculations relate to the period between LoE and December 2007, a period which differs in length for each of the INNs and countries. Missed savings in the period 2000 – 2007 in relation to expiries from the period before 2000 are not taken into account. Nor are missed savings in relation to the list of INNs under consideration materialising after 2007.
- (219) In order to appraise the impact of these potential savings, these savings should be compared with the aggregate expenditure and savings on medicines for originator and generic products, on the sample investigated. These figures can again be measured, for each INN and country pair for the period between the date of LoE and December 2007. By considering the price index before expiry (equal to 1) with the price index as it developed over time with an average time to entry of seven months, the aggregate savings derived over the period between LoE and December 2007 due to generic entry can be estimated at about € 15 billion (white area A in Figure 24), at constant (pre-expiry) volumes. The aggregate expenditure (value sales) in the period between LoE and 2007, net of these savings, is in the order of € 50 billion (grey area B, including shaded surface). Therefore, the € 3 billion in savings should be compared to a universe worth an approximate € 50 billion. Had entry been immediate following LoE, this expenditure could have been € 3 billion (or 5%) lower (indicated by the shaded surface).¹⁵⁰ Compared to the actual savings of € 15 billion, it can be concluded that savings could have been 20% higher than they actually were.

¹⁴⁹ This estimate is based on 17 Member States only, where sufficient observations were available; for further details on methodology, see Annexes to Chapter A.

¹⁵⁰ It should be noted that the total expenditure on prescription medicine at retail level amounted to € 190 billion in 2007 in the EU. Of these sales approximately € 93 billion (or 49%) are sales of products not (or no longer) benefiting from patent protection. Of the aggregate expenditure of € 50 billion (post expiry, at constant volumes), about € 10 billion relates to 2007. This number is thus considerably smaller as it relates to a specific subset of the prescription medicines, namely those that faced loss of exclusivity in the reference period 2000 – 2007.

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Figure 24: Aggregate value sales, aggregate savings for generic entry after seven months following LoE and potential savings if entry were immediate. (approximation; sample: E75 list; expiries in 2000 – 2006; all INNs with entry; weighted by INN; month 0 = LoE; index = 1 for price six months before LoE)



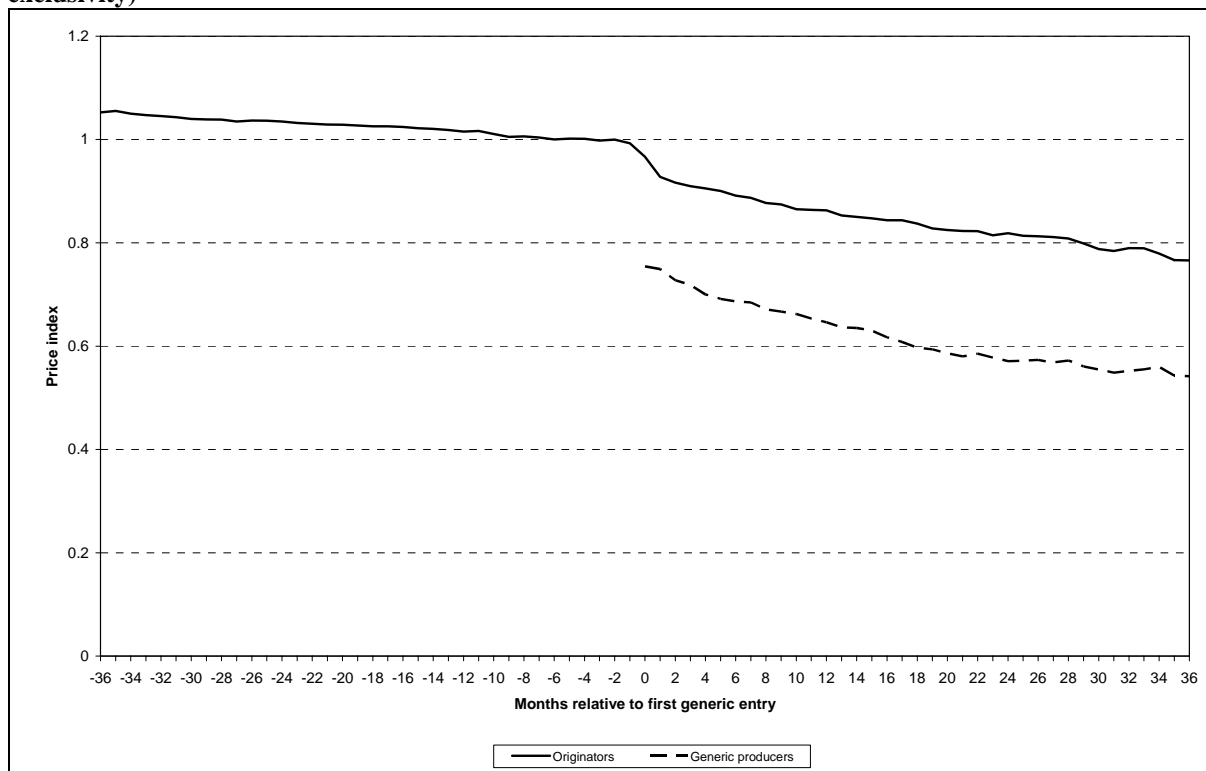
Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

- (220) It should be noted that the figure of € 3 billion is likely to provide a lower bound of the potential savings due to earlier entry. Likewise, the figure of € 15 billion probably represents a lower bound on total savings due to generic entry. After all, the E75 list of molecules contains many, but not all expiries in all Member States.¹⁵¹ Further, the above calculations have been made at constant volumes. As will be described in further detail below (in Subsection B.1.3.2.2.), INNs that turn generic may attract demand away from (expensive) substitute INNs that are still patent protected.
- (221) The above mentioned price indices describe the impact of entry on average prices. As an average, they reflect the combined impact of price decreases on individual products (both originator and generic) and the importance that these products have in terms of sales. A more detailed view can be obtained by looking separately at the indices for originator products and generic products. Figure 25 provides an overview of the level of development of these separate indices over time.

¹⁵¹ As described in the Annex on Methodology, the list of E75 molecules represents over 90% of the value of all expiries in France, Germany, and the UK in the period 2000 – 2007, however. It is likely to comprise the vast majority of expiries in other Member States as well.

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Figure 25: Development of originator and generic price indices for INNs with generic entry (sample: E75 list, all INNs with entry; weighted by INN; month 0 = entry; index = 1 for price six months before loss of exclusivity)



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

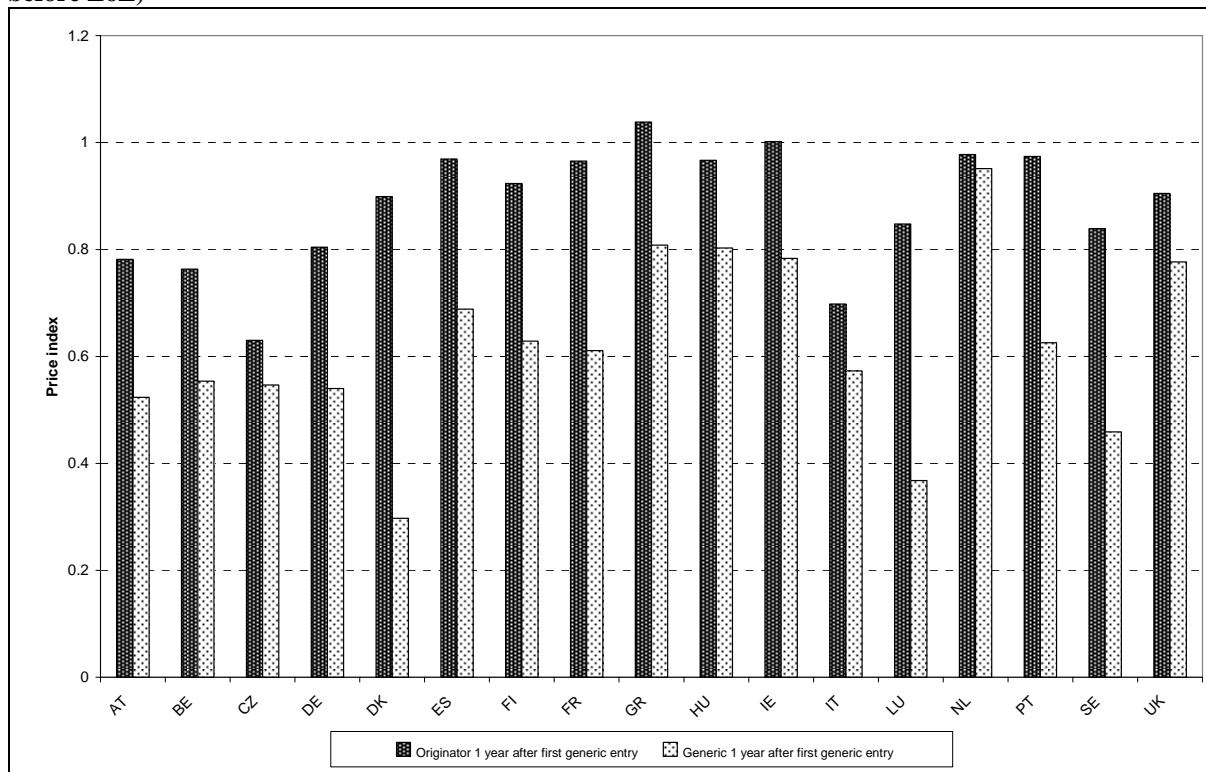
- (222) Figure 25 shows that generics typically come onto the market at a price that is about 25% lower than the price of the originator products prior to LoE. In other words, the generic:originator price ratio on entry is about 0.75. Over time, the generic-originator price ratio drops to about 0.55. Also the price levels of the originator products for INNs facing generic entry appear to decrease, albeit to a lesser extent.
- (223) Also the price levels of the originator products for INNs facing generic entry appear to decrease, albeit to a lesser extent. This may be related to a range of factors. For those products that lost exclusivity, there may have been a price response by originator companies in the face of increased (generic) competition. The presence of price regulation, which in some countries obliges originators to keep the prices of their products within a certain range from the lowest priced (generic) products, may also have played a role. At the same time, originator companies may have continued to enjoy a certain degree of brand recognition or loyalty on the part of patients and doctors, allowing them to charge a higher price than generic companies.¹⁵²

¹⁵² Further, not all products belonging to a given INN of an originator company may have lost exclusivity at the same time, allowing an originator company to continue to charge mark-ups on these exclusive products. It should be noted that the price index for originator companies displayed in Figure 24 is a composite index of all products sold by the originator companies under the INNs concerned.

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(224) These EU averages reported so far hide considerable variation between the EU Member States. Figure 26 and Figure 27 provide an overview of the price impact in a range of countries, measured one year after entry and two years after entry, respectively.

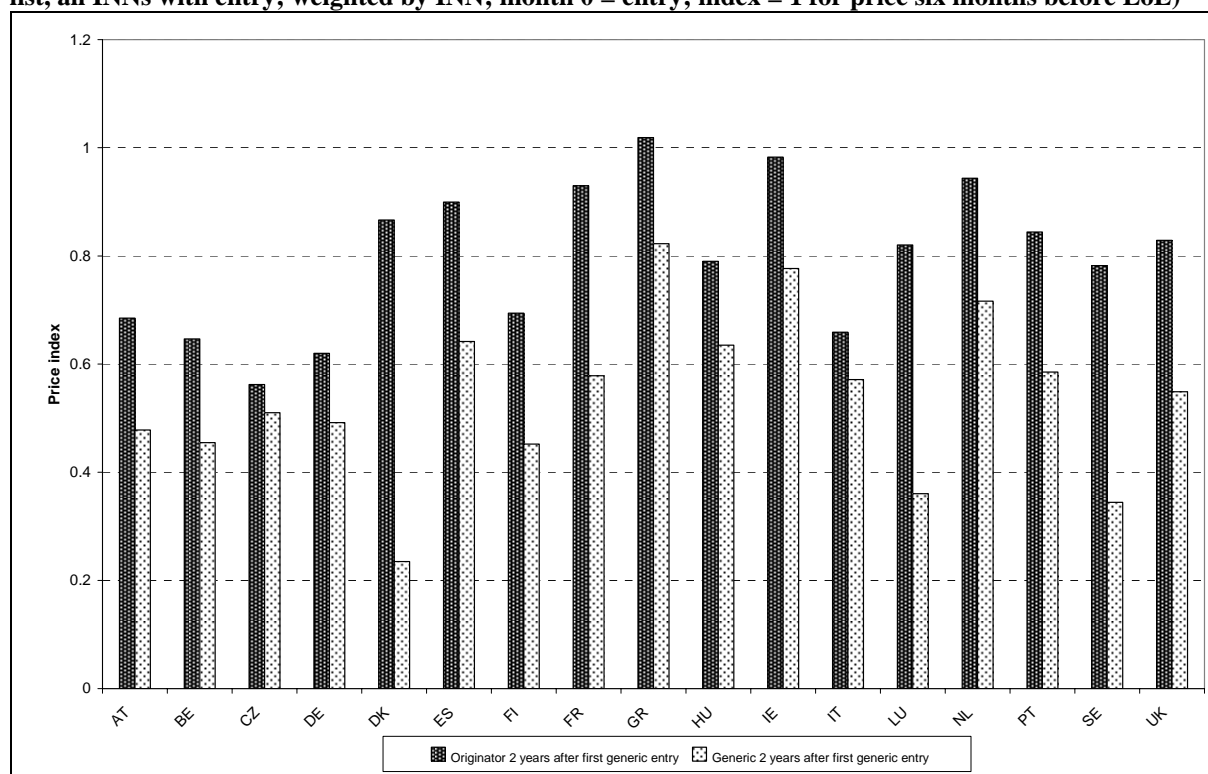
Figure 26: Development of originator and generic prices in the first year, by country (sample: E75 list, LoE in 2000-2005; all INNs with entry; weighted by INN; month 0 = entry; index = 1 for price six months before LoE)



Source: Pharmaceutical Sector Inquiry (partially based on IMS data).

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Figure 27: Development of originator and generic prices in the first two years, by country (sample: E75 list, all INNs with entry; weighted by INN; month 0 = entry; index = 1 for price six months before LoE)

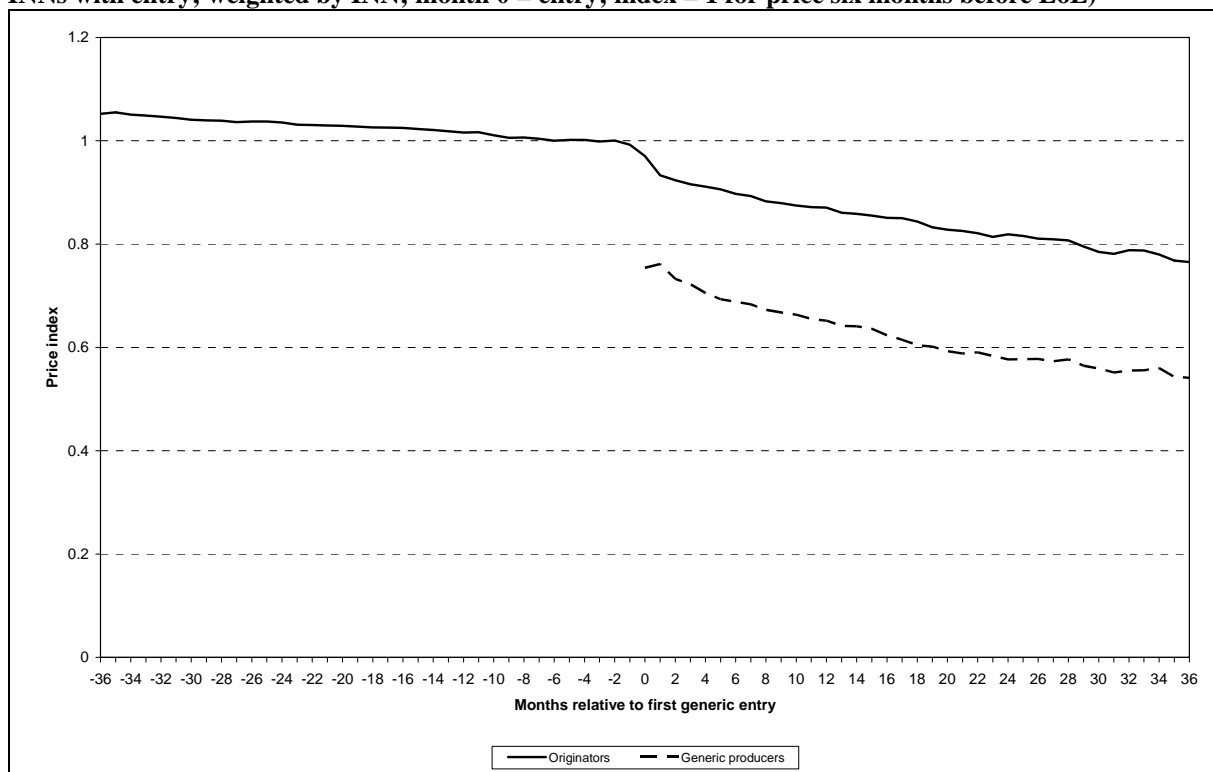


Source: Pharmaceutical Sector Inquiry (partially based on IMS data).

- (225) The charts show that generic entry leads to the biggest generic price decreases in countries such as Sweden, Finland, Denmark, Austria, Germany, Belgium and Luxemburg. In each of these countries average generic prices after two years appear to be more than 50% below the price of the originator price prior to LoE. In Sweden, Denmark and Luxemburg price drops of this nature are typically achieved within the first year of entry already. Also within Member States, there was quite some variation among the various INNs.
- (226) The indices reported so far relate to the prices of all products sold under the INN. The originator index may include products that have lost exclusivity and products that are still protected. An alternative way to present the impact of generic entry on prices is to consider only the prices of originator products (formulations) which have been exposed to generic entry. This is presented in Figure 28. Although this measure is more focused than the average indices described earlier, it is not necessarily more accurate or informative. It provides a different perspective. After all, as part of the life cycle strategy for INNs, originator companies may well have succeeded in shifting some of the demand towards formulations of the INN that still benefit from exclusivity (including second generation products) or even to other (exclusive) INNs altogether.

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Figure 28: Trends in originator and generic prices for products with generic entry (sample: E75 list, all INNs with entry; weighted by INN; month 0 = entry; index = 1 for price six months before LoE)



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

- (227) Regression analysis sheds further light on the price effects following generic entry.¹⁵³ First, the number of generic entrants appears to have a small but statistically significant effect on the price decrease that eventually emerges in the market. It also appears that the per capita value of the INN prior to LoE has a positive and statistically significant effect on the price decrease.
- (228) Further, as regards the regulatory variables, the analysis indicates that policies involving price caps/mandatory discounts for generics, while leading to (imposed) price decreases in the short term, in the longer run appear to lead to higher prices relative to the regimes without price cap. One of the possible explanations for this pattern could be that a price cap can become a focal point for the generic companies and lead to higher prices than otherwise would have been the case.
- (229) The models used also tend to indicate that regimes with compulsory generic substitution for pharmacists and encouraging doctors to prescribe the INN (as opposed to a particular brand) appear to be favourable to price competition. The same holds for policies involving differential co-payment for patients, reimbursement of medicines at the level of the lowest priced product and a frequent adjustment of reimbursement levels to take account of price developments in the market.

¹⁵³ See Annex to Chapter B.1.3.: Econometric Analysis.

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1.3.2.2. *Effects on Volumes*

- (230) The second main dimension in which generic entry may have an impact is on the volume of products sold and the market shares of the originator and generic companies.
- (231) The combined market share of the generic companies is often referred to as the "generic penetration rate". The higher the penetration rate, the greater the savings for the health system are likely to be (for a given market size).
- (232) Table 13 presents, for the EU as a whole, the generic penetration rate for the INNs in the E75 sample covered by this report that faced generic entry. The penetration rate is measured one year and two years after LoE. Once again the set of INNs is limited in order to allow enough time to lapse before measuring the impact of generic entry. It is given in both volume¹⁵⁴ and value terms (right-hand column).

Table 13: Generic penetration (EU average; sample: E75 list, all INNs with entry; weighted by INN)

	Generic penetration rate (volumes)	Generic penetration rate (value)
Measured one year after first generic entry (INNs expired in 2006 or earlier)	30%	25%
Measured two years after first generic entry (INNS expired in 2005 or earlier)	45%	38%

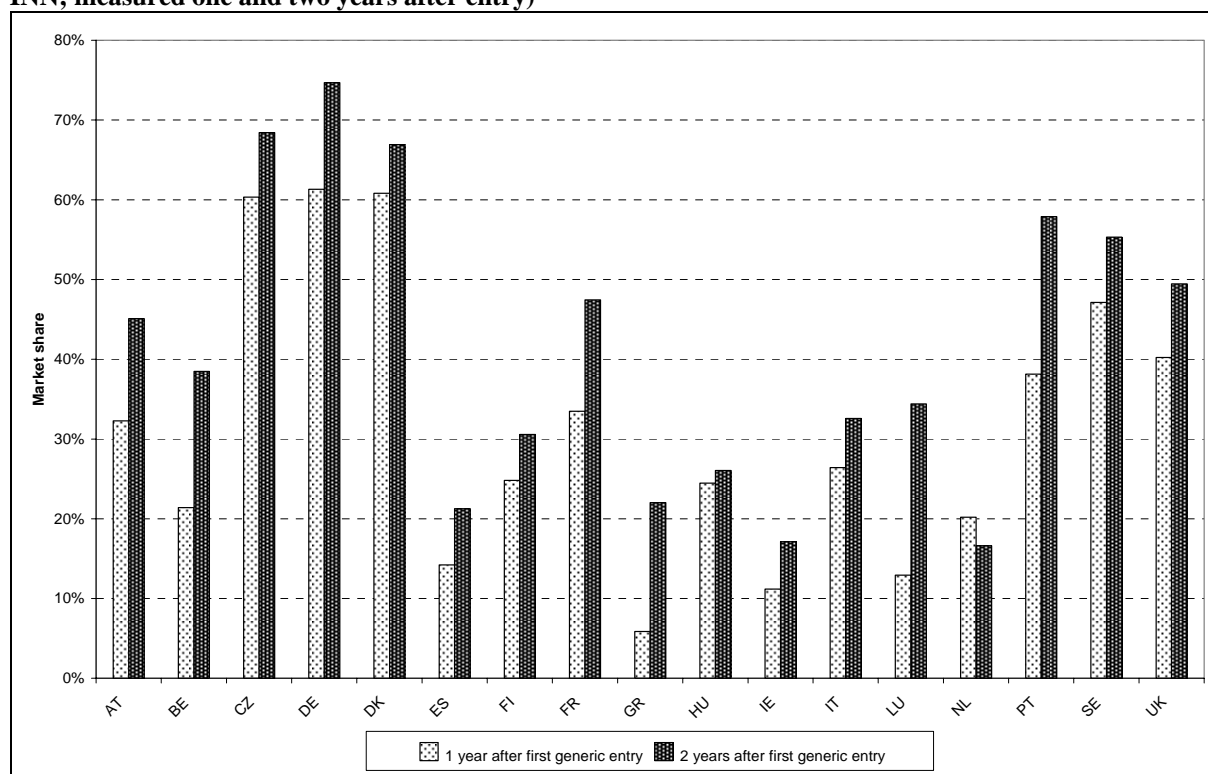
Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

- (233) Again, there is considerable variation between the individual Member States. Figure 29 and Figure 30 show the generic penetration rate in a number of countries, again measured one year and two years after LoE, by volume and value respectively.

¹⁵⁴ For this volume index, IMS data on Standard Units are used in order to be able to aggregate consumption across different types of formulation (tablets, capsules, injections, etc.)

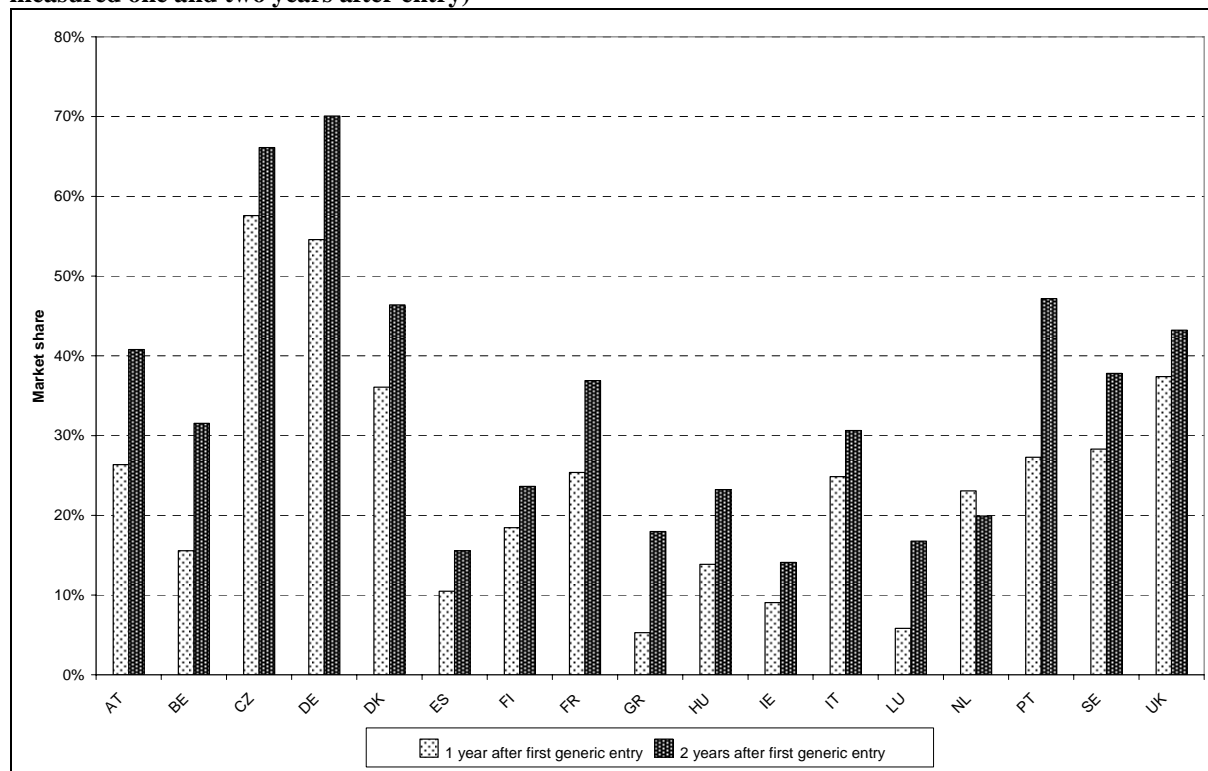
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Figure 29: Generic penetration by volume, by MS (sample: E75 list, all INNs with entry; weighted by INN; measured one and two years after entry)



Source: Pharmaceutical Sector Inquiry (partially based on IMS data).

Figure 30: Generic penetration by value, by MS (sample: E75 list, all INNs with entry; weighted by INN; measured one and two years after entry)



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

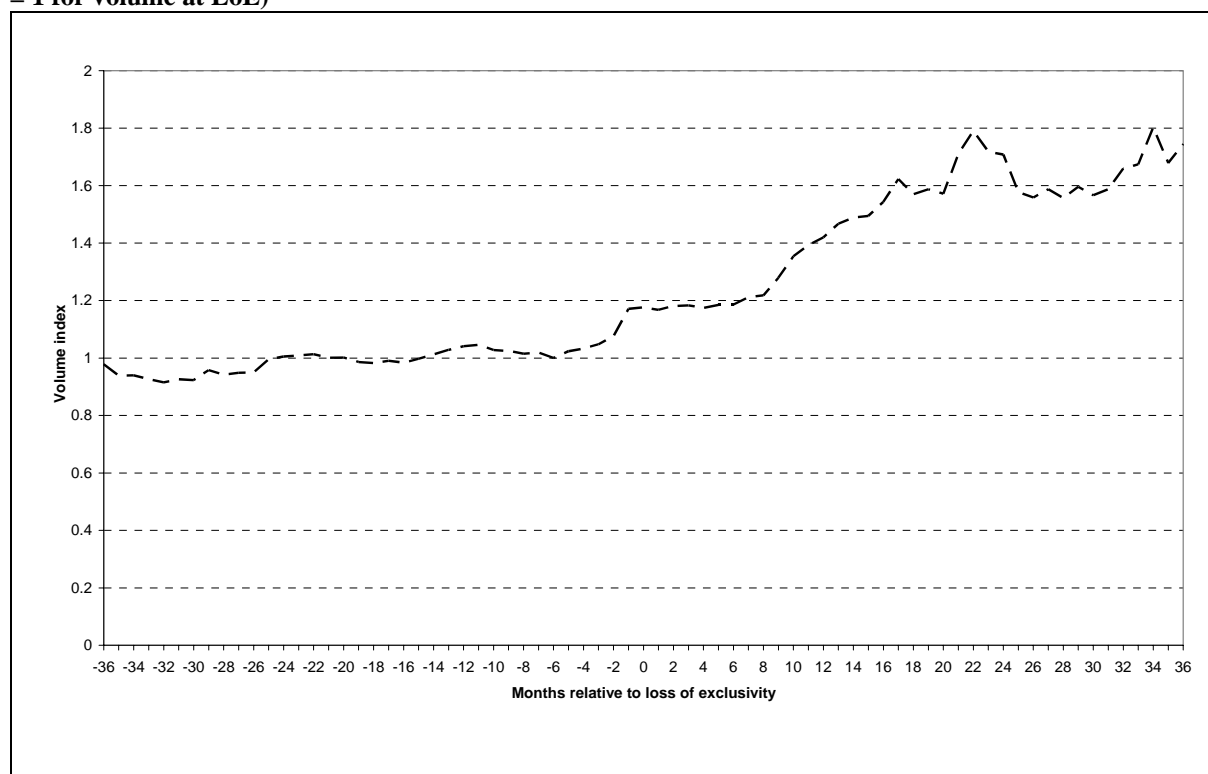
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- (234) Measured by volume and value entry by generic companies appears to have had a very strong effect in Germany, the Czech Republic, Denmark and the UK. In Germany and the Czech Republic, generic companies built up a more than 50% share by value and volumes already within the first year. Measured only by volume, Denmark also shows a market share of generic companies exceeding 50% within the first year after entry.
- (235) Regression analysis suggests that regulatory policies requiring pharmacists to dispense generic products when available and encouraging doctors to prescribe the substance (as opposed to a particular brand), tend to have a positive effect on the degree of generic drug penetration. The same holds for policies involving reimbursement of medicines at the level of the lowest priced product and a frequent adjustment of reimbursement levels to take account of price developments in the market. By contrast, the analysis indicates that policies involving price caps/mandatory discounts for generics appears to reduce the level of generic penetration relative to the regimes without such price caps/mandatory discounts.
- (236) Further, INNs where the originator company controlled the entry process by way of early distribution agreements tend to have lower generic market penetration. This might be consistent with a first mover's advantage that is conferred upon the selected company, which has the effect of limiting generic penetration.
- (237) Generic entry – especially when it is accompanied by significant price reductions – may also lead to an increase in overall consumption of the medicine. Figure 31 plots the development of the overall volume over time by considering an index, which is set at a level equal to one (1) six months prior to the end of the exclusivity period¹⁵⁵.

¹⁵⁵ The measure is taken six months before entry.

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Figure 31: Volume effects of generic entry (sample: E75 list; all INNs with entry; weighted by INN; index = 1 for volume at LoE)



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

(238) In the three years before the LoE, the consumption volume index remained fairly close to the 1.0 benchmark, but after generic entry the volumes consumed started to rise steadily. This may be partly related to the fact that the lower prices for the INNs losing exclusivity draws demand away from substitute products based on other INNs. This phenomenon is analysed in greater detail in the next section.

1.3.2.3. Potential Effects of Generic Entry on Other Products

(239) Whenever a generic company enters with a generic version of a given INN, in the sense that it starts selling (some of the) formulations of the INN that have lost their exclusivity, this may have an impact not only on sales of the INN concerned (in particular, the total level of sales and the sales of the originator), but also on the sales of products based on different INNs.

(240) The presence of such patterns was studied on the basis of regression analysis on a limited sample of INNs¹⁵⁶. To identify potential substitution patterns, the analysis looked at the evolution of volumes of other INNs that were sold in the same ATC4 when the loss of exclusivity took place. Specifically, the analysis focused on the extent of correlation between, on the one hand, the volume of INNs sold in the same ATC4 class after LoE and, on the other hand, the prices of the INN of reference losing

¹⁵⁶ See Annex to Chapter B.1.3.: Econometric Analysis.

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exclusivity. ATC4 classes relate to sets of INNs that share, to a greater or lesser extent, some therapeutic characteristics.¹⁵⁷ Therefore, for the purpose of the sector inquiry, they constitute a starting point for the group of INNs within which to analyse potential patterns of substitution.¹⁵⁸

- (241) The analysis performed appears to confirm for certain INNs the existence of some correlation between the volume of INNs sold in the same ATC4 and the INN of reference losing exclusivity. In a number of cases, the sales of products based on different INNs appear to go down with the entry of generic companies (and the resulting price drop) of the INN of reference. This applied to about a fifth of INNs in the ATC4 classes considered.
- (242) At the same time, for about two thirds of INNs in these classes, no significant correlation could be established.

1.3.3. Responses of Originators

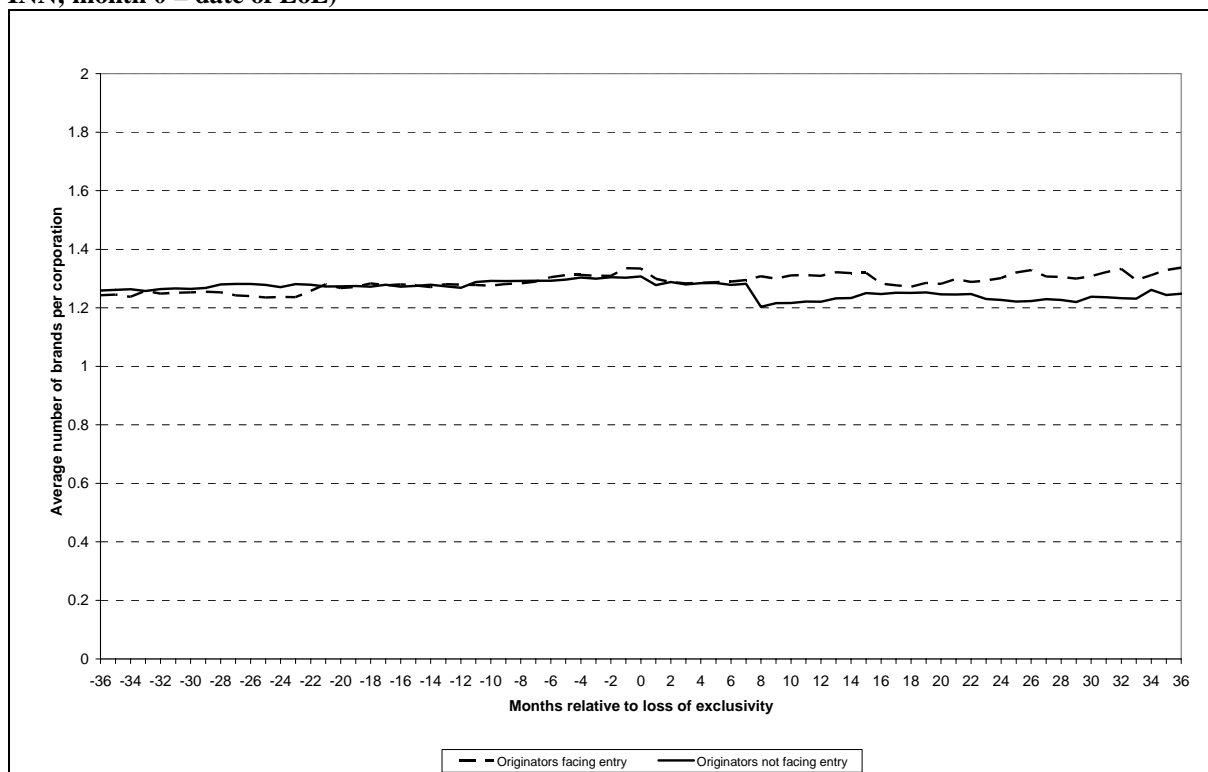
- (243) As indicated in this report, there are a number of ways in which the originator can anticipate or react to the entry of generics into the market. For instance, the originator can react in the form of product proliferation, advertising, pricing or litigation.
- (244) The first interesting point is how the product and brand portfolios develop over time. Figure 32 and Figure 33 below show the average number of brands per company and the average number of formulations per brand over time, respectively, differentiating between cases with and without generic entry.
- (245) In terms of number of brands per corporation there appears to be little difference between originators facing entry and not facing entry. Nor do there appear to be major developments over time in this respect, although a very slight increase might be observed in the number of brands per company in the period leading up to LoE in those instances where entry took place. The average number of formulations per brand before LoE appears to show an increase in those instances where entry took place, whereas a relative decline in the number is visible in instances without entry. One tentative conclusion is that in the period before the INNs lose exclusivity, originator firms facing the prospect of entry have a tendency to increase the number of formulations per brand in anticipation of future generic entry.

¹⁵⁷ Cf. World Health Organisation, <http://www.whooc.no/atcddd/atcssystem.html>.

¹⁵⁸ It should be emphasized, however, that the focus of this analysis is on correlation between variables, not causality. Further, no position is taken on the economic significance of the estimated coefficients, e.g. whether they are large or small in the context of the ATC class.

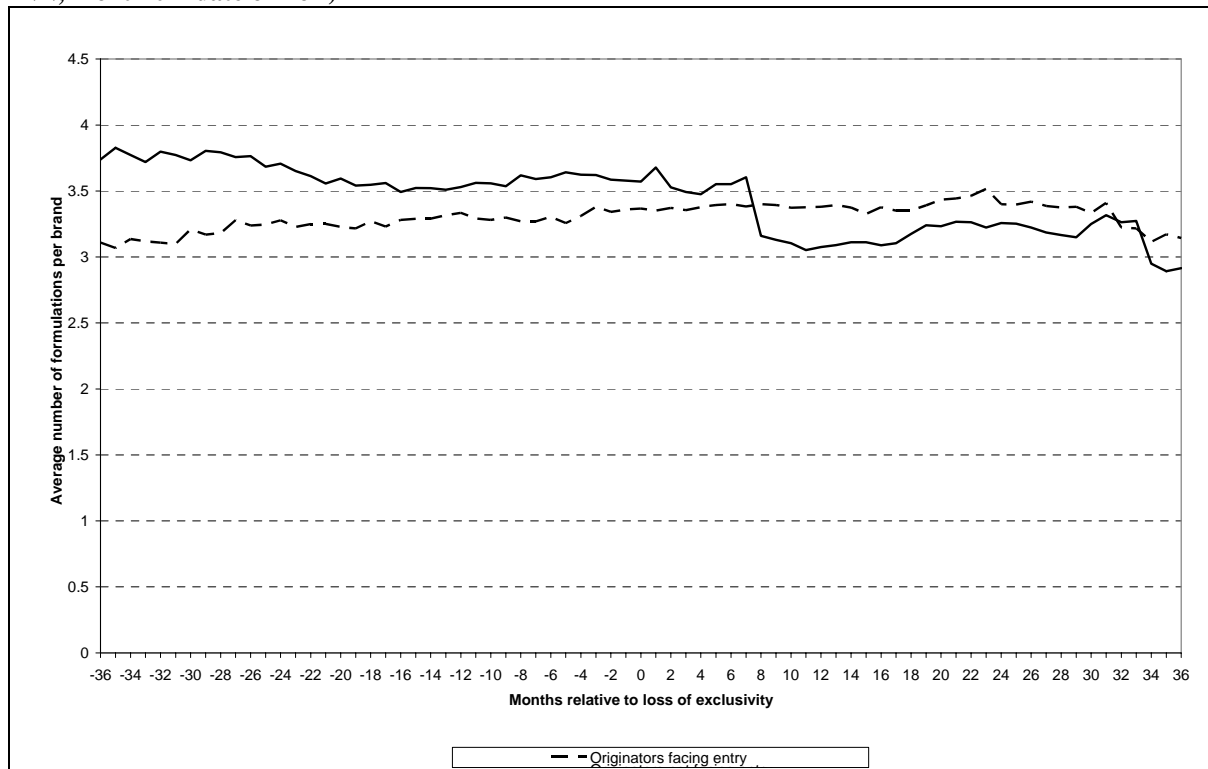
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Figure 32: Average number of brands per company (sample: E75 list; all INNs with entry; weighted by INN; month 0 = date of LoE)



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

Figure 33: Average number of products per brand (sample: E75 list; all INNs with entry; weighted by INN; month 0 = date of LoE)

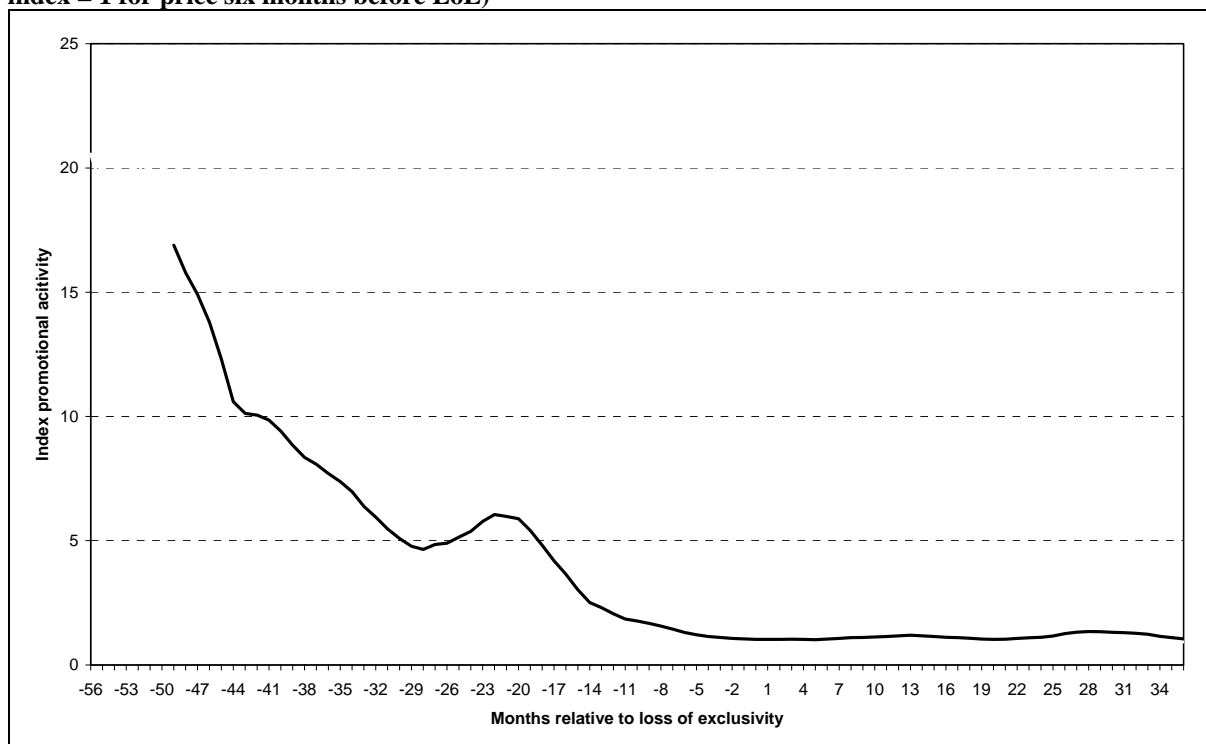


Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

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- (246) Promotional activities (e.g. in the form of detailing activities, sales representatives informing doctors, advertisement) are another tool that may be used to influence the demand for individual products. In particular, as indicated in the other sections of this report, it makes sense to divert promotional expenditure away from products that have lost exclusivity to products that are still protected.
- (247) The below graph presents the development over time of promotional activity. It appears that already well before the time of loss of exclusivity promotional activities decrease significantly. Around the time of loss of exclusivity, these activities stand at less than 10% of the level attained four years earlier. There is quite some variation across countries and INNs, however.

Figure 34: Promotional activity over time (sample: E75 list; weighted by INN; month 0 = date of LoE; index = 1 for price six months before LoE)



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

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Summary

The sector inquiry looked at the economic conditions surrounding generic entry. The inquiry found that about half of the medicines subject to in depth investigation faced generic entry within the first year after loss of patents (including SPC) and data exclusivity (EU average). Measured in value terms, these medicines represent about 70% of sales (sales value in the year of expiry).

It took more than seven months, on a weighted average basis, for generic entry to occur once originator medicines lost exclusivity. For the highest selling medicines, for which rapid entry matters most, it took four months on average before market entry. However, considerable variations exist across Member States and across medicines.

Delays are important as the price at which generic companies enter the market was, on average, 25% lower than the price of the originator medicines prior to the loss of exclusivity. Two years after entry, prices of generic medicines were on average 40% below the former originator price. Also the prices of originator products appear to drop following generic entry. The market share (in volume terms) of the generic companies was about 30% at the end of the first year and 45% after two years. In other words, any delay will have a significant cost / revenue impact.

In markets where generic medicines become available, average savings to the health system (as measured by the development of a weighted price index of originator and generic products) are almost 20% one year after the first generic entry, and about 25% after two years (EU average). The inquiry points to considerable differences, however, in the effect of entry of generics in the various EU Member States and across medicines.

In relation to a sample of medicines analysed in the period 2000 to 2007, the report estimates that savings due to generic entry could have been 20% higher than they actually were, if entry had taken place immediately following loss of exclusivity. According to the in-depth analysis of this sample, the aggregate expenditure amounting to about € 50 billion for the period after loss of exclusivity would have been about € 15 billion higher without generic entry (evaluated at constant volumes). However, additional savings of some € 3 billion could have been attained, had entry taken place immediately.

Econometric analysis suggests that a number of factors have an influence on the observed pattern and effect of generic entry, e.g. the turnover of the originator medicines before the expiry of the patent/data exclusivity or the regulatory environment. For instance, Member States which oblige pharmacists to dispense the cheapest generic medicines whenever possible appear to show earlier entry and greater savings for their health budgets. Likewise, generic uptake seems to be faster and ultimately generic prices seem to decrease more in Member States which do not oblige the generic companies to respect a certain price cap (e.g. a fixed percentage of the originator product price).

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2. The Regulatory Framework

- (248) This section deals with the regulatory framework within the EU that stakeholders need to respect. While there is general consensus that the pharmaceutical sector is highly regulated along the entire value chain (including R&D activities), three areas of legislation seem to be of particular importance for the purpose of the pharmaceutical industry and this sector inquiry: (a) the legislation governing patents¹⁵⁹, (b) the legislation governing marketing authorisations and (c) the legislation governing pricing and reimbursement of pharmaceutical products.
- (249) The rules governing these areas set the framework in which the companies operate. They therefore determine the conditions for competition. At the same time these rules might provide the companies with opportunities to exploit the legislative framework for their ends, as will be shown in the subsequent sections of the report.
- (250) In order to facilitate understanding of the subsequent parts of this report, this section will briefly sketch the main aspects of the regulatory framework for patents, marketing authorisations and pricing and reimbursement.

2.1. Patents

2.1.1. *The Rationale Behind Patents*

- (251) A patent is a legal title protecting an invention, which can be a product or a process, by granting its holder (usually an individual or a company) the right to prevent third parties from making, using, offering for sale, selling or importing the product (including the product obtained directly by a patented process) without the patent holder's prior consent.¹⁶⁰ In order to ensure sufficient compensation to the inventor for his or her creative work, preserve incentives for research and development in general, and stimulate commercialisation of the invention, patent protection gives the innovator an exclusive right to the commercial exploitation of the invention for a certain period of time.¹⁶¹ In Europe, patent protection may be obtained for up to 20 years.¹⁶² This

¹⁵⁹ While other intellectual property rights such as trademarks also play an important role for the pharmaceutical sector, it is submitted that the protection of trademarks plays a role in particular for parallel trade, which is not covered by the sector inquiry. For this reason it was decided to concentrate in the subsequent description on the legislation governing patents and patent protection.

¹⁶⁰ Article 28(1) TRIPS (WTO Agreement on Trade-Related Aspects of Intellectual Property Rights).

¹⁶¹ In the absence of this exclusive right, competitors could copy the invention while they have not incurred the cost of research and development (including the cost of failed attempts at invention) and thus offer the product at a much lower price than the inventor. The inventor would be driven out of the market and innovation in general would be deterred.

¹⁶² In accordance with Article 33 TRIPS, Article 63 of the European Patent Convention (EPC) provides that the term of a European patent is 20 years from the date of filing of the application. A patent may,

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period is calculated from the date the patent application is filed at the patent office of the territory concerned, which therefore determines the ultimate date to which the patent protection may extend for that territory.¹⁶³

- (252) During the period of patent exclusivity, the patent holder may be able to charge a price for the product resulting from the invention that is higher, often far higher, than its marginal cost of production. Patent owners may also conclude licence contracts, allowing others (usually in exchange for a fixed fee and/or royalties based on sales) to use or sell their invention. Patent holders may also cross-license the right to use their patented inventions.¹⁶⁴ The period of 20 years reflects the assessment by the legislator

however, expire before the full 20 years have elapsed if the patent holder fails to pay annual renewal fees for the patent. See the section on national validation further below.

¹⁶³ The system of "first to file" is used in Europe and most other parts of the world, as opposed to the "first to invent" system traditionally used in the USA. Under the Paris Convention for the Protection of Industrial Property, if within 12 months following the first application in any of the member states to the Convention an applicant makes further patent applications for the same invention in other member states, then, for the purpose of the patent examination, these subsequent applications will be regarded as if they had been made at the date of the first application (the "priority date"). Patents are territorial titles and inventors therefore have a major interest in getting the priority date of filing recognised for subsequent patent applications concerning the same invention in other countries. This recognition eliminates the risk that a subsequent patent application by the inventor is rejected on the ground that between the priority filing date and the date of the subsequent filing (a) the invention entered into the public domain through publication; or (b) someone else lodged an application for the same invention. Recognition of the priority date of filing reduces uncertainty for the inventor. The EPC recognises priority rights for first filings in any member of the WTO as well as in any state party to the Paris Convention.

¹⁶⁴ The patent law of Member States generally allows for compulsory licences to be granted if necessary. Examples are Article 48 of the UK Patents Act 1977 (as amended) and Article L 613-11 of the French Law No. 92-597 of July 1, 1992, on the Intellectual Property Code. The possibility of compulsory licensing is also foreseen to be part of the framework of the Community patent and unified judiciary. Already the Paris Convention for the Protection of Industrial Property of 1883 provided in Article 5 that "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work". The right of governments to issue compulsory licences in certain circumstances was more recently recognised in Article 30 of the WTO TRIPS Agreement, where it is stated: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties". Article 31 of TRIPS goes on to provide detailed provisions for the use of this possibility. Compulsory licences may, for instance, be granted by the public authorities (a patent office or a court) in cases where the patent holder does not exploit the invention himself and refuses to grant another party a licence on reasonable terms, in particular when that other party needs to use the invention to work an invention of his own or the invention is needed for the public good.

In Europe, compulsory licence provisions have been very rarely used in practice, including in the area of pharmaceuticals. In the sector inquiry, only two cases were identified where compulsory licences had been issued. Both of these cases concerned Italy. In the first case, the Italian Patent and Trademark Office referred the matter to the Italian Competition Authority. The latter adopted an interim order ordering the grant of a licence to the company requesting the licence. According to the patent holder, the company concerned never made use of the licence. Subsequently, the Competition Authority accepted a commitment from the patent holder to grant a non-exclusive, non-royalty bearing licence to any company requesting it and closed the case. Eleven licences were granted under this commitment. In the second case, the Italian Patent and Trademark Office itself granted a compulsory licence. This licence was

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that the end of this period is the point in time where the cost to society of continued patent protection, in the form of extra profits to the patent holder resulting from its exclusive position, starts exceeding the benefits.¹⁶⁵ The knowledge that patent protection is limited in time will also encourage the patent owner to create new inventions, which can again be patented. It is therefore generally accepted that time limits on patents stimulate innovation.

- (253) The pharmaceutical sector relies very heavily on patents to protect inventions (as compared to, for instance, secrecy, trade marks or first mover advantages in sectors with short product life cycles) and this most commonly up until the very moment of patent expiry. The importance of patents for the pharmaceutical sector was emphasised by EFPIA as follows:

"The extent to which IPR protection is an essential part of a particular industry's business model will largely depend on the cost, risk and time involved in bringing an innovative product to market, and on the cost and risk of imitation. [...] Given the clear disparity between the high cost and risk of innovation in the pharmaceutical sector and the low cost and risk of imitation, it is self-evident that exclusivity and thus protection from imitation is needed if there is to be innovation."¹⁶⁶

- (254) Patent rights are not designed to fence off the patent right holder from competition by other originator producers bringing to market competing products based on their own inventions. In the pharmaceutical field, such competition between patent-protected medicines for the same therapeutic use remains possible and, according to an association of originator companies, in fact takes place in many classes of medicines.
- (255) As a return for patent protection, the information contained in the patent application enters into the public domain through publication. This information may, at least in

subsequently revoked upon request of the two parties concerned after they had reached a settlement. Under the settlement, an exclusive licence was issued.

As for compulsory licences in general, it has been submitted by the UK Intellectual Property Office that in the UK such requests - although not very common - have occasionally been made in other sectors than pharmaceuticals.

¹⁶⁵ Unless the inventor sells the patent or grants a licence, the product resulting from the invention will first have to be marketed before it can start producing a reward for the inventor. The time between the patent application and the first marketing of the product concerned should therefore be deducted from the 20-year period to obtain the real period in which the invention produces a reward for the inventor. Since new pharmaceutical products take an exceptionally long time before they can be marketed, Community legislation provides for the possibility of "supplementary protection certificates" (SPCs) in the pharmaceutical field, extending the patent-related period of exclusivity. This period may be further extended by fulfilling certain requirements related to paediatric use research. Moreover, data exclusivity protection for new medicines can also extend the period of exclusive marketing. These mechanisms are explained further in this section.

¹⁶⁶ EFPIA: Intellectual Property and Pharmaceuticals, June 2008, pages 12 and 15.

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Europe, be immediately used by others for the purpose of further research.¹⁶⁷ Publication of patent applications raises the aggregate amount of technological and scientific knowledge available to society, which may then be built upon, thus promoting further innovation and the development of new inventions. Publication may thus lead to the subsequent invention of completely new products or processes. Publication also allows third parties, including competitors, to improve the originally patented product and obtain a patent on the improvement.¹⁶⁸ The patent system is thus designed to foster innovation, not only by the patent owner, but also by competitors.¹⁶⁹ In doing so, it ultimately enhances competition.¹⁷⁰

- (256) Once the period of protection of the invention has expired, anyone may, in principle, use the invention commercially without the authorisation of the original patent holder.¹⁷¹ It is at this stage that, after having obtained a marketing authorisation from the national authorities, producers of generic medicines will normally enter the market with generic versions of the previously patented active ingredient, thus creating competition for essentially the same medicine. At that point, competition will no longer take place exclusively within the originator industry. There will now also be competition between the originator company whose product is no longer covered by patent protection and its generic competitors. This type of competition will be based mainly on price and marketing effort. Indeed, competition may now even arise between the generic versions of the off-patent medicine and other medicines still under patent protection for the same therapeutic use.

¹⁶⁷ This possibility to legally "use" the patented invention for experimentation (without a licence) is generally referred to as the "research exemption". Its purpose is to stimulate further inventions. A research exemption is laid down in Article 27(b) of the 1975 Luxemburg Convention on the Community Patent (the Community Patent Convention). Although this Convention never entered into force, the principle of a research exemption enshrined in it has been adopted widely in the national legislation of EU Member States and has been applied by national courts, albeit not always with the same clearly defined scope.

¹⁶⁸ To the extent that the improvement makes use of the previously patented invention, a licence would normally have to be obtained from the original patent holder in order to be able to market the improved product. In this case, it may be in the interest of both patent holders to cross-license each other.

¹⁶⁹ The company having made the original invention is, however, likely to have a natural advantage over its competitors when it comes to further developing its own original invention, especially if it has itself undertaken the commercial exploitation of that original invention. During the public consultation, one association of originator companies referred to this as a company "using its superior knowledge of its own products to devise and protect new and valuable improvements for the benefit of patients and prescribers".

¹⁷⁰ Another legal exemption allowing the "use" of the patented invention is enshrined in Article 10(6) of Directive 2001/83/EC, as amended by Directive 2004/27/EC), which allows generic competitors to conduct the necessary studies and trials for their application for a marketing authorisation for a generic version of a medicine. See the section on marketing authorisation further below.

¹⁷¹ Other regulatory provisions, such as the need to obtain a marketing authorisation before putting a medicine on the market, remain of course applicable and have to be complied with.

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(257) Apart from the above-described traditional functions of the patent system (in particular the exclusivity function with as its counterpart the function of adding to public knowledge) certain additional functions of patents have recently increased in importance. These include:

- retaining the freedom to develop one's own innovation further ("freedom to operate"); in particular in the pharmaceutical sector, a patent may be applied for not so much with a view to commercialising the invention itself, but rather in order to be able to carry out further R&D as regards the compound or process in question without later risking to infringe any patent that a third party might have acquired on the initial invention; thus, originator companies may apply for patents on new active chemical entities even before their precise therapeutic function is known;
- being accumulated as tradable assets (bargaining function), for instance, also in the pharmaceutical field, with a view to concluding a cross-licence agreement or to becoming a participant in a patent pool;
- protecting an innovation that may develop into an industry-wide technological standard (standardisation function); this function is less important in the pharmaceutical field;
- being accumulated as financial assets to secure investments (financing function);
- enhancing a company's high-tech reputation (image function).

2.1.2. Substantive Criteria for Obtaining a Patent in Europe

(258) Patent offices are government bodies that may grant a patent or reject the patent application based on whether or not the application fulfils the requirements for patentability. These criteria have over time been largely harmonised within Europe based on the European Patent Convention (EPC) of 1973.¹⁷² On 13 December 2007, a new, revised Convention, often referred to as EPC 2000, entered into force, which contained a number of changes to the previous EPC, some of which are directly relevant to pharmaceuticals patents. Given that most pharmaceutical companies prefer to use the European Patent Office (EPO)¹⁷³ to obtain patents in Europe¹⁷⁴, in the

¹⁷² The EPC is an inter-governmental agreement which now has 36 Contracting States, including all EU Member States and several countries not members of the EU (for instance Norway, Switzerland, Turkey). A further five countries (Albania, Bosnia and Herzegovina, the Former Yugoslav Republic of Macedonia, and Serbia) allow granted European patents to be extended to their territories upon request. The EPC was revised in 1991 and again in 2000. The EPC 2000 entered into force on 13 December 2007 and contains a number of new or amended provisions relevant to pharmaceutical patents (OJ EPO, Special Edition No 4, p. 55).

¹⁷³ The EPO commenced operations in 1978. It has about 4,000 patent examiners and total staff numbers around 6,500. Its headquarters are at Munich, Germany. Representatives of the contracting states of the EPC sit on the Administrative Council of the European Patent Organisation.

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following, the patentability criteria of the EPC will be described, and not those of the national patent offices in the EU. The latter are, however, largely similar, at least at the level of general principles.

- (259) In the pharmaceutical industry, inventions mainly relate to new active ingredients with a therapeutic function, to new formulations of already existing active ingredients or to new ways of producing active ingredients. All of these are in principle patentable. Although the general public often thinks differently, it is not a requirement of patentability that a new medicine is more effective in therapeutic action than an already existing medicine.
- (260) Patents covering new active ingredients can also be referred to as "primary", "basic" or "compound" patents. Patents covering products containing active ingredients already covered by a primary patent, or covering new production processes for the production of active ingredients already covered by a primary patent, are sometimes referred to as "secondary patents". For further details on the types of patents that can be found in the pharmaceutical sector, reference is made to the Annex to Chapter B.2.1: Claim Types.
- (261) In accordance with Article 52(1) EPC, a patent will be granted if:
- the invention is new;
 - the invention involves an inventive step; and
 - the invention is susceptible of industrial application.¹⁷⁵

There are also a number of exceptions to patentability laid down in the EPC.

First Condition: Novelty

- (262) An invention is new if it does not form part of the "state of the art". In Europe, this concept comprises everything made available to the public, in any form or way, before the date of filing of the patent application. Such publicly available information is called "prior art".

Second Condition: Inventive Step

- (263) A patent involves an inventive step if the invention, having regard to the state of the art, is not obvious to a person skilled in the art. In order to assess this, the EPO follows the "problem-solution approach", consisting of three stages of analysis. First, the closest prior art is determined.¹⁷⁶ Then the objective technical problem to be solved is

¹⁷⁴ This emerges from the replies of originator companies to the Commission's requests for information.

¹⁷⁵ For further details, please see also Article 27 TRIPs.

¹⁷⁶ The closest prior art is that combination of already known features which constitutes the most promising starting point for development leading to the claimed invention.

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established, based on the difference between the claimed invention and the closest prior art. Finally, the EPO considers whether the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person. In this last assessment, a careful balance is sought: On the one hand, innovation could be stifled if patents were granted too restrictively. On the other hand, competition in the market place could be negatively affected by granting a legal exclusivity that may later have to be revoked. It is an important interest of society, therefore, that patent offices strike the right balance.

Third Condition: Industrial Application

- (264) Being susceptible of industrial application simply means that the invention can be made or used in any kind of industry, including agriculture.

Exceptions to Patentability

- (265) Article 52(2) EPC states that (a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; and (d) presentations of information cannot be considered to be inventions.
- (266) Article 53 EPC furthermore excludes (a) inventions, the commercial exploitation of which would be contrary to "ordre public"; (b) plant or animal varieties or essentially biological processes for the production of plants or animals¹⁷⁷; and (c) methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.

2.1.3. European Regulatory Framework for Patents

- (267) Even at present, more than 50 years after the foundation of the European Economic Community, it is not possible to obtain a unitary patent that is valid and enforceable throughout the Community. A Community Patent Convention was signed in Luxembourg in 1975, but never entered into force for lack of ratification by Member States. In 2000, the Commission put forward a proposal for a Council Regulation

¹⁷⁷ Article 1 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions requires Member States to protect biotechnological inventions under national patent law. According to Article 3 of the Directive, for the purposes of the Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature. Although the EPO is not formally bound by the Directive, the EPC Implementing Regulations were amended in 1999 to introduce extensions and clarifications binding the EPO and the national courts of the Contracting States, designed to ensure that the EPC would continue to be interpreted in line with the Directive.

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creating a Community patent¹⁷⁸, but this proposal has not yet been adopted. Accompanying proposals to establish a Community Patent Court, with appeals before the Court of First Instance¹⁷⁹, and to confer jurisdiction on the European Court of Justice in disputes relating to the Community patent¹⁸⁰ have also remained in deliberation. Most recently, in a Communication of 2007, the Commission has stated that the creation of a single Community patent continues to be a key objective for Europe. With respect to litigation, the Commission has indicated that the way forward could be to create a unified and specialised patent judiciary with competence for litigation on both European patents and future Community patents (thus avoiding duplication of jurisdictions). This judiciary would comprise a limited number of first instance chambers as well as a fully centralised appeal court which would ensure uniformity of interpretation.¹⁸¹ The European Court of Justice would rule on preliminary questions asked by the court structure established in the framework of the Unified Patent Litigation System on the interpretation of EC law and on the validity and interpretation of acts of the institutions of the Community.¹⁸²

- (268) At the moment, patents in the EU can be obtained only by filing a national application at each respective national patent office of the Member States or by filing a single patent application at the European Patent Office (EPO).¹⁸³ However, in the latter case, although only a single examination procedure will have to be undergone, national validation¹⁸⁴ of the "European patent" granted by the EPO in each Member State where the patent owner wishes the patent to exist and to be enforceable will still be necessary. The "European patent" – as it exists today – is thus merely a bundle of national patents

¹⁷⁸ Proposal for a Council Regulation on the Community patent, COM(2000) 0412 final (OJ C 337, 28.11.2000, pp. 278-290).

¹⁷⁹ Proposal for a Council Decision establishing the Community Patent Court and concerning appeals before the Court of First Instance, COM(2003) 0828 final.

¹⁸⁰ Proposal for a Council Decision conferring jurisdiction on the Court of Justice in disputes relating to the Community patent, COM(2003) 0827 final.

¹⁸¹ A ruling by a first instance chamber on a Community patent would automatically apply throughout the Community. For European patents resulting in a bundle of national patents, a ruling by a first instance chamber on any of the national patents would apply to all Member States where the European patent had been validated.

¹⁸² See the Communication from the Commission to the European Parliament and the Council - Enhancing the patent system in Europe, COM(2007) 0165 final. The purpose of this communication is to revitalise the debate on the patent system in Europe. See also the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: An Industrial Property Rights Strategy for Europe, COM(2008) 0465 final. For the most recent draft text on the Community patent, see <http://register.consilium.europa.eu/pdf/en/09/st08/st08588.en09.pdf>. For the most recent draft text on the unified patent judiciary, see <http://register.consilium.europa.eu/pdf/en/09/st07/st07928.en09.pdf>.

¹⁸³ For the purpose of this report, there is no need to describe the application route through the international Patent Co-operation Treaty (PCT).

¹⁸⁴ See the sub-section on national validation further below.

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granted on the basis of a centralised procedure at the EPO. Moreover, given that substantive patent law has not yet been fully harmonised between Member States, some (minor) differences may still exist in the protection offered to patent holders in different Member States¹⁸⁵.

- (269) Since, as already mentioned, most pharmaceutical companies prefer to use the European Patent Office (EPO) to obtain patents in Europe, in the following, the examination procedures before the EPO will be described, and not those of the national patent offices in the EU. The text below focuses on the actual treatment of patent applications at the EPO after they have been filed there.

2.1.4. The Examination at the EPO Leading up to the Grant or Rejection of a Patent

- (270) According to the EPO, on average, the procedure at the EPO takes about three and a half years¹⁸⁶ from the date the patent application is filed with the EPO until it is completed with the granting of a European patent, the abandonment by the applicant of the patent application or the rejection of the patent application. There are two main stages in the European procedure leading up to the EPO's decision to grant or reject a European patent:
- (271) **Examination of formalities and search report preparation.** The Receiving Section of the EPO checks that the application meets all the formal requirements. If the formal requirements are met, the Search Division of the EPO will prepare a search report listing prior art documents that are the most relevant to assess the novelty and non-obviousness of the invention of the application. Certain types of prior art, however, such as public prior use by a third party, may be "unsearchable" as they are not contained in databases and evidence of it may not be found in non-patent literature. The search report is sent to the applicant together with a preliminary written opinion on whether the application seems to meet the substantive requirements of patentability. The application, the search report and the preliminary opinion are all made accessible to the public simultaneously, as soon as possible after the expiry of a period of 18 months from the priority date. This disclosure allows third parties to take note of the claimed invention and, if they so desire, to make third party observations under Article 115 EPC.
- (272) **Substantive examination.** Following consideration of the search report and the preliminary opinion, the applicant may withdraw the application or ask for the application, with or without amendments, to be examined. In the latter case, the Examining Division of the EPO will, at the applicant's request, undertake a full

¹⁸⁵ It should be noted that, according to comments received in the public consultation, in some Member States (examples mentioned are Spain, Greece, Portugal and Finland) patent protection of pharmaceutical products (as opposed to processes) was not possible in the past. These exceptions disappeared in the 1990s.

¹⁸⁶ In 2008, a granted patent was published on average 43 months after the application was received. Irrespective of the outcome, it took the EPO an average of 39 months to complete the procedure. EPO Annual Report 2008, p. 22.

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examination. The request must be made within six months after publication of the search report and preliminary opinion. The examination itself may include one or more cycles of written objections from the Examining Division and written submissions from the applicant. Oral proceedings with the applicant may also be organised. The examination does not, however, include any experiments to verify applicant allegations. Nor can the examining division commission its own experts. If the EPO decides to grant a patent, it will publish a mention of the grant and the patent specification¹⁸⁷ in the European Patent Bulletin. The grant will take effect with the publication and will apply for a period of 20 years from the date the application was filed with the EPO. Patents granted by the EPO are also referred to as "European patents".

- (273) If, during the examination, the application is seen not to respect the principle of unity of invention, the applicant may be asked to file one or more divisional applications, each covering a separate inventive concept. Divisional applications may also be filed at the initiative of the applicant. Voluntary divisional applications may even be identical to the parent application. Divisional applications will have the same priority and filing dates as the parent application, but will be treated as new applications procedurally. They will therefore normally be granted or rejected some time after the parent application, but, if granted, the divisional patent will have the same expiry date as the parent patent.¹⁸⁸ The possibility to file divisional applications provides opportunities to applicants to extend the period during which a patent application covering subject-matter contained in the parent application is left pending.
- (274) The role of third parties during the examination is, at present, limited. They may make written observations on the patentability of the invention. In these observations they can for instance point out existing prior art not yet identified. But the examination procedure remains *ex parte*, which is to say that the applicant is the only party before the EPO. There is no possibility for a hearing or for expert witnesses to be heard. Third parties do not receive any direct feedback from the EPO on the extent to which their observations have been taken into account.
- (275) Procedures exist within the EPO to speed up, upon request, the process leading to the grant or refusal of a patent, taking into account the interest applicants may have in obtaining a speedy decision on their application. But applicants may also have an interest in drawing out procedures and delaying a final decision on their patent application. This may be the case, for instance, where the applicant needs more time to further develop the invention and its commercial applications. It is also possible that the patent application is weak and likely to be rejected, but the applicant wants to maintain legal uncertainty for potential competitors in the market place for as long as possible. The filing of multiple divisional applications could, for instance, be used for this purpose. At present, the EPO does not have many procedural tools at its disposal

¹⁸⁷ A patent specification is the text of the patent as granted. It contains a description of the invention, any drawings that may exist, and the claims.

¹⁸⁸ For further details see Article 76 EPC.

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to prevent or counter delaying tactics by applicants, apart from the possibility for examiners to summon oral proceedings in order to speed up matters.

(276) In 2008, the EPO received 146,500 patent applications, an increase of 3.6% compared to 2007.¹⁸⁹ In 2008, in total, 49.5% of final actions (outcomes) in examination were grants, down from 51% in 2007.¹⁹⁰ This lower percentage of grants may be seen as a first result of the EPO's increasing focus on ensuring the quality of granted patents.¹⁹¹

2.1.5. Opposition and Appeal at the EPO

(277) Following the grant or rejection of a European patent there may be further stages before the EPO:

If the patent application is rejected:

- appeal against a decision to reject. Appeal against a rejection is possible. Unless the case is remitted to the first instance for further processing, a final decision will then be taken by the Board of Appeal. This procedure will normally take about two years. No further appeal from this decision is possible.

If the patent is granted:

- opposition proceedings. A third party (often a competitor) may, within nine months after the publication of the grant of the European patent, file an opposition against the granted patent. Opponents and the owner of the patent are parties to the opposition proceedings, which are therefore *inter partes*. Oppositions can only be filed on the grounds that an invention is not patentable under Articles 52-57 EPC, that it does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a skilled person in the art, or that the subject-matter of the European patent extends beyond the content of the application as filed. After an exchange of written submissions by the parties, the Opposition Division of the EPO will normally convene oral proceedings with the parties and may hear expert witnesses. The opposition procedure typically takes about two years¹⁹² and can have one of three

¹⁸⁹ EPO Annual Report 2008, p. 17. For an examination of patent applications in the field of pharmaceuticals, see Chapter C.1.2.

¹⁹⁰ The grant rate of 49.5% does not mean that 50.5% of applications are rejected by the EPO. Even though the number of formal refusals by the EPO increased by 42% in 2008 compared to 2007, the absolute number is still small (around 5% of all applications). The vast majority of not granted applications were abandoned by the applicant at any time during the procedure. Of course, abandonment may often take place because a rejection is anticipated.

¹⁹¹ See Chapter D.1.3.

¹⁹² In cases where an infringement action in respect of a European patent is pending before a national court of a Contracting State, a party or a national court may request the accelerated processing of pending

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outcomes: rejection of the opposition (maintenance of the patent as granted); revocation of the patent; or maintenance of the patent in amended form.¹⁹³

In 2007, 5.2% of granted patent applications at the EPO were opposed.¹⁹⁴ In the same year, taking as a basis all decisions in opposition cases (without appeal) reached in that year, the granted patent was revoked in 38% of cases and maintained in amended form in 30% of cases, whereas the opposition was rejected in 32% of cases.¹⁹⁵

- appeal after opposition. Following the opposition procedure, an appeal against the decision to reject the opposition, restrict in amended form or revoke the patent is still possible and can be filed by any party to the proceedings adversely affected by that decision. Such appeals are heard by the Boards of Appeal and the procedure typically takes up to three years.

National Validation and Patent Protection

- (278) A granted European patent takes effect from the date on which the mention of its grant is published in the European Patent Bulletin. The European patent is published in the language of the proceedings (English, French or German), together with a translation of the claims in the two other official languages of the EPO.
- (279) National law governs the conditions under which the European patent takes effect in EPC contracting states, which include all 27 EU Member States. A European patent must be validated at the national patent offices of the designated EPC contracting states before it can be enforced in the countries concerned. Validation generally requires the meeting of national translation requirements,¹⁹⁶ including the payment of

opposition proceedings, with the effect that the EPO will make every reasonable effort to ensure that the next procedural action be issued within three months of the receipt of the request. A similar possibility to accelerate the procedure as far as the procedural regulations allow also exists before the Boards of Appeal. Accelerated processing may be requested by either party to the proceeding. No additional costs are involved. In 2007, accelerated processing was requested in less than 2% of opposition proceedings (including those where no infringement action took place simultaneously), which indicates that parties make little use of this possibility. Source: EPO.

¹⁹³ If the opposition is withdrawn, for instance because of a settlement between the patent holder and the challenger(s), the EPO may continue the opposition proceedings of its own motion, even without the participation of the parties. See Rule 84 of the Implementing Regulations to the Convention on the Grant of European Patents.

¹⁹⁴ EPO, Annual Report 2007, p. 22. This percentage remained unchanged in 2008. See EPO Annual Report 2008, page 22.

¹⁹⁵ EPO, Annual Report 2007, p. 23, See Chapter C.1.2. for data specification to pharmaceuticals.

¹⁹⁶ These translation requirements (and the accompanying publication fee) have recently been alleviated with the entry into force of the so-called London Agreement. This optional agreement is aimed at reducing the cost of translating patents granted by the EPO. It was concluded at an intergovernmental conference held in London on 17 October 2001 and entered into force on 1 May 2008. It is not an EU legal instrument. At present under the London Agreement, the European patent takes effect directly, without any translation

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national publication fees, if any, as well as the payment of annual renewal fees, in each country in which the patent holder wishes the patent to be valid. If renewal fees are not paid, the patent will lapse. Patent owners must normally use the services of national patent agents for this purpose. The costs involved for patent owners are considerably higher in the EU than in the USA or Japan.¹⁹⁷

- (280) Provided the patent has been validated in the Member State concerned, it grants full protection to the patent holder in the territory concerned from the date of the publication of the mention of the grant of the European patent. This allows the patent holder to ask the national courts to order that any (imminent) infringements cease and to claim full damages. Moreover, under Article 67 EPC, provisional protection may already be obtained from the date of publication of the application. The scope of such protection is determined by the national law of the Member State concerned, with some providing only for the payment of reasonable compensation for infringement occurring during the period of provisional protection. Moreover, in many Member States, legal action on this basis is only possible once the patent has been granted.
- (281) The protection offered by a patent therefore applies as follows:

Box: Civil protection conferred by patent rights

From priority date until date of publication of patent application (18 months after the priority date¹⁹⁸): no specific protection. In this period, patent applicants usually keep the invention secret.

From date of publication of patent application until date of publication of mention of grant: provisional protection (in many Member States limited to reasonable compensation).

From date of publication of mention of grant until expiry of patent: full protection (legal enforcement actions and full damages).¹⁹⁹

- (282) As long as a granted patent has not been revoked by the EPO or by a national court, the risk of damage claims by the patent holder acts as a significant deterrent to generic market entry. This shows that when the EPO grants a patent for a pharmaceutical

and without any publication fee in France, Germany, the UK, Switzerland/Liechtenstein and Monaco. In Latvia, Lithuania and Slovenia, the European patent takes effect if the patent proprietor files a translation of the claims in the national language of the state concerned and pays the publication fee. In Denmark, the Netherlands, Sweden, Croatia and Iceland, the European patent takes effect if the patent proprietor files a translation of the claims in the national language of the state concerned and a translation into English of the description and pays the publication fee. In the 19 other EPC contracting states, a full translation of the European patent into the language of the state concerned is still required as well as the payment of a publication fee.

¹⁹⁷ For further details see footnote 106.

¹⁹⁸ The availability of protection may be hastened by applying for early publication of the patent application. See Article 93(1)(b) EPC.

¹⁹⁹ For the protection offered by supplementary protection certificates (SPCs), see further below.

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product, it has immediate and important commercial consequences in the market, even if the patent may subsequently be revoked or amended in opposition.

2.1.6. National Enforcement and Invalidity Proceedings

(283) Once a European patent has been validated by a national patent office, the patent becomes legally enforceable in that Member State. The exact enforcement procedure open to the patent holder differs for each Member State, subject to a certain degree of harmonisation based on Community legislation.²⁰⁰ For instance, if a generic company sells – or is about to sell – the patented product in the territory concerned, the patent holder may ask the national court to issue an interim injunction ordering the generic company, often subject to a penalty payment, to refrain from selling the allegedly infringing product.²⁰¹ The main infringement proceedings, which may take several years, will then determine whether the generic product in fact infringes the patent. Especially if the generic company had already started selling the product in the territory concerned, compensation for any damage suffered may be claimed and awarded in the main proceedings.²⁰² The generic company, being the defendant in the main proceedings for enforcement, may in most Member States make a counterclaim of invalidity of the patent.²⁰³ In an action for an interim injunction, however, such a counterclaim may not be enough to prevent interim measures from being imposed.²⁰⁴

²⁰⁰ See in particular Corrigendum to Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 195, 2.6.2004).

²⁰¹ During the consultation period, originator companies remarked that the patent holder may be liable to appropriate compensation if it is subsequently found that there was no infringement. See Article 9(7) of the Corrigendum to Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 195, 2.6.2004). Such compensation could relate to the sales the generic company did not realise because of the interim injunction. Generic companies, from their side, remarked that the lost revenue incurred by the generic company will normally be less than the revenue gained by the originator from the product concerned in the period for which the interim injunction had been given, simply because the generic price for the product will normally be lower than that of the originator company. In their view, it remains, therefore, a relatively risk free operation for an originator company to ask for an interim injunction. This would change, however, if health insurers were legally able to – and actually did – claim damages in court from too high prices for patients resulting from unjustified legal protection for the originator product.

²⁰² For the period of provisional protection, between the moment of publication of the patent application and the moment of the publication of the patent grant, Article 67 EPC requires Contracting States to ensure that the applicant can claim compensation reasonable in the circumstances from any person who has used the invention in their territory. Following publication of the mention of the patent grant, full compensation of any losses suffered may be claimed, depending also on whether the infringer knew or should have known that he or she was infringing.

²⁰³ However, in Germany, for instance, infringement and invalidity proceedings are separate.

²⁰⁴ In an action for an interim injunction, the judge may order interlocutory measures if he or she is satisfied with a sufficient degree of certainty that the applicant is rightholder and that the applicant's right is being infringed (or that such infringement is imminent). See Corrigendum to Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 195, 2.6.2004), Article 9(3). Such measure may, in appropriate cases, even be taken "without

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Reportedly, there are considerable differences between the courts in different Member States in the ease or reluctance with which they grant interim measures.²⁰⁵ Depending on national law, a generic company may also take the initiative itself to ask for a declaratory ruling of non-infringement prior to launching a generic product²⁰⁶, or launch a revocation proceeding²⁰⁷ before the court.

- (284) In the absence of a unified patent litigation system in the Community, the national courts of each Member State are competent to determine the validity of a patent in their own territory. This means that any legal action needed to enforce or to invalidate a patent or any action for a declaratory ruling of non-infringement, has to be brought before the national courts of each country concerned.²⁰⁸ This forces both challengers and enforcers to multiply national court procedures, at considerable cost to all parties. Moreover, there is a considerable risk of diverging judgments in different Member

the defendant having been heard, in particular where any delay would cause irreparable harm to the rightholder". The judge may, however, ask the patent holder to provide adequate security to ensure compensation for any prejudice suffered by the defendant and may, where it is subsequently found that no infringement has taken place, order such compensation. Provisional measures taken without the defendant having been heard are subject to review at the request of the defendant, once the latter has been notified. See Article 9(4) of the same Directive.

²⁰⁵ Information based on replies from originator companies to the Commission's requests for information. Belgium is mentioned as a country where it is very easy to obtain an injunction. In the United Kingdom, the patent holder has to show that there is a serious issue to be tried in order to obtain an injunction. Reportedly, in Germany and the Netherlands the courts may take the merits of the case into account in considering whether to grant an interim injunction.

²⁰⁶ According to replies from generic companies to the Commission's requests for information, in many Member States declaratory rulings of non-infringement are not possible or subject to disclosure to the originator of confidential product information.

²⁰⁷ Strictly speaking, invalidity of a patent would be claimed as a defence in an enforcement action, whereas if a company takes the initiative to attack a patent, this would normally be called an action to revoke the patent. However, in practice the precise terminology may differ. For the purpose of this report, the terms "invalidity", "revocation" and "annulment" are used interchangeably.

²⁰⁸ The courts of the Member State in which the patent has been validated have exclusive jurisdiction in proceedings concerning the registration or validity of that patent, irrespective of the domicile of the parties and irrespective of how the question of validity of the patent was raised in a proceeding (for instance, in objection to an infringement action or in support of a declaratory action seeking to establish that there has been no infringement of the patent). See Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (OJ L 12, 16.01.2001), in particular Article 22. See also Case C-4/03, *Gesellschaft für Antriebstechnik mbH & Co. KG v. Lamellen und Kupplungsbau Beteiligungs KG*, judgment of 13 July 2006, [2006] ECR I-6509, in which the European Court of Justice held that exclusive jurisdiction applies whatever the form of proceedings in which the issue of a patent's validity is raised, be it by way of an action or a plea in objection. See also Case C-539/03 *Roche Nederland BV and Others v Frederick Primus and Milton Goldenberg*, judgment of 13 July 2006, [2006] ECR I-6535, in which the ECJ confirmed that, given the current legal framework in place, each national patent can only be enforced before the national court where that patent is been validated, even if similar alleged infringements are taking place by other legal entities of the same undertaking in other Member States. The same logically applies to claims for invalidity of patents.

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States on the substantive question of whether the same patent granted by the EPO is infringed or invalid.²⁰⁹

- (285) Divergences regarding the validity of a patent may also exist between national courts and the EPO. If the EPO revokes a European patent in opposition (or appeal), that patent will be revoked in its entirety and *ab initio* in all designated Member States. Such a revoked European patent can therefore no longer be enforced in national courts. The reverse, however, is not true: if the EPO upholds a European patent in opposition (or appeal), that patent may still be held invalid by national courts for their own territory. For instance, in certain Member States, such as the United Kingdom, it is possible for a patent to be upheld in opposition by the EPO, but to be held invalid by the national court, either before or even after the EPO has given its final ruling. In certain other Member States, however, national courts may decide to stay the proceedings until after the EPO has given a final ruling, in order to take that ruling into account, even if the national court is not bound by the EPO ruling.²¹⁰
- (286) Several originator companies mentioned that the grant of a patent creates a legal presumption of validity. In this respect it should be noted, first of all, that European patents granted by the EPO are open to opposition and appeal from third parties, without any presumption by the EPO regarding the status of the patent. On this issue, an association of patent attorneys stated during the public consultation that:

"... the patent system is an *ex parte* procedure, which has to deal with huge volumes of applications. It is inevitable that when patents are subjected to a more detailed scrutiny in *inter partes* proceedings a substantial number will be found not to meet the standard".

- (287) Secondly, with respect to the situation before national courts in Europe, one patent judge stated during the public consultation that:

"... one cannot ever expect the grant of a patent by a Patent Office to be also a certificate of validity. It never has been and never will be. In truth the Patent Office is a kind of coarse filter – rejecting clearly bad cases but having to allow those which may be good".

²⁰⁹ Even if the European Court of Justice held in Case C-539/03 that there is no risk of contradictory decisions for the formal reason that each national procedure involves a defendant domiciled in that Member State and concerns acts committed in the territory of that Member State only, nevertheless, on substance, the different national courts will all deal with the same question of whether the patent is valid or not. They may therefore come to different conclusions on this question, depending also, as the European Court of Justice points out in the same case, on the context of the relevant national law in force in that Member State. As a result, the validity of a patent granted by the EPO may be interpreted differently by the courts of different Member States.

²¹⁰ In Germany, where infringement and invalidity proceedings are separate, it is not possible to initiate invalidity proceedings while an opposition is still pending at the EPO. Infringement proceedings, on the other hand, may be initiated pending opposition, but may be stayed by the Court until after the EPO has given a final ruling.

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(288) A law firm submitted during the public consultation that:

"... the ultimate fact is that there are simply patents which are upheld by a court, and patents which are revoked by a court" and "Indeed, a large proportion of patents which are invalidated by courts are held invalid over prior art which was not known to the patentee or to the Patent Office. In addition, it is our experience that, where a patent is invalidated by prior art, the invalidating fact in many cases is not expressly stated, but is found only on repetition of an experiment described in the earlier – something which no prior art search or Patent Office examiner can discover".

(289) An association of intellectual property lawyers stated during the public consultation that:

"... In circumstances where judges (and patent examiners) frequently differ as to the validity of a given patent, it is not surprising that only a small number of patents can be regarded as "robust": in most cases, the patentee cannot be fully confident that the patent will be upheld".

(290) In infringement proceedings the defendant may raise a counterclaim of non-infringement or invalidity of the patent. In procedural terms, judges will normally follow the rule that the burden of the proof of facts lies on the party relying on those facts. This means that first the patentee has to provide evidence that a patent has been granted to it, that the patent is in force in the Member State concerned and that it covers the subject matter of the dispute²¹¹. Then the burden of proof will normally shift to the other party, the defendant, to prove either that the patent is not infringed or that it is invalid. On this last question, the judge will make up his or her own mind, where necessary through expert witnesses and through evidence received from experiments, rather than assume that the patent in question must be valid simply because it has been granted by the EPO after an ex parte procedure with the applicant.

(291) As published by the European Generics Association, certain national courts have separate procedures for enforcement and invalidation of patents, which, as they are not linked, means that invalidity of the patent cannot be raised as defence against an enforcement action.²¹² Another point noted by generic companies is that before certain national courts it is difficult to challenge the validity of the granted European patent as long as opposition proceedings before the EPO are pending.²¹³ In that case, the court may wait until the EPO has given a final ruling. This may delay the national ruling by

²¹¹ Compare Article 9(3) of Corrigendum to Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights.

²¹² Germany, Hungary, the Czech Republic and Poland are mentioned. See European Generic Medicines Association (EGA): Patent-related Barriers to Market Entry for Generic Medicines in the European Union, May 2008, p. 21. However, in Germany, for instance, the court competent for the action for infringement may consider staying the procedure until the decision on the validity of the patent has been taken.

²¹³ Germany, Austria, Slovenia and Sweden have been mentioned as examples in replies from generic companies to the Commission's requests for information.

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up to five years. All that time, the parties concerned face uncertainty over the validity of the patent.

2.1.7. Settlements

- (292) Court proceedings to enforce or invalidate a patent may also be settled between the parties. In such a settlement the party that initiated the court proceedings will agree to withdraw its case. Depending on the expected outcome of the court case the withdrawing party may receive some benefit from the other party.

2.1.8. Supplementary Protection Certificates

- (293) Council Regulation (EEC) No 1768/92 of 18 June 1992 created a supplementary protection certificate (SPC) for medicinal products.²¹⁴ The SPC amounts to a kind of extension of the patent right for a maximum of five years. However, the SPC extends only to the specific medicinal product and uses which had been authorised. SPCs were introduced to compensate for the length of time it takes between a patent application for a medicinal product and the time when that product can for the first time be effectively marketed in the European Economic Area (EEA). The Regulation provides that holders of both a patent and an SPC for a medicinal product must be able to enjoy a maximum period of up to 15 years' effective protection in every Member State from the time the medicinal product in question first receives marketing authorisation in the EEA. The purpose is to give medicinal products an effective period of protected marketing comparable to other industries with less stringent pre-marketing requirements.
- (294) The following table shows by way of example how the SPC works in practice,²¹⁵ i.e. how it can lead to the extension of marketing exclusivity for pharmaceutical products:

²¹⁴ Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, 2.7.1992, pp. 1-5). A Spanish association of originator companies commented in the public consultation that SPCs were introduced in Spain only in January 1998.

²¹⁵ For the sake of simplification, months and days have not been taken into account.

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Box: Protection through SPC

Patent application = 1985

Patent expiry = 2005 (20 years later)

If first marketing authorisation in EU = 1990 => 15 years patent protection, no SPC protection. Total protection = 15 years. Protection ends with patent expiry in 2005.

If first marketing authorisation in EU = 1993 => 12 years patent protection + 3 years SPC protection. Total protection = 15 years. Protection ends in 2008.

If first marketing authorisation in EU = 1995 => 10 years patent protection + 5 years SPC protection. Total protection = 15 years. Protection ends in 2010.

If first marketing authorisation in EU = 2000 => 5 years patent protection + 5 years SPC protection. Total protection = 10 years. Protection ends in 2010.

If first marketing authorisation in EU = 2001 => 4 years patent protection + 5 years SPC protection. Total protection = 9 years. Protection ends in 2010.²¹⁶

- (295) SPCs do not apply to all pharmaceutical patents. Certificate applications may be made for any product which is protected by a basic patent²¹⁷ on the territory of a Member State and which has received marketing authorisation in that Member State as a medicinal product in accordance with the Community code concerning medicinal products for human use. The application for an SPC must be lodged in each Member State concerned within six months of the date on which marketing authorisation in that particular Member State was granted. This creates legal certainty for potential generic competitors, since they will know at an early stage when the period of protection of the medicinal product is due to expire and when they can start preparations for market entry. The Regulation provides that any person may submit an application or bring an action for a declaration of invalidity of the certificate. An appeal is also possible.
- (296) To correctly calculate the duration of the SPC, the Member State concerned must be informed by the applicant of the date of the first grant of a marketing authorisation for the product anywhere in the EEA. In one case pursued by the European Commission, AstraZeneca, an originator company, had made misleading representations to national

²¹⁶ For an explanation of how the period of marketing exclusivity under Directive 2001/83/EC as amended by Directive 2004/27/EC may add to the overall period of protection for the patent holder, see the next section on marketing authorisations (B.2.2.).

²¹⁷ Article 1 of the Regulation defines "basic patent" as a patent which protects the active ingredient(s) of a medicinal product. The main aim of the Regulation is to stimulate research in the EU into new active ingredients. According to point 11 of the Explanatory Memorandum to the proposal for the Council Regulation (COM(90) 0101 final), as cited in Case C-431/04 Massachusetts Institute of Technology, judgment of 4 May 2006, [2006] ECR I-4089, paragraph 19, "the proposal for a Regulation therefore concerns only new medicinal products. It does not involve granting a [SPC] for all medicinal products that are authorised to be placed on the market. Only one SPC may be granted for any one product, a product being understood to mean an active substance in the strict sense. Minor changes to a medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new [SPC]".

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authorities concerning the date of first marketing authorisation in the EU, deliberately using a later date. The Commission considered this an abuse of a dominant position. In its Decision, the Commission imposed a fine of € 60 million on AstraZeneca.²¹⁸

- (297) Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use provides for a "six-month" extension of the SPC duration under certain conditions in order to encourage research on paediatric applications of medicines.

Summary

In Europe, patent protection can last up to 20 years from the date of a patent application. For the pharmaceutical sector, where the time between filing a patent application and market launch can be significantly longer than in other sectors, supplementary protection certificates (SPCs) can be issued. These extend the effective protection of products already on the market by a maximum of five years.

Despite significant efforts, neither a Community patent nor a Community jurisdiction for patent matters exist. The European Patent Office handles centralised patent applications (and opposition and appeal procedures relating to granted patents). However, once granted, the European patent turns into a bundle of national patent rights, which, in court, must be challenged at national level. This can lead to diverging national decisions and is costly and time-consuming for all stakeholders concerned.

²¹⁸ Commission Decision of 15 June 2005 in Case COMP/A.37.507/F3 - AstraZeneca, currently under appeal. AstraZeneca claimed that the date to be used for the calculation of the SPC was the date of "effective marketing", i.e. after conclusion of the pricing and reimbursement negotiations with the national authorities, rather than the earlier date on which the technical marketing authorisation was granted. AstraZeneca was successful at some, but by no means all national patent offices in obtaining in this manner an excessively long SPC period. In those Member States where AstraZeneca was successful, the expiry date was often later corrected by the national courts, in proceedings brought by its competitors. The fine of € 60 million was imposed for two separate infringements, one of which was the one described here. A preliminary ruling in the case was also made by the European Court of Justice in Case C-127/00 Hässle AB v Ratiopharm GmbH, [2003] ECR I-14781. The Court ruled that the concept of first authorisation to place on the market in the Community refers solely to the first marketing authorisation granted in any of the Member States and does not refer to authorisations on pricing or reimbursement of medicines.

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2.2. Marketing Authorisations

(298) In the EU²¹⁹, medicinal products may only be placed on the market after they have obtained marketing authorisation (MA): MAs are therefore of crucial importance for producers of medicinal products, be they either originator companies or generic companies. Two types of authorisations are available:

- *National authorisations*, which are issued by the competent authorities of the EU Member States and cover their own territory. A national authorisation can be recognised by other EU Member States by using the mutual recognition procedure (MRP). Moreover, in case where no national MA has yet been granted, the decentralised procedure (DCP) allows for the submission of an application in several Member States at the same time and for the choice of one Member State which will act as Reference Member State (RMS);

- *Community authorisations*, which are issued by the European Commission for the entire territory of the EU on the basis of the centralised procedure. This procedure has the advantage for the applicant that a single application will provide him with an authorisation allowing him direct access to all EU markets.

(299) Each marketing authorisation decision is taken on the basis of scientific criteria concerning the quality, safety and efficacy of the medicinal product concerned: these three criteria are used to assess the risk-benefit balance of the notified medicinal product. The underlying objective of MAs is the need to protect public health within the Community. For this reason, factors such as the appropriateness of the pricing, the level of reimbursement or the patent status of the product should not be taken into account when assessing the risk-benefit balance.²²⁰

²¹⁹ Norway, Iceland and Liechtenstein which together with the EU27 form the EEA have agreed to adopt, through the EEA agreement, the *acquis communautaire* on medicinal products. They are therefore parties to the Community marketing authorisation procedures, with the only exception that legally binding acts adopted by the EU (e.g. Commissions decisions) do not directly confer rights and obligations but have first to be transposed into legally binding acts in the respective countries. The Marketing Authorisations granted by Norway, Iceland and Liechtenstein are eligible for the mutual recognition procedures in the same way as marketing authorisations granted by Member States. In this section, reference is made only to the EU as it is the scope of the sector inquiry.

²²⁰ See Article 81 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1 (as last amended by Regulation (EC) No 1394/2007, OJ L 324, 10.12.2007, p. 12) and Article 126 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67 (as last amended by Directive 2008/27/EC, OJ L 81, 20.3.2008, p. 45). Each reference in the text to Regulation (EC) No 726/2004 will refer to the Regulation as amended ("Regulation"). Each reference in the text to Directive 2001/83/EC will refer to the Directive as amended ("Directive"). Article 81 of the Regulation and Article 126 of the Directive provide that an authorisation to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in the Regulation and in the Directive. This principle was already foreseen in Article 68 of Regulation (EEC) N°2309/93 of

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- (300) Within the framework of the sector inquiry, data on applications for marketing authorisation procedures was gathered.²²¹ In general, the data collected shows that the number of applications for marketing authorisations increased over the period 2000 – 2007 for a large number of Member States.²²² The reported information also shows that for some Member States, the number of applications submitted by generic companies increased more significantly compared to the number of applications by originator companies.²²³ The information provided by EMEA shows that the number of applications based on the centralised procedure increased over the period 2000 – 2007.²²⁴ Concerning the number of marketing authorisations granted, it follows from the data available that, over the period 2000-2007, the number of authorisations granted increased (trend) over the period in some Member States^{225 226} and decreased in others.²²⁷ The number of authorisations granted by the Commission on the basis of the scientific evaluation of the EMEA also increased. The data collected shows that there is a growing backlog as regards the treatment of applications for marketing authorisations in the national procedures, which concerns the applications of both originator companies and generic companies. This backlog seems to be more important in some Member States which act in general as RMS such as for example Germany and the UK.²²⁸

22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ L 214, 24.8.1993, p. 1) which has been replaced by Regulation N° 726/2004 and in Article 126 of Directive 2001/83/EC before its amendment.

- ²²¹ The conclusions hereafter are based on the data provided by the national MA authorities and EMEA in answer to requests for information from the Commission. However, the data provided does not appear to be complete or reliable in the same way for all Member States or, in some cases, does not allow to draw conclusions.
- ²²² There is an increase (trend) over the period 2000-2007 in Austria, Belgium, Bulgaria, the Czech Republic, Germany, France, Greece, Hungary, Ireland, the Netherlands, Portugal, Romania and Slovenia.
- ²²³ This concerns for example Austria, Belgium, Germany and Portugal.
- ²²⁴ The number of applications reported for 2000 was 36 and 93 for 2007. This includes three applications by generic companies reported for 2006 and eight for 2007. Given the fact that the centralised procedure started to apply in 1995 (as introduced by Regulation (EEC) n°2309/93) and that data exclusivity for centrally authorised products was of ten years under this regulation, generic applications in the centralised procedure started in 2006.
- ²²⁵ For example Austria, the Czech Republic, Denmark, France, Germany, the Netherlands, Portugal and Slovenia.
- ²²⁶ The increase in the number of applications for marketing authorisation as well as in the number of marketing authorisations granted in some Member States does not reflect an increase in the number of novel medicines (new molecular entities) launched over the period 2000-2007. See Figure 5 in Section 1.1.2.4., which shows that the number of such medicines reaching the market has decreased over time.
- ²²⁷ For example Belgium, Bulgaria, Greece, Hungary, Ireland, Latvia and Romania.
- ²²⁸ For further details see Chapter D.2.

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- (301) For the purpose of the present chapter, it has been decided to describe the current regulatory framework. The regulatory framework in force prior to its amendments will be described in detail when relevant.
- (302) It should be highlighted that the EU regulatory framework applicable during the time period covered by the sector inquiry was amended following the adoption of the Review Package in 2004. The new legal framework put in place consists in particular of Regulation (EC) N°726/2004 and Directive 2004/27/EC amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use. In addition to changes relating to the marketing authorisation procedures (widened scope of the centralised procedure; quicker centralised procedure; improved mutual recognition procedure), the new rules amend the procedure for the authorisation of generics and the data exclusivity rules.²²⁹ The rules on data exclusivity have been harmonised throughout the Community as described in detail below. The following provisions were introduced to improve the possibilities for the authorisation of generic medicines:
- clear definition of reference and generic medicinal product;
 - notion of global marketing authorisation for the purposes of data exclusivity (to clarify that only the initial MA, and not subsequent developments of a product trigger data exclusivity);
 - definition of data requirements for biosimilars;
 - possibility to authorise a generic in one Member State using a reference product in another Member State;
 - possibility to authorise a generic even if the reference product is no longer authorised;
 - "Bolar clause"; (for details see below)
 - clarification that the Summary of Product Characteristics (SmPC) of a generic product may be adapted to reflect use patents for the reference product;
 - choice for generics of centrally authorised products to be authorised centrally or nationally.
- (303) In addition, towards the end of the period covered by the sector inquiry, the centralised procedure has become available to generics, as the first products authorised under the centralised procedure (applicable since 1995) have come to the end of their data

²²⁹ The main changes came into force end 2005. For these reasons, the regulatory framework relating to marketing authorisation for generic products is different as of 2005. Certain of the changes codify the case-law of the ECJ, e.g. the case law on global marketing authorisation (see footnote 250). The new rules on data exclusivity will only be effective as of 2013.

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exclusivity period. The number of applications for marketing authorisation through centralised procedure is increasing for generic products.²³⁰

2.2.1. Centralised Procedure – Community Authorisation

- (304) *Legal basis.* Regulation (EC) No 726/2004²³¹ (hereafter "Regulation") lays down a centralised Community procedure for authorisation of medicinal products based on a single application, a single evaluation and a single authorisation.²³²
- (305) *Scope.* Pursuant to the Regulation, the use of the centralised procedure is compulsory²³³ in particular for biotechnology medicinal products²³⁴, orphan medicinal products²³⁵ and medicinal products containing an entirely new active substance for which the therapeutic indication is the treatment of specific diseases²³⁶. On the other hand, the use of the centralised procedure is optional for other medicinal products not appearing in the Annex of the Regulation and containing a new active substance not yet authorised in the Community, medicinal products which constitute a significant therapeutic, scientific or technical innovation or which are in the interest of patients at Community level.²³⁷ Generic applications of centrally authorised medicinal products may be authorised via the centralised procedure or alternatively via the national, mutual or decentralised procedure under certain conditions.²³⁸

²³⁰ For data on the number of applications see footnote 224.

²³¹ Regulation (EC) N° 726/2004 has replaced Regulation (EEC) No 2309/93 (see footnote 220).

²³² The Regulation refers to the Directive in relation to several provisions, for example: definitions, particulars and documents to be included in the applications.

²³³ Article 3(1) of the Regulation refers to the products listed in the Annex to the Regulation, for which the use of the centralised procedure is compulsory.

²³⁴ Products developed by means of one of the following biotechnological processes: recombinant DNA technology; controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells and hybridoma and monoclonal antibody methods.

²³⁵ A medicinal product will be designated as orphan when the criteria of Article 3 of Regulation (EC) No 141/2000 are fulfilled, for example, where it can be established that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the Community at the time of the application and there exists no satisfactory method of diagnosis, prevention or treatment authorised in the Community. Orphan designated medicinal products are included in the mandatory scope of the centralised procedure since the adoption of the Review Package in 2004.

²³⁶ Those diseases are AIDS, cancer, diabetes and neurodegenerative diseases: new active substances for the treatment of such diseases are included in the mandatory scope of the centralised procedure since the adoption of the Review Package in 2004.

²³⁷ Article 3 of the Regulation.

²³⁸ Article 3(3) of the Regulation.

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- (306) *Procedure.* Applications for Community authorisation must be submitted to the EMEA²³⁹. Each application must be made in accordance with a specific format called the EU common technical document (CTD).²⁴⁰ Information that must be included in any application comprises in particular²⁴¹: the name and the qualitative and quantitative particulars of all the constituents of the medicinal product, the manufacturing method, therapeutic indications, contra-indications and side-effects, posology, pharmaceutical form, method and route of administration, expected shelf life, reasons for precautionary and safety measures during storage and administration of the medicinal product and disposal of waste, the risk to the environment, the results of pharmaceutical, pre-clinical tests and clinical trials, a summary of the product characteristics and a mock-up of the packaging together with a package leaflet.²⁴²
- (307) In cases where MA is requested for a generic product of a previously authorised product, it is possible for the applicant to file a so-called "abridged" application in which he is exempted from the requirement to prove safety and efficacy through pre-clinical tests and clinical trials. In this case, the authority relies on the tests and trials for the reference product (submitted by the manufacturer of the original product when seeking MA for its product) but only after the expiry of a period of data exclusivity which protects the data relating to the reference medicinal product. These rules will be described in detail below.
- (308) In cases where MA is requested for a biological medicinal product²⁴³ similar to a reference medicinal product authorised in the Community (generally called "biosimilar"), specific rules apply considering the complexity of the biological products^{244, 245}. For such products, an abridged application is possible ("similar

²³⁹ The European Medicines Agency based in London, previously called European Agency for the Evaluation of Medicinal Products in accordance with Regulation (EEC) N°2309/93.

²⁴⁰ This requirement is applicable since 1 July 2003. It is also applicable for national procedures and is outlined in the Notice to Applicants, Vol B2: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/b/update_200805/ctd_05-2008.pdf.

²⁴¹ Pursuant to Article 6 of the Regulation, particulars and documents which have to be included in the application are set out in Articles 8(3), 10, 10a, 10 b or 11 of and Annex I to the Directive.

²⁴² Applicants have the opportunity to hold "pre-submission meetings" with the EMEA: at least seven months before submission, applicants should notify their intention to submit an application and give an estimate of the month of submission. In practice, the date and time of delivery of the dossier to the EMEA should be arranged in advance in relation to the programme of scheduled meetings of the Committee for Medicinal Products for Human Use (CHMP).

²⁴³ A biological medicinal product is a product whose active substance is made of or derived from a living organism.

²⁴⁴ For such products, it appears that the information required in case of a generic does not usually permit to demonstrate the similar nature of two biological products: see recital 15 of Directive 2004/27/EC.

²⁴⁵ As mentioned above, medicinal products based on biotechnology have to be authorised via the centralised procedure. If a biological product is not manufactured by means of a biotechnological process, it can be authorised via the national route. The same applies to biosimilars.

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biological application")²⁴⁶, but additional data has to be provided (in particular the toxicological and clinical profile of the biosimilar) in order to prove the similar nature in terms of quality, safety and efficacy of the biosimilar and the reference medicinal product. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I of the Directive and the related detailed guidelines.²⁴⁷ Such procedure makes the procedure for MA of biosimilar products more costly than the procedure for generics.

- (309) *Opinion of the CHMP and decision.* Within the EMEA, the Committee for Medicinal Products for Human Use (CHMP) is responsible for drawing up the opinion of the EMEA on whether or not MA can be granted. In order to prepare its opinion, the CHMP will examine whether the product concerned meets the necessary quality, safety and efficacy requirements. The members of the CHMP are national experts appointed by the competent national authorities. Based on the qualifications of those experts and their expression of interest in relation to a specific file, the CHMP will appoint a rapporteur and if appropriate a co-rapporteur. The scientific evaluation of the application will therefore in practice be carried out by those national experts²⁴⁸ who will prepare an assessment report with the administrative support of the EMEA.²⁴⁹ If the opinion is unfavourable, the possibility exists for the applicant to request the EMEA to re-examine the application before a final opinion is issued. All final opinions of the CHMP (positive or negative) are published on the EMEA website.
- (310) The opinion will then be sent to the European Commission, which takes the final decision after consulting the Member States. The decision can deviate from the opinion of the CHMP, but in this case the Commission must state in detail the reasons for the deviation. A decision granting MA contains the summary of the product characteristics along with the labelling and package leaflet.²⁵⁰

²⁴⁶ See Article 10(4) of the Directive. The legislative framework for the evaluation and approval of biosimilar products has been established with Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 159, 27.06.2003, p. 46) and further developed by Directive 2004/27. The data exclusivity rules as exposed below apply to biosimilars.

²⁴⁷ The general principles to be applied are addressed in the Guideline on Similar Biological Medicinal Products of 30 October 2005, CHMP/437/04 which covers biological products containing biotechnology-derived proteins; immunologicals such as vaccines and allergens; blood or plasma derived products and other biological medicinal products.

²⁴⁸ The rapporteur and co-rapporteur are working with a whole team of national experts and rely on national facilities to carry out the scientific evaluation of the file.

²⁴⁹ It is in particular stipulated that the members of the CHMP and experts responsible for the evaluation of applications rely on the scientific evaluation and resources made available by national competent authorities (Article 61(6) of the Regulation).

²⁵⁰ It should be noted that once a first marketing authorisation is granted to a given product, all subsequent development of the product (all variations and extensions thereof, as well as any additional strengths, pharmaceutical forms, administration routes or presentations authorised through separate procedures and under a different name, granted to the holder of the initial marketing authorisation) will be considered as part of the same "global marketing authorisation" for the purpose of applying the rules of data and

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- (311) Under the centralised procedure, applications are made in English²⁵¹. However, after the adoption of the opinion of the CHMP, the applicant must provide the EMEA with translations of the summary of the product characteristics, the conditions of the MA, the labelling and the package leaflet in all EU official languages.²⁵²
- (312) The standard timetable for the scientific evaluation of a centralised application allows 210 days for the adoption of the CHMP opinion²⁵³ starting from the date of receipt of a valid application. This time limit can be suspended if the applicant is required by the CHMP to provide supplementary information. Within 15 days after receipt of the opinion, the Commission shall prepare a draft of the decision. The final decision will be taken within 15 days after the end of the consultation with the Member States. As all Commission decisions, such decisions may be challenged pursuant the rules of the Treaty.
- (313) The basic fee for MA to be paid by the applicant is € 242,600. In addition, the MA holder has to pay an annual fee of € 87,000 covering the costs connected with the supervision of the authorised medicinal product.²⁵⁴ In the case of an abridged application, the basic fee is reduced to € 94,100 and the annual fee to € 21,700.
- (314) *Effects of Community authorisation.* Once MA is granted under the centralised procedure, the medicinal product may be put on the market in all EU Member States. The MA has an initial duration of five years and may be renewed on the basis of a re-evaluation of the risk-benefit balance upon application by the holder at least six months before expiry of the five-year period.²⁵⁵ Any authorisation which is not followed by an actual placing on the market of the authorised product within three years of being granted will cease to be valid. The same applies to an authorised

marketing exclusivity (Article 6(1) of the Directive). This means that the period of data exclusivity will be counted from the date of the initial marketing authorisation and that, once it expires, generics may be authorised for all those developments regardless of the point in time when they were authorised. This rule was introduced in the Directive by Directive 2004/27/EC, codifying the case-law of the ECJ, (Judgement of the Court of Justice of 3 December 1998, in case-368/96, *The Queen v. The Licensing Authority, ex parte Generics (UK) Ltd, The Wellcome Foundation and Glaxo Operations UK Ltd*).

²⁵¹ See Eudralex – Volume 2 - Pharmaceutical Legislation – Notice to applicants, Vol 2A, Chapter 7 General Information, p. 6: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/a/vol2a_chap7_2007-07.pdf

²⁵² Those documents will be annexed to the Commission Decision.

²⁵³ An accelerated assessment may be requested in the case of medicinal products which are of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation.

²⁵⁴ The annual fee has been introduced to cover the costs connected with the supervision of authorised medicinal products and maintenance of the MA: the MA holder has to pay the fee each year starting from the first anniversary of the MA.

²⁵⁵ Pursuant to Article 14 of the Regulation, once renewed, the MA will normally be valid for an unlimited period unless it is decided to proceed, on justified grounds relating to pharmacovigilance, with one additional five-year renewal.

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product previously placed on the market which is absent from the market for a period of three consecutive years.

- (315) It is important to note that, under the current legislation, generic companies can rely on the previously granted MA for the reference product even if MA for the reference product is withdrawn.²⁵⁶ Moreover, under the current legislation, a generic application may be filed in one Member State with reference to an originator product authorised in another Member State.²⁵⁷

Studies and Trials with a View to Obtaining MA

- (316) During the public consultation, it has been submitted that prior to the introduction of the so called Bolar provision (hereafter: Bolar provision)²⁵⁸ in the EU regulatory framework and therefore for most of the period of the sector inquiry, most of national patent laws generally prevented generics from conducting bioequivalence studies or trials within the EU necessary to obtain marketing authorisation. It is argued that it is likely that the large majority of the E75 would fall within this category and that in the case of patent expiry before 31 October 2005²⁵⁹, generics would face the delay of waiting for the end of patent expiry to conduct such tests.
- (317) Prior to the introduction of the Bolar provision in the EU regulatory framework following the adoption of the Review Package in 2004, pre-patent-expiry development was not regulated at EU level: the issue was ruled at national level. It appears that the "research exemption" originally foreseen in the Community Patent Convention as a general exemption from patent infringement for "acts done for experimental purposes relating to the subject-matter of the patented invention"²⁶⁰ was widely adopted in the national patent legislations of EU Member States.²⁶¹ However, legal uncertainty existed whether it covered pre-patent expiry testing in the EU. Indeed, the research exemption was originally meant to allow for academic research and the notion of "experimental purposes relating to the subject matter of the invention" being difficult to interpret, national courts have applied it albeit not always with the same clearly

²⁵⁶ Article 10(1) of the Directive as amended by Directive 2004/27/EC. This was questionable under the old legislation and created the potential for abuse. In this respect see the Commission Decision of 15 June 2005 in Case COMP/A. 37.507/F3 - AstraZeneca, currently under appeal before the Court of First Instance (T-321/05).

²⁵⁷ This provision increasing the opportunities for market access for generic medicines was introduced in the regulatory framework in 2004 and applies since 2005.

²⁵⁸ Article 10 (6) of Directive 2001/83/EC as amended by Directive 2004/27/EC: this provision was to be transposed by Member States by 31 October 2005.

²⁵⁹ Date fixed for the transposition by the Member States.

²⁶⁰ See Chapter B.2.1. above.

²⁶¹ See by way of example Article L 613-5 of the French patent Law or Section 60 (5) (b), UK Patents Act.

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defined scope.²⁶² It should however be mentioned that the national patent laws of Hungary, Slovenia, Portugal and Poland included provisions allowing the tests of generic drugs in connection with an application for marketing authorization: pre-patent-expiry testing and developing necessary to obtain a MA was therefore allowed in those countries during the period covered by the sector inquiry.²⁶³ This situation led generic manufacturers to carry out their product development and related testing in countries where the basic patent had already expired or where such protection did not exist, outside the EU or in European countries where a Bolar-type provision existed or in EU Member States where experimental work was in certain cases permitted and this in order to avoid the delays that they would have faced if they would have waited for the patent expiry in a Member State before starting the testing.^{264 265}

- (318) Since the inclusion of the Bolar provision in the EU regulatory framework, generic producers are permitted to conduct within the EU the necessary studies and trials with a view to obtaining MA for their products:²⁶⁶ indeed, as long as these activities are strictly necessary to prepare for an MA application, they are not deemed to infringe patents rights or SPCs for medicinal products. This provision creates a safe harbour for certain tests and studies while the reference product is still patent-protected in the EU

²⁶² By way of example of the different interpretations, the position of the UK Court of Appeal in the case *Monsanto v Stauffer* case (1985) should be noted as it held that the experimental use provision did not protect trials by generic companies aimed at securing regulatory approval. In Germany, the view adopted was more liberal as the German Supreme Court held in case 68/97, *Klinische Versuche II* (1997) that generation of tests data legitimately required to obtain regulatory marketing approval can qualify for the experimental use exemption provided that such tests also advanced the state of art in some way (in that case, seek further information about the uses of the drug, its side-effects and other consequences of treatment). In Italy, courts of first instance adopted a somewhat contradictory line.

²⁶³ Some argue that it was also the case in Spain but there does not seem to be a consensus on the interpretation of the law prior to the introduction of the Bolar provision in the Spanish law.

²⁶⁴ The information gathered in the framework of the sector inquiry from the generic companies confirms the above. Generic companies claim they were carrying out their product development and related testing with a view to obtaining marketing authorisation in countries where the basic patent had already expired, where it did not exist or where the testing was authorised: i.e. in Canada, India or Australia; in European countries where a Bolar-type provision existed for example Poland, Portugal or Hungary or in EU Member States where experimental work was in certain cases permitted based on the experimental use exemption.

²⁶⁵ In general generic companies confirm that the situation in Europe prior to the Bolar provision did not delay the entry of generics but that it simply moved the trials and development work outside of Europe as in their view the time to enter on the market should ideally be the expiry of the basic patent and SPC for the API in the product. Few generic companies claim that the introduction of the Bolar provision has had an impact on the time to enter of generic products on the EU markets because experimental work could now be done within the EU. Most of the generic companies claim that the introduction of the Bolar provision in the EU regulatory system did not affect the choice of countries where they conduct the necessary trials and studies. Some companies however underline that they consider conducting trials and testing in the EU in the future and that this could have an impact on the generic development. It should be noted that the Bolar provision applies since 2005.

²⁶⁶ Pursuant to Article 10 (6), the necessary studies and trials which are exempted from patent infringement are the one conducted with a view to abridged applications (Article 10(1) and (2)), hybrid applications (Article 10(3)) and biosimilar applications (Article 10(4)).

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so as to enable the generic producer to apply for marketing authorisation once the eight-year period of data exclusivity granted to the holder of the original MA has elapsed.

Data and marketing exclusivity rules

- (319) In general terms, data exclusivity means that MA bodies are not allowed to process an abridged application for marketing a generic drug before a certain number of years after the first marketing authorisation for the originator product has elapsed.²⁶⁷ The provisions described hereafter on data and marketing exclusivity apply to applications filed in the framework of the centralised procedure as well as to applications filed in the framework of national authorisations procedures.
- (320) Rules on data exclusivity have been further harmonised at the EU level in 2004.²⁶⁸ However, the new periods of protection (hereafter: new harmonised rules) do not apply to reference medicinal products for which the initial application for authorisation was submitted before the implementation of the new legislation (20 November 2005 for centrally authorised products and 30 October 2005 for nationally authorised products)²⁶⁹ with the consequence that the new harmonised rules take full effect in 2013 and therefore do not cover the time scope of the sector inquiry. This section will first expose the rules relevant for the sector inquiry and then expose the new harmonised rules.
- (321) *Data exclusivity rules for marketing authorisations for reference medicinal products submitted before 20 November 2005/30 October 2005:* Reference medicinal products for which the initial application was made before the mentioned dates continue to benefit from the period of protection of six or ten years depending on the Member State that granted the marketing authorisation and whether the product has been authorised through centralised procedure or national procedure.²⁷⁰ In practice, for products authorised through national procedures, the periods of protection vary

²⁶⁷ The rules on data exclusivity do not prevent another producer to file an application for MA before the end of the data exclusivity period for a product with the same qualitative and quantitative composition and pharmaceutical form. In such a case he is not authorised to use the abridged procedure for generic products and has to provide the results of the pre-clinical tests and clinical trials. However, the original MA holder may benefit from a de facto protection if other stakeholders consider it uneconomical to repeat the extensive trials and tests which would be needed for obtaining MA for the competing product.

²⁶⁸ Directive 2004/27/EC amending Directive 2001/83/EC, and Regulation 726/2004 have introduced new rules concerning the data and marketing exclusivity periods and harmonised those rules across the EU.

²⁶⁹ Pursuant to Article 89 of the Regulation, which concerns products authorised through the centralised procedure, the new periods of protection do not apply to those reference medicinal products for which the initial application based on the Regulation was submitted before 20 November 2005. As regards nationally authorised products, Article 2 of Directive 2004/27/EC states that the new period of protection does not apply to those reference medicinal products for which an application for authorisation was submitted before the date of transposition referred to in Article 3 of the same text i.e. 30 October 2005.

²⁷⁰ For further details see Article 10, 1, (a) (iii) of Directive 2001/83/EC.

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between countries.²⁷¹ Medicinal products which have been authorised through the centralised procedure benefit from a ten-year period of protection.²⁷²

- (322) Based on the above, where MA is requested for a generic product of an original medicinal product which has been authorized for six or ten years, the generic applicant is not required to provide the results of the pre-clinical toxicological and pharmacological tests and clinical trials: he can file for a so called abridged application. All he has to do is to demonstrate that his product is essentially similar (a generic product)²⁷³ to the original medicinal product, and then he can simply refer to the results of toxicological and pharmacological tests or the results of clinical trials for the reference medicinal product. In such a case, the generic applicant will however have to wait the expiry of the regulatory protection period before he can file for MA.²⁷⁴
- (323) It is important to note that the provisions on data exclusivity apply in parallel with provisions on patents/SPCs described in the previous section. Accordingly, pharmaceutical products can be protected against generic competition in two ways: through patents/SPCs or through data exclusivity; and the "loss of exclusivity" (sometimes also referred to as "LoE") occurs, when both forms of protection expire.²⁷⁵ It should be mentioned that in the majority of cases, the data exclusivity period term expires before relevant patents and SPCs: data exclusivity period extends beyond the term of relevant patents and SPCs only in the case of unusually lengthy development times.²⁷⁶

²⁷¹ Ten years for national authorisations granted by: Belgium, Germany, France, Italy, the Netherlands, Sweden, the UK and Luxemburg and six years for national authorisations granted by: Austria, Denmark, Finland, Ireland, Portugal, Spain, Greece, Poland, the Czech Republic, Hungary, Lithuania, Latvia, Slovenia, Slovakia, Malta, Estonia, Cyprus, and also Norway, Liechtenstein and Iceland.

²⁷² For further details see Article 13(4) of Regulation (EEC) No 2309/93.

²⁷³ The concept of "essentially similar" was discussed at length in the case law. In case C-368/96 (op. cit.), the ECJ concluded that "a medicinal product is essentially similar to an original medicinal product where it satisfies the criteria of having the same quantitative and qualitative composition in terms of active principles, of having the same pharmaceutical form and of being bioequivalent, unless it is apparent in the light of scientific knowledge that it differs significantly from the original product as regards safety or efficacy". This definition established by the ECJ was introduced in the Directive by Directive 2004/27/EC (Article 10(2)(b) of the Directive).

²⁷⁴ The period of data exclusivity will effectively be shorter than six or ten years in case of developments of a product after its original authorisation. Indeed, it has been made clear that a generic manufacturer can use an abridged application, based upon the original full application, for all therapeutic indications and all pharmaceutical forms, strengths of dose and dosage scheduled authorized for the original product, even if some of those indications, pharmaceutical forms, strengths of dose and dosage schedules have been authorized for a period less than six or ten years (see for example Case C-368/96, op. cit.). This case-law is now reflected in Article 6(1) of the Directive as amended (global marketing authorisation).

²⁷⁵ According to the submission of EFPIA received in the framework of the Sector Inquiry (See Annex 9 to EFPIA's submission of 17 June 2008, Intellectual Property and Pharmaceuticals, p. 34), the application for a marketing authorisation by a generic company is not an act of patent infringement.

²⁷⁶ This is confirmed by the data gathered in the framework of the sector inquiry: see Section B.1.3.1.2. See also EFPIA, Intellectual Property and Pharmaceuticals, op. cit., p. 21.

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- (324) The following table shows by way of example how the LoE works in practice in cases where the data exclusivity period in the Member States concerned was ten years.²⁷⁷

Box: Loss of exclusivity in practice

Patent application = 1985	Patent expiry = 2005 (20 years later)
- If first marketing authorisation in EU = 1990	
=> 15 years patent protection, no SPC protection. Total protection = 15 years. Protection ends with patent expiry in 2005.	
=> 10 years data exclusivity ending in 2000	
LoE in 2005 with patent expiry	
- If first marketing authorisation in EU = 1998	
=> 7 years patent protection + 5 years SPC protection. Total protection = 12 years. Protection ends in 2010.	
=> 10 years data exclusivity ending in 2008.	
LoE in 2010 with SPC expiry	
- If first marketing authorisation in EU = 2001	
=> 4 years patent protection + 5 years SPC protection. Total protection = 9 years. Protection ends in 2010.	
=> 10 years data exclusivity ending in 2011	
LoE in 2011 with end of data exclusivity	

- (325) *Data and marketing exclusivity rules for marketing authorisation applications submitted after 20 November 2005/30 October 2005:* The six or ten years of protection under the previous rules are replaced by a period of ten years broken down into the so called 8+2 formula. As explained above, the new harmonised rules do not cover the time scope of the sector inquiry. As they apply to marketing authorisation applications for original products submitted after 20 November 2005/30 October 2005, the eight-

²⁷⁷ In cases where LoE occurs with data exclusivity expiry the holder of the marketing authorisation will benefit from a protection period which is de facto longer than the regulatory protection period as the generic applicant will have to be granted MA before he can market his product.

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year protection period for such applications will expire at the earliest in 2013. For a generic product of a reference medicinal product for which the initial application was made after the mentioned dates, an abridged application²⁷⁸ is possible after eight years from the initial marketing authorisation (data exclusivity period).²⁷⁹

- (326) However, and this is new in comparison with the previous rules, the new harmonised rules also provide that the original MA holder benefits from a ten-year period of marketing exclusivity for the reference medicinal product.²⁸⁰ This means that a generic product authorised on the basis of an abridged application cannot be placed on the market until ten years have elapsed from the date of the MA for the reference product. When the ten-year period of marketing exclusivity has elapsed, the generic product can be launched on the market, provided that no new therapeutic indication with a significant clinical benefit has been approved for the reference product during the first eight years following the MA. If there is such an approval, the reference product obtains a non-cumulative period of one year of additional marketing exclusivity. This system is commonly referred to as 8 + 2 (+ 1) Formula.
- (327) The new harmonised rules therefore extend the period of data protection as regards reference medicinal products in those member States where the period of protection under the previous rules was of six years. At the same time, it reduces it for reference medicinal products authorised through the centralised procedure and, at national level, in those Member States where the period of protection under the previous rules was of ten years, whilst maintaining the marketing exclusivity period of ten years. These rules also harmonise the period of protection for reference medicinal products across the Community.
- (328) The other key novelty of the new data exclusivity rules relate to the possibility that certain therapeutic new indications trigger extensions of the periods of protection. This applies to the originator product under the 8+2(+1) formula as described above (ten year-year period of marketing exclusivity extended with one year in the case of new indication with a significant clinical benefit for the indication).^{281 282}
- (329) The following graph summarises the new harmonised provisions on data and marketing exclusivity:

²⁷⁸ Directive 2004/27/EC provides a definition of "generic" product and "reference medicinal product".

²⁷⁹ For further details see Article 10 of the Directive and Article 14(11) of the Regulation.

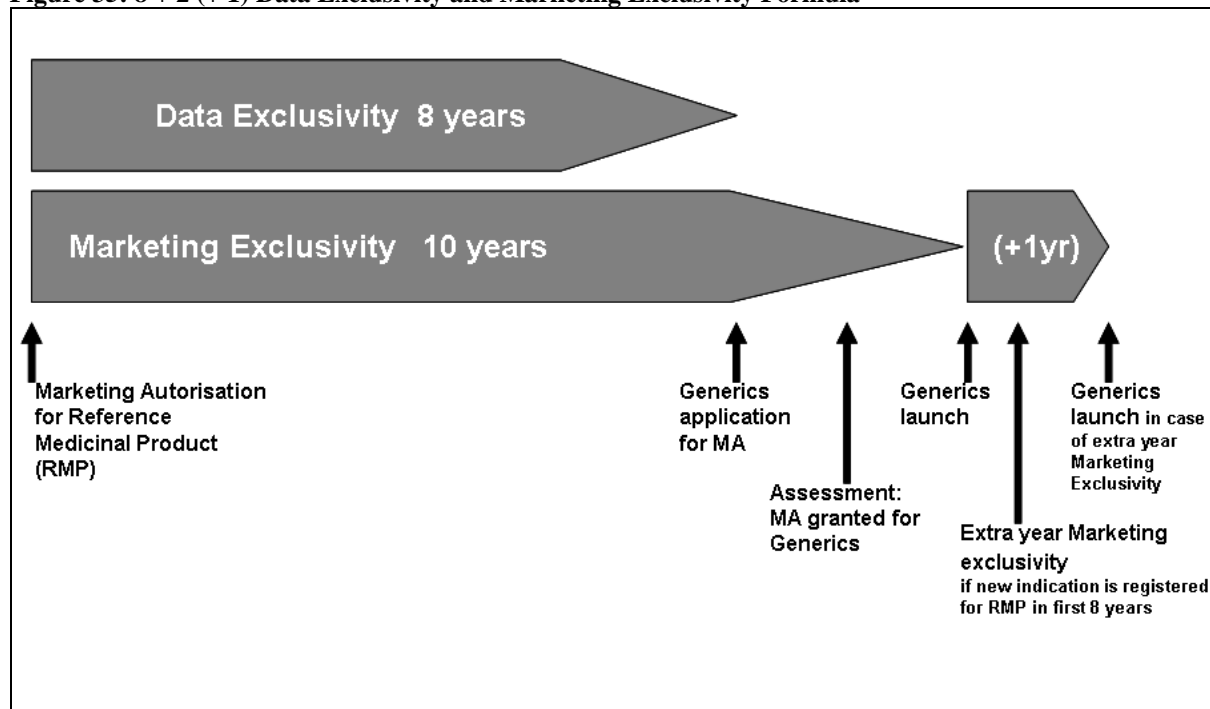
²⁸⁰ Marketing exclusivity is foreseen in Article 10 of the Directive and in Article 14(11) of the Regulation.

²⁸¹ Article 10(1) of the Directive.

²⁸² It should also be mentioned that a non cumulative period of one year of data protection is available to manufacturers when an application is made for a new indication for a well established substance provided that significant pre-clinical or clinical studies were carried out in relation to the new indication (Article 10(5) of the Directive).

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Figure 35: 8 + 2 (+ 1) Data Exclusivity and Marketing Exclusivity Formula



Source: Pharmaceutical Sector Inquiry

2.2.2. National Authorisation Procedure at Member State Level – Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP)

- (330) Existing national procedures in the Member States have been harmonised by Directive 2001/83 (the "Directive").^{283 284} The substantive test carried out for the granting of MA on the basis of the centralised procedure and on the basis of the national procedure is identical: each MA decision is taken on the basis of scientific criteria concerning the quality, safety and efficacy of the medicinal product concerned. The arrangements described above in relation to the centralised procedure such as the so-called abridged procedure, data and marketing exclusivity, duration of authorisation and possible renewal and withdrawal, are also provided for in the Directive. In addition, the Directive contains the provisions covering the MRP and the DCP²⁸⁵.
- (331) With the exception of medicinal products subject to the centralised procedure, the MRP and DCP procedures must be used in relation to applications for MA for

²⁸³ Article 17 provides in particular that Member States will take the appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of 210 days after the submission of a valid application.

²⁸⁴ The Court of Justice has ruled that Directive 2001/83 lays down a complete harmonisation in the field of authorisation procedures for medicinal products (see Judgement of the Court of 20 September 2007 in case C-84/06, Staat der Nederlanden/Antroposona and others, para. 41).

²⁸⁵ The DCP has been introduced by Directive 2004/27/EC.

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medicinal products in more than one Member State. In such cases, the applicant must submit an application to the competent authorities of each of the Member States where MA is sought. The application is based on an identical dossier containing the same information and particulars as for the centralised procedure²⁸⁶ and a list of the Member States concerned by the application.

- (332) *Mutual recognition procedure.* Where a medicinal product has already received MA at the time of the application in a given Member State (hereinafter the Reference Member State or RMS), the other Member States concerned will recognise the MA granted by the RMS by approving the assessment report, the summary of the product characteristics, the labelling and package leaflet and grant MA with a harmonised summary of the product characteristics, package leaflet and labelling.²⁸⁷
- (333) If a Member State cannot approve the assessment report, the summary of the product characteristics, the labelling and the package leaflet on the grounds of potential serious risk to public health, the points of disagreement are referred to the coordination group. If, within the coordination group, the Member States fail to reach agreement on the action to be taken, the Commission takes, following the opinion of the CHMP, the decision addressed to all Member States and reported for information to marketing authorisation holder or applicant.
- (334) *Decentralised procedure.* In cases where a medicinal product has not been granted MA at the time of the application, the RMS will prepare the draft assessment report on the medicinal product which will be sent to the Member States concerned and to the applicant together with the draft summary of the product characteristics, and the draft of the labelling and package leaflet. The RMS will act as central point for the Member States concerned and the applicant. The other Member States concerned will approve the assessment report, the summary of the product characteristics, the labelling and package leaflet and grant MA in accordance with the approved assessment report, the summary of the product characteristics, package leaflet and labelling as approved. If a Member State cannot approve the assessment report, the summary of the product characteristics, the labelling and the package leaflet on the grounds of potential serious risk to public health, the points of disagreement are referred to the coordination group. The procedure for resolving dissents is the same as for the MRP.²⁸⁸
- (335) National marketing authorisation decisions are challengeable pursuant to the provisions of the national law in force.²⁸⁹

²⁸⁶ Information and particulars referred to in Articles 8, 10, 10a, 10b and 10c of the Directive.

²⁸⁷ The procedure is described in Article 28 of the Directive.

²⁸⁸ The procedure is described in title 29 of the Directive.

²⁸⁹ Article 125 of the Directive.

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2.2.3. Patent Linkage

(336) Patent linkage refers to the practice of linking the granting of MA, the pricing and reimbursement status or any regulatory approval for a generic medicinal product, to the status of a patent (application) for the originator reference product. Under EU law, it is not allowed to link marketing authorisation to the patent status of the originator reference product. Article 81 of the Regulation and Article 126 of the Directive provide that authorisation to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in the Regulation²⁹⁰ and the Directive. Since the status of a patent (application) is not included in the grounds set out in the Regulation and in the Directive, it cannot be used as an argument for refusing, suspending or revoking MA.²⁹¹ During the public consultation, it has been submitted that the patent status can have a bearing on MA or should be considered by authorities dealing with MA: In this respect, reference is made to Article 10(1) of Directive 2001/83/EC and to Article 3 (3) (b) of Regulation 726/2004. It should be recalled however that in accordance to Article 81 of the Regulation and Article 126 of the Directive, MA bodies should disregard the patent situation of the originator reference product while dealing with the application for MA for generic medicinal products. As stated above, the authorisation to market a medicinal product is taken on the basis of scientific criteria concerning the quality, safety and efficacy of the medicinal product concerned: these criteria are related to public health considerations and no other criteria should be taken into account.²⁹² All other issues relating to private law such as for example, the patent status of the medicinal product is to be dealt with on the basis of patent laws before the competent courts: such courts will have to determine whether or not there is a patent infringement.

²⁹⁰ See also Article 68 of Regulation (EEC) 2309/93 which has been replaced by Article 81 of the Regulation.

²⁹¹ See however the findings set out in Chapter C.2.5. of this report.

²⁹² For more details on patent linkage cases see Section C.2.5.1.1. in particular Table 24.

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Summary

In order to maintain public health standards, marketing authorisation procedures verify that medicines are safe, effective and of good quality. Detailed results of (pre-) clinical tests and clinical trials must be submitted for a new medicine. Generic medicines also require marketing authorisations, but applications need not resubmit detailed tests and trials results, if it is shown that the generic product is bio-equivalent to a medicine previously authorised. However abridged applications of this kind are only permitted once the originator company's data relating to the pre-clinical tests and clinical trials is no longer protected.

Marketing authorisation procedures are regulated by EU law. There is a centralised application procedure leading to authorisation for the entire EU or national procedures which result in national authorisations that can benefit from mutual recognition in other Member States. The scope of the centralised procedures has been extended over the years. Since 2005 it also applies to generic products.

Marketing authorisations are issued on the basis of scientific criteria concerning the quality, safety and efficacy of the medicinal product concerned. While dealing with such applications, the marketing authorisation bodies should disregard all other criteria such as the patent status of the reference medicinal product.

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2.3. Pricing and Reimbursement

- (337) Prices and reimbursement levels for medicines are a national competence dealt with by each EU Member State on a national or regional level. As a consequence, pricing and reimbursement decisions are subject to a complex *acquis* of national legislations and regulations and the national policies vary significantly within the EU.
- (338) Nevertheless, EU Member States share three common objectives: (1) they want to ensure that their patients in need have access to the necessary medicines; (2) they want to ensure that health budgets remain under control to ensure sustainability of the health system (short and long term); and (3) they want to create/maintain incentives for further innovation. Each Member State decides which weight it gives to each of these objectives. The national balancing exercise will depend on factors such as available resources or health needs of the population. It might also depend on political priorities, such as the structure of the pharmaceutical industry in the Member State (significant R&D activities, strong generic industry).
- (339) In spite of the national competence, all Member States must ensure that any national measure to control the prices of medicinal products or to restrict the range of medicinal products covered by their national health insurance systems complies with the requirements of Directive 89/105/EEC²⁹³ (the "Transparency Directive") and the EC Treaty. This legal framework requires in particular that pricing and reimbursement decisions are taken in a transparent manner, i.e. within clear timelines, on the basis of objective and verifiable criteria, with a statement of reasons and with a public communication and with an opportunity to appeal.
- (340) Although taken at national level, it needs to be noted from the outset that the pricing and reimbursement decisions of an individual Member State also influence those of other EU Member States, in particular through practices such as cross-border price comparisons (cross-border reference pricing) or trade between Member States.
- (341) For the purpose of this report, it was considered appropriate to focus on pricing and reimbursement of medicines that are supplied through retail pharmacies, i.e. outside of hospitals. The usual price-setting mechanisms for medicines sold to hospitals differ significantly from those applied in the retail segment. Hospital pharmacies most often negotiate prices directly with manufacturers, often through tendering procedures or within the context of risk-sharing agreements²⁹⁴.

²⁹³ Directive 89/105/EEC of the Council of 21 December 1989 relating to the transparency of measures regulating the process of medicinal products for human use and their inclusion in the scope of national insurance systems (OJ L 40, 11.2.1989, pp. 8-11).

²⁹⁴ Risk-sharing practices allow hospitals to use highly innovative and very expensive medicines without fully proven value. Hospital funding of these medicines will depend on the clinical outcome.

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2.3.1. Factors Considered when Setting Prices for Medicines

- (342) In general, national pricing policies consider three key factors:
- (a) The price level ex-factory, which determines the main cost factor for the medicine. To arrive at the retail price level, the margins for the wholesalers and pharmacists as well as the VAT are added.
 - (b) The reimbursement level, expressed as a percentage of the retail price. This will determine how much of the retail price is paid by public funds. The remaining part, also referred to as co-payment, is paid by the patient or his private supplementary insurance. The reimbursement level can often be decisive for the question whether a medicine is accessible to the patient (group) concerned.²⁹⁵
 - (c) (Potential) restrictions on stakeholders such as doctors or pharmacists, which will determine how often and under what conditions a medicine can be prescribed, dispensed and used.
- (343) These three issues are often considered jointly when a decision on the price level for a medicine is taken. They allow the authorities to control the overall budget per medicine, which is mathematically defined as: (a) price per medicine at retail level × (b) reimbursement level in % × (c) volume of medicines used. In some cases, authorities and companies agree immediately on an overall budget, instead of the three separate factors.
- (344) Member States adopt a long list of practices that affect pricing decisions. There are practices focusing on (a) prices and/or (b) reimbursement levels, which are generally referred to as "supply side practices". And there are practices focusing on (c) use of the medicine called "demand side practices". Some policies combine supply- and demand-side practices. The most important practices are summarised below.
- (345) It is however important to note here that the pricing landscape is dynamic. Member States continuously evaluate the outcomes of their decisions and take action where necessary. For a good snapshot of the 2006 landscape, reference is made to study "Analysis of differences and commonalities in pricing and reimbursement systems in Europe" developed on the sidelines of the Working Group Pricing of the Pharmaceutical Forum by the Andalusian School of Public Health (see also Table 14 and Table 15). In addition the Austrian Federal Institute for Health (Österreichisches Bundesinstitut für Gesundheitswesen, ÖBIG) prepared a study for DG Competition in 2006 entitled: "Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States".

²⁹⁵ Authorities therefore often foresee higher reimbursement, or lower co-payment, to chronically ill or socially disfavoured patients. The higher the co-payment, the lower the expected demand, as patients will choose for products with a limited co-payment whenever possible.

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2.3.2. Supply-Side Practices

Initial Pricing and Reimbursement Decisions

- (346) Most Member States apply a direct control on the initial price of reimbursed medicines. Only Denmark, Germany, Malta, Sweden and the UK were reported to allow companies to freely set their initial price levels (state of play: 2006). Nevertheless, in several of these so-called free-price countries, medicines will only be reimbursed up to a certain amount or on condition that the price is considered acceptable. In practice, this strongly influences the price a company chooses to offer. Hence reimbursement conditions often create an indirect price control.
- (347) In order to determine the price and reimbursement level of a new medicine, an increasing number of Member States try to understand the clinical performance and/or the economic impact of a medicine. They therefore perform specific assessments (commonly referred to as health technology assessments) and compare the requested price to the added value that the medicine brings.
- (348) Many Member States also compare the requested price to the prices of the same medicine in a selection of other countries. This is called cross-border referencing and works with a so-called basket of reference countries.²⁹⁶ As a consequence, prices set in one country can create a point of reference for subsequent price negotiations elsewhere in the EU. Producers of pharmaceutical products take this into account when they apply for pricing, as an originator company observed:

"[...] most manufacturers put in place launch strategies to minimise the negative impact of reference pricing systems on the average selling price of their products across Europe."

- (349) One commonly used strategy is to grant hidden discounts on the official price list, which do not influence the reference price used in other Member States, as the following quote confirms:²⁹⁷

"... only the Official Published List Price is referenced to other countries. The respective Ministry of Health in the various EU countries only takes this Official Published List Price for reference pricing. Further discounts such as free goods or any kind of rebates are given at the discretion of the respective companies and are not visible and not monitored by the MOH's [Ministries of Health]."

- (350) Many originator companies confirmed during the sector inquiry that pharmaceutical companies aim at marketing their products as soon as possible. However, it can be observed that products are often marketed first in the larger EU Member States. Many originator companies reported that traditionally the UK and Germany are amongst the

²⁹⁶ This basket is different for each country, and is often defined in the national legislation.

²⁹⁷ Discounts can be given at initio or at a subsequent stage (see also section below).

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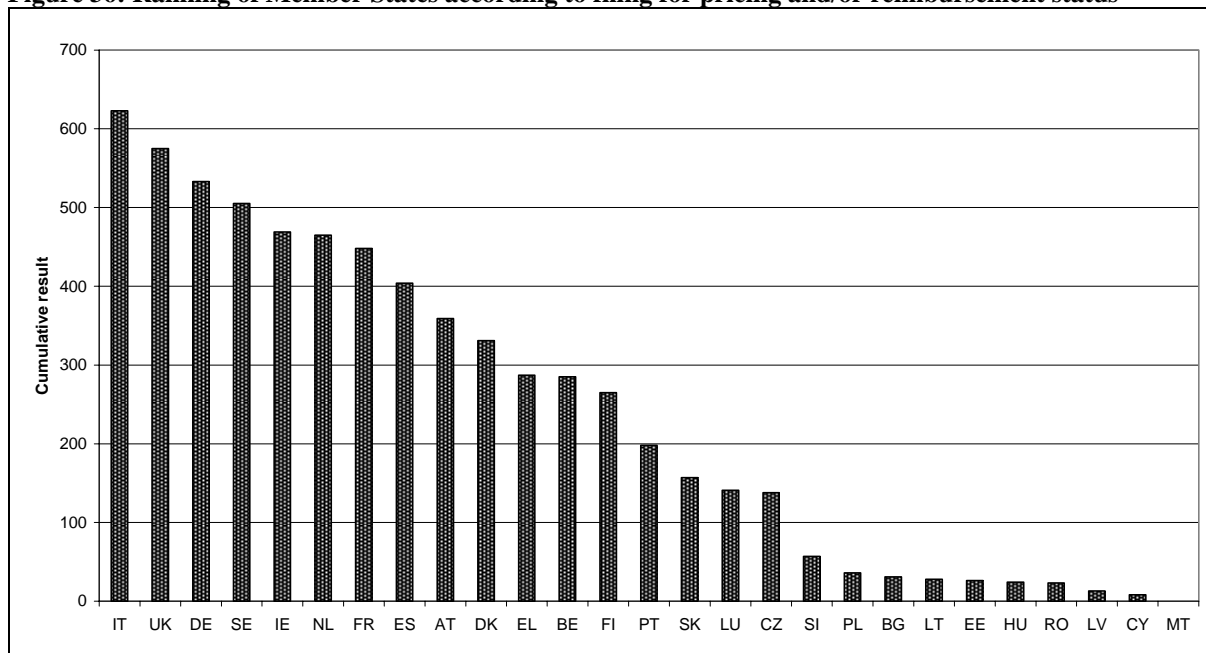
early launch countries as they allow companies to freely set prices without prior price approval. In particular in Germany, this usually results in a relatively high price, and hence a relatively high point of reference for cross-border referencing.

- (351) In addition, originator companies reported that in France, Italy, the Netherlands and Sweden, they may submit a pricing and reimbursement dossier before the marketing authorisation is officially granted. In these countries, the only condition is a positive CHMP (Committee for Human Medicinal Products at the EMEA)²⁹⁸ opinion. In most other Member States, a submission for pricing and/or reimbursement can only be made after the marketing authorisation has been granted.
- (352) The importance of reference pricing for the considerations of originator companies where to launch first a product as explained above is confirmed by the data that was gathered during the sector inquiry. Figure 36 provides an overview of the EU Member States ranked according to their popularity amongst companies to apply early for a pricing and/or reimbursement status. As can be seen, some of the free-price countries (United Kingdom, Germany, Sweden) and/or the countries with so-called positive CHMP opinion (Italy and Sweden) form the top four countries to start a pricing and/or reimbursement application when taking into account the reference pricing system that many other Member States apply.

²⁹⁸ For further details on CHMP, please refer to Chapter B.2.2.

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Figure 36: Ranking of Member States according to filing for pricing and/or reimbursement status



Source: Pharmaceutical Sector Inquiry

Note: The ranking above is based on respondent companies' replies to the question which requested them to provide information on the first five most recently launched INNs and to order chronologically the first ten EU27 Member States in which they approached the pricing/reimbursement body. In constructing the ranking, a Member State to which the pricing/reimbursement body a company had turned to first received 10 points, second 9 points, third 8 points, and so forth.

- (353) Figure 36 also shows that countries with small markets (Cyprus, Malta) and countries with less per capita purchasing power (Poland, Bulgaria, Lithuania, Latvia, Estonia, Hungary, Romania) are generally not taken as reference countries. Originator companies are reluctant to make first price applications in these last countries as a generally lower price level might lead to low prices elsewhere via cross-border referencing.
- (354) Another comparison, which is often used by Member States (in particular for reimbursement levels), weighs the requested price for a new medicine against the price for medicines that have similar therapeutic effects and are already available (so-called therapeutic reference pricing: all medicines with a comparable therapeutic effect get the same reimbursement).
- (355) Member States have stopped comparing the requested price with the cost of developing and producing the medicine (so-called cost-plus pricing). The necessary information to do so is very difficult to obtain and in the end this practice would reward inefficient developments at high cost.
- (356) For generic medicines, two types of regimes exist for initial pricing and reimbursement; either there are no controls, then competition created by the growing number of generics is supposed to bring down prices; or the prices and reimbursement levels of the generics are set by legislation at a (minimum) level of X% below the price of the originator product (price-linkage).

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- (357) It needs to be noted that the price agreed between manufacturers and authorities will also influence prices for other actors in the supply chain in cases where the margins that wholesalers and pharmacists earn for distributing or retailing the medicine are defined as a fraction/percentage of the price agreed upon with the manufacturer.²⁹⁹

Additional Pricing and Reimbursement Measures

- (358) The initial price and reimbursement decisions are often subject to subsequent measures. For example it is common practice to negotiate discounts and/or rebates between the companies and the authorities or other funding parties (e.g. mutual insurance schemes). Such discounts and rebates can bring the real price significantly under the official price. As these agreements tend to be confidential, the general public or authorities in other Member States are not informed about the magnitude of these discounts and/or rebates.
- (359) The Commission services also have observed that when generic companies enter the market at a lower price than the originator product, the originator company sometimes offers free goods on top of a certain order, as the following quote reveals:

"Free goods will be used to match the generic price or to maintain current co-payment levels in the respective markets. The maximum free goods deal will be 10 + 6 resulting in a net selling price of [product X] capsules of [X euro]."

- (360) It should be noted that the originator company that is quoted above granted a 40% discount by giving 6 boxes for free for each ten boxes of medicines that were bought.
- (361) Although they are strictly speaking not part of the pricing/reimbursement decisions, payback and/or price-volume agreements can significantly reduce the overall spending and thus the ultimate price per medicine. In payback agreements companies agree to refund (part of) the revenue earned above a pre-agreed budget. In price-volume agreements, companies agree to charge lower prices once certain pre-agreed volume

²⁹⁹ Price competition at the wholesale level takes place in many Member States: wholesalers need to offer discounts to pharmacists to retain their customers. Price competition at the retail level seems more limited even in situations where only maximum prices are set.

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thresholds are exceeded.³⁰⁰ Finally, there are profit-control³⁰¹ agreements in some Member States. In such agreements companies refund (part of) the profit earned above a pre-agreed limit. Competent authorities of Member States are usually not informed or aware about all these additional pricing and reimbursement interventions in other Member States. This significantly complicates and reduces the value of cross-border reference pricing.

(362) An overview of supply side practices is given in the table below.

³⁰⁰ For example, in 2006 payback was reported in Belgium, France, Hungary, Italy, Portugal, Romania and the United Kingdom. Price-volume agreements were reported in 2006 in Estonia, France, Hungary, Latvia, Portugal, Sweden and Slovakia.

³⁰¹ For example, in 2006 profit control was reported in Portugal, Romania and the United Kingdom.

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Table 14: Overview of supply-side practices in EU Member States in 2006

	Free pricing	Assessment of Clinical performance	Economic evaluation	Compare to cost of existing treatments	Cross-border price comparisons	Cost plus calculations	Discounts/ rebates	Price freezes/cuts	Payback	Price-Volume agreements	Profit control
AT		V	V	V	V		V				
BE		V	V	V	V			V	V		
CY					V						
DE	V						V				
DK	V										
EE			V	V	V					V	
EL					V	V	V	V			
ES		V		V	V	V	V	V			
FI		V	V	V	V			V			
FR		V		V	V		V	V	V	V	
HU				V	V		V		V	V	
IE		V	V	V	V		V	V			
IT		V	V	V			V	V	V		V
LT					V						
LV		V	V	V						V	
MT	V										
NL					V			V			
PL		V			V						
PT		V	V	V	V			V	V	V	
RO					V		V		V		V
SE	V		V							V	
SK		V	V		V					V	V
SI			V		V						
UK	V							V	V		V
	Initial pricing and reimbursement						Additional pricing and reimbursement measures				

Source: 2006 Survey, with EU Member States representatives in the Pharmaceutical Forum, Andalusian School of Public Health

Note: Regarding Sweden, pricing is free for prescription medicines but only the medicine is not included in the reimbursement system. However, almost all prescription medicines are included in the reimbursement system. Note that currently a clinical assessment and the comparison of costs of existing treatment are necessary in an economic evaluation. Price-volume agreements do not exist for out-patient medicines

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2.3.3. Demand-Side Practices

- (363) Three actors decide on the demand for and utilisation of a medicine: the doctor who prescribes it, the pharmacist who dispenses it and the patient who needs it. To steer the decisions of these three actors, authorities often apply a set of demand-side practices.

Practices Targeted at Prescribing Doctors

- (364) Almost all Member States develop guidelines and inform doctors on efficient prescribing practices. Some Member States go further and make some prescribing behaviour mandatory, e.g. to prescribe an active substance (INN) rather than a brand, once generic versions are available. This will allow the pharmacist to choose the cheapest version/brand available with this active substance (unless there is a medical necessity for a specific product).
- (365) In some countries individual prescribing behaviour is monitored and rewarded, e.g. doctors are asked to respect a budget or a prescribe quota or target percentage of cheaper medicines and can get a financial bonus if they respect this budget, quota or target. Steering the prescribing behaviour of a doctor is considered to be particularly relevant when the doctor has the choice between medicines of competing originator companies.
- (366) For some more expensive products, authorities will establish strict criteria and conditions of use. As a consequence, doctors might have to organise additional diagnostic testing and/or administration, before being allowed to prescribe these expensive products.

Practices Targeted at Dispensing Pharmacists

- (367) Pharmacists can have a significant impact on the cost of treating certain diseases when they are entitled to substitute a medicine with a cheaper (i.e. often a generic) version. Some Member States explicitly lay down this right for pharmacies in their legislation. In this case, pharmacists will make substitutions if they are incentivised to do so either by being able to make bigger margins or because of their regulated tariff structures. Others go further and make it mandatory for pharmacies to substitute. In such cases the pharmacies must dispense the cheapest version of the active substance available.
- (368) To fully promote cost-awareness, Member States often align the financial incentives for pharmacies so that it becomes attractive to dispense a cheaper generic version. At the very least dispensing a cheaper version should not bring financial disadvantages (which would be the case if a pharmacist is exclusively paid by receiving a fixed percentage of the retail price). A few Member States count on market dynamics and make pharmacists negotiate for lower prices with their suppliers, by claiming back part of the expected savings (so-called claw-back). Steering the dispensing behaviour of pharmacists is considered to be particularly relevant when there is a choice between different generic versions available.

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Practices Targeted at Patients

- (369) As long as public budgets cover the full costs of medicines, patients will not be cost-sensitive. Most Member States therefore ask patients to bear part of the costs of medicines, through co-payment or other forms of cost sharing.³⁰² In certain Member States therapeutic reference pricing is introduced, which allows patients to obtain one product free of co-payment. If the patient nevertheless opts for another more expensive medicine, he/she will have to pay the difference. Many Member States have organised information campaigns for patients in order to educate and potentially steer their use of pharmaceuticals, e.g. to use less antibiotics and/or more generics.

2.3.4. Policies Combining Supply- and Demand-Side Practices

- (370) To control costs effectively, pricing policies need to include supply-side as well as demand-side practices. Supply-side practices should ensure that medicines are available at relatively low prices. Demand-side practices should then ensure that the lower-priced medicines are used most frequently. Without a combination of these practices, it can often be observed that utilisation/demand shifts away from the cheapest medicine supplied towards more expensive alternatives, which in the end will not allow expenditure to be controlled.
- (371) The combination of demand- and supply-side practices is a concept often found in generic policies, e.g. through a reference price practice. By limiting and equalizing reimbursement for similar medicines, this practice combines on the supply side an incentive for companies to lower their prices, with on the demand side a financial incentive for patients to choose the cheapest alternative. Stimulating parallel imports is another example, where pharmacists are financially incentivised and sometimes even legally obliged to dispense medicines that are obtained at reduced prices.
- (372) An overview of demand-side practices is given in the table below.

³⁰² Cyprus, France, Malta and Slovenia were reported as only exceptions in 2006.

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Table 15: Overview of demand-side practices in EU Member States in 2006

	Prescription guidelines	Education and information	Monitoring of prescriptions	Prescription quotas	Pharmaceutical budgets	Financial incentives	(Generic) substitution	Financial incentives	Claw-back	Information / education	Cost-sharing
AT	V	V	V			V			V	V	V
BE	V	V	V	V		V			V	V	V
CY							V				
DE	V	V	V	V		V	V			V	V
DK	V	V	V				V			V	V
EE	V	V								V	V
EL			V								V
ES	V	V	V	V	V	V	V			V	V
FI	V	V	V				V			V	V
FR	V	V	V				V	V		V	
HU	V		V				V				V
IE		V	V					V		V	V
IT	V	V	V				V	V	V	V	V
LT	V										V
LV	V		V	V	V		V				V
MT	V						V				
NL	V	V	V			V	V	V	V	V	V
PL		V					V		V	V	V
PT	V	V	V				V			V	V
RO		V	V		V		V			V	V
SE	V	V	V		V	V	V			V	V
SK	V	V	V				V			V	V
SI	V	V	V				V				
UK	V	V	V		V	V		V	V	V	V
	Prescribing doctors						Dispensing pharmacists			Patients	

Source: 2006 Survey, with EU Member States representatives in the Pharmaceutical Forum, Andalusian School of Public Health

2.3.5. Recent Efforts by Health Insurers to Bring Down Prices for Patients

- (373) Two new practices by Dutch and German health insurers were reported to have been successful in bringing down prices of off-patent products for patients, but also led to significant controversies. They are examples of how the paying instances (the public and private health insurers who have to reimburse, often completely, the generic medicines bought by patients) can stimulate price competition between suppliers in highly regulated markets, where patients themselves are often not price-sensitive. The experience in those two countries could contribute to a better understanding of the optimal design features of tendering systems in such regulated markets (see Chapter D.3. for the policy conclusions on tendering systems).³⁰³ The section also describes the use of rebate contracts by German health insurers for products that are still patent protected.

The Preference Policy of Dutch Health Insurers

- (374) Dutch law allows health insurers, which have been privatised, to limit patients' reimbursement of medicines that use the same active ingredient to a single supplier. This has led health insurers to conduct a so-called "preference policy" for a number of generic medicines, selecting the cheapest supplier(s) whose products alone will be reimbursed during a certain period of time. The selection of the suppliers follows the same logic as a tender process, where the bidder with the lowest price is selected. However, in the Netherlands, the cheapest suppliers have been selected based on the prices they publish in the so-called G-Standard or Taxe, a publicly available list containing all gross prices of medicines to pharmacies, which are at the same time the maximum resale prices from pharmacies to patients. This selection process renders the prices offered automatically applicable to all sales of the suppliers concerned in the Netherlands, including to health insurers that have not followed any preference policy.
- (375) Since 2005, the preference policy has been implemented by all health insurers collectively on three widely sold products – the so-called "collective preference policy". This policy initially led to moderate price decreases only. But since 1 June 2008 at least 40 more products in total have been added on an individual basis by four of the five major Dutch health insurers – the so-called "individual preference policy". In this individual policy, the precise procedure followed and the products and the period selected differs between the insurers. Also some insurers not only select the company with the lowest bid, but use a price range of up to 5% allowing more than one preferred supplier (for example in order to ensure supply to the whole market). In return for the low price, the selected supplier(s) obtain(s) exclusivity from the health insurer for a predetermined time period, typically six to twelve months, for the medicine concerned. Except for cases of medical necessity, the patients of the health

³⁰³ It should be noted, however, that these tender (or tender-like) procedures for mainly generic medicines are distinct from the practice of concluding rebate contracts for patent-protected products.

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insurer concerned have to use, if they want to be reimbursed, the medicine of the supplier(s) selected.

- (376) Very significant price reductions have been achieved since 1 June 2008 through the individual preference policy. Stichting Farmaceutische Kengetallen reported the price decreases below for the six top-selling products:

Table 16: Reported price decreases in the Netherlands (2008)

Product	Preferred supplier	Price in May	Price in June	Change
Omeprazol tablets/capsules 20 mg	Ratiopharm	€ 0.36	€ 0.05	-88%
Alendroninezuur tablets 70 mg	Centrafarm	€ 4.99	€ 0.36	-93%
Omeprazol tablets/capsules 40 mg	Centrafarm	€ 0.65	€ 0.09	-86%
Paroxetine tablets 20 mg	Ratiopharm	€ 0.37	€ 0.07	-82%
Simvastatine tablets 40 mg	Actavis	€ 0.27	€ 0.04	-84%
Pravastatine tablets 40 mg	Focus Pharma	€ 0.54	€ 0.13	-76%

Note: Price level: Gross purchase prices to pharmacies = maximum resale prices from pharmacies to patients

- (377) It should be noted that these are decreases from a generic price level in the Netherlands that was, through an agreement with the government, already at least 50% below the former originator price for the medicine. As a result of the price decreases obtained through the preference policy, discounts from the gross price that suppliers previously gave to pharmacists were largely eliminated for the products concerned. Indeed, according to Dutch press reports, most of the savings made by health insurers result from the elimination of rebates previously given by suppliers and distributors to pharmacies rather than from decreases in suppliers' net ex factory prices.
- (378) The price reductions are estimated to lead to annual cost savings for the Dutch health system of between € 200 million and € 400 million. The savings result from the price reductions for the product concerned and expected substitution effects. It is also inherent in the system that non-selected suppliers will have an incentive to lower their prices to the lowest level to become attractive to those insurance companies that have not committed themselves to certain suppliers under an individual preference policy, but that simply reimburse only the cheapest medicines on the market (within a band of 5%). These price decreases of non-selected suppliers did in fact take place in the months following the preference round of June 2008.
- (379) The preference policy has led to considerable controversy in the Netherlands. Patients expressed concerns when they had to switch medicines. Pharmacists complained that they lost an important part of their revenues. They brought their case to court, but the court ruled that the preference policy was legal. The Dutch association of generic producers also tried to stop the health insurers from going ahead with the preference policy through court proceedings claiming among other things that the policy is incompatible with competition law. The Dutch courts rejected this argument. In parallel, in April 2008 the Commission sent the stakeholders concerned information requests in the context of the sector inquiry when the Commission became aware that insurers might be tempted to enter into an agreement with other stakeholders to waive their right to carry out preference policies in return for cost cuts. The individual preference policy was then implemented as originally planned.

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- (380) Generic companies continue to criticise as anti-competitive the fact that the selection of the least expensive supplier is made on the basis of published Taxe prices that apply not just to the health insurer(s) conducting a preference policy, but to all health insurers in the Netherlands. It must be observed, however, that before the introduction of the preference system, there was essentially no price competition for generic products at the level of patients in the Netherlands at all. Suppliers did compete for the favour of pharmacies, by offering them large discounts from the gross prices published in the Taxe, but pharmacies sold to patients at the level of those Taxe prices (which, as mentioned, function simultaneously as the maximum resale price to patients). Patients therefore did not benefit from this so-called "margin competition". Moreover, before the introduction of the preference policy, the published Taxe prices for generic products were often identical or very similar between the different suppliers, there being no economic incentive for suppliers to reduce them (indeed, a supplier that reduced its gross price could only offer lower discounts to pharmacies and would thus sell less, not more). The preference policy therefore seems to have introduced at least an important first element of competition for the market between suppliers at the level of patients.
- (381) This having been said, it is also clear that to the extent that all health insurers benefit from the same published price decreases for the same products for the same periods, competition between health insurers for these medicines purchases is eliminated. Even though the costs concerned represent only a relatively small portion of the total health care packages offered by health insurers to patients, in a fully competitive system the prices offered by a supplier to an individual health insurer would not be known to, and would not apply to, other health insurers. Each health insurer would have to compete with the others to obtain the cheapest purchases of medicines. Suppliers, from their side, would be free to offer lower prices to one health insurer than to another. Possibly this result could be achieved through a true tendering system operated by each individual health insurer and using secret price offers. In March 2009, one large health insurer initiated such secret tendering. The Commission will continue to follow developments in the Netherlands very closely in this respect.
- (382) Another aspect the Commission will continue to follow very closely is whether patients will truly benefit from the price reductions obtained. The savings made by health insurers in 2008 led to a smaller contribution by the state to the cost of public health care and therefore did benefit Dutch tax payers. It would, from a competition policy perspective, be even better if the savings made directly benefitted the patients of the health insurer that achieved these savings, as that would stimulate all health insurers to compete by trying to achieve the lowest purchase prices and to pass on the benefits to their own patients through improved health care packages or reduced insurance premiums (which might mean in times of overall cost increases a smaller increase in premiums).

Tendering Procedures by German Sickness Insurance Funds

- (383) In Germany, the statutory sickness insurance funds can award rebate contracts to bring down prices for the patients. These framework contracts specify the discounts that suppliers of pharmaceuticals, mainly generic but occasionally also originator companies, give to the sickness funds. The scope of the contracts used to vary widely, but this has changed since January 2009 when a new law entered into force. Basically, it

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excludes tenders covering several substances (so-called portfolio contracts), thereby strengthening tenders for specific active ingredients. The cost savings are achieved as pharmacies are obliged by law – as from April 2007 – to supply the patients insured with the respective health insurer only with products that are covered by rebate contracts if available. In addition the need for co-payments by patients is expected to decrease.

- (384) The industry has expressed concerns that the practice might not be compatible with European and national law. In particular, a breach of the rules governing public procurement and of competition law was claimed. With respect to the public procurement rules it was argued that for generic substances European-wide tenders are required. In response the Commission launched infringement proceedings against Germany, which led the German authorities to change the legislation in order to bring the procurement practice of sickness insurance funds in line with community law. With respect to competition law it was argued that the tender process could lead to foreclosure and possibly market concentration. To assess the matter under EC competition law is complex, as the European Court of Justice (ECJ) has expressed hesitations in other – non-related – cases as to whether public sickness funds can be viewed as undertakings, a prerequisite for the application of European competition law.³⁰⁴
- (385) In response to the criticism received, the largest German sickness fund AOK launched in August 2008 its third tender round concerning 64 generic substances corresponding to 46% of its total demand of medicines. This time the rebate contracts were tendered EU wide. Moreover, a new element of the tender procedure was to divide Germany into 5 regions ("Gebietslose") where separate tenders are conducted. The regions were designed such as to cover similar numbers of insured in each region. Per substance and region one rebate contract with a single supplier of pharmaceuticals was concluded. The contracts run for two years with an option to extend them for half a year. The division into independent regional tenders as well as the separate tender for each substance was supposed to enable also small generic companies to participate e.g. with respect to the risk associated with supply failures. For most substances a single company won the tenders in all regions. Some of the prices are reported to be very low.

Rebate Contracts for Patent Protected Products in Germany

- (386) Under German law rebate contracts can also be used as a cost containment measure to lower prices for patent protected products.
- (387) For products that still benefit from market exclusivity, German law provides for direct negotiations between the sickness funds and the originator companies. The duration of those contracts concluded before LoE can be extended beyond LoE without the need for a tender procedure. The law obliges pharmacists to dispense the product subject to

³⁰⁴ Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01 *AOK Bundesverband and Others v Ichthyol-Gesellschaft Cordes, Hermani & Co. and Others* [2004], ECR 2004 I-02493.

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the rebate contract if the patient is insured with the sickness fund that is the other party to the contract.

- (388) During the public consultation, it has been submitted that rebate contracts between originator companies and sickness funds concerning patent protected products should expire with the LoE of the product concerned in order to allow for generic entry. In this respect it has also been argued that sickness funds might not be able to fully anticipate the market evolution when entering into rebate contracts.
- (389) In the course of the sector inquiry, the originator companies were asked to provide information on all rebate contracts that they have concluded since 2007 with a public or private health insurer and for which the duration extended beyond LoE. Based on the data submitted³⁰⁵, 139 rebate contracts were concluded by twelve different originator companies covering 27 different INNs. The Commission services also received information on other contracts concluded prior to 2007 which were however not analysed in detail for the purpose of this section.
- (390) It is apparent from the information received that rebate contracts for patent protected products were sometimes concluded to avoid co-payments by the patients³⁰⁶ or, in case the specific product was not reimbursable as it gave rise to higher costs than prescription of other products, to compensate the sickness funds for the higher costs associated with the treatment with the specific product concerned.
- (391) Usually, the rebate contracts were concluded for a specific originator product, INN or product market defined in the contract. Whereas the clear majority of the rebate contracts covered only one product, INN or product market, some contracts included up to seven different INNs or product markets.
- (392) The number of rebate contracts concluded per company and per product/INN varied between one and 48. Accordingly, the total amount of annual sales covered by the contracts differed significantly, mainly depending on the product concerned and the size of the sickness fund. Usually, originator companies entered into separate contracts with different health insurance funds or associations of health insurance funds. However, sometimes several health insurers were covered by the same rebate contract and/or the contract allowed for the accession of other health insurers or associations.
- (393) More than half of the rebate contracts (72) were concluded in the last year before LoE, whereas 56 rebate contracts were concluded more than three years before LoE. The remaining eleven agreements were concluded between one and three years before LoE. For about half of the agreements (27) that were concluded well in advance of LoE (more than three years) generic companies already received a marketing authorisation for a generic version of the originator product covered by the rebate contracts.

³⁰⁵ It has to be noted that 42 of the 43 originator companies replied to the questionnaires.

³⁰⁶ See above para. (369).

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- (394) The majority of the rebate contracts (82 agreements), had an initial duration of maximum 18 months. Seventeen rebate contracts had a duration of between 18 and 68 months and 40 agreements were entered into for an indefinite time period. However, one has to note that the clear majority of the rebate contracts that were entered into for a fixed period of time provided for a tacit renewal, i.e. in the absence of duly notice by either party the contract was extended for some months or another year or even for an indefinite time period.
- (395) Beside an extraordinary right of early termination, the agreements usually provided for a right of early termination or to stop the tacit renewal which had to respect certain notice periods and cancellation dates. Some agreements foresee an automatic adjustment of the rebate granted according to the changes of the reference or the reimbursement prices or if a generic is launched or they allow for renegotiations of the rebates if other products are available on the market.

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Summary

In almost all Member States the pricing and reimbursement status of a prescription medicine must be determined before launch if funded under the social security system. The underlying objective is to maintain control over national health budgets.

A number of Member States apply policies supporting the sale of generic medicines by combining demand and supply side pricing practices, such as obliging pharmacists to always dispense the cheapest product. In certain Member States health insurers have recently become active in controlling prices for medicines, e.g. through tender procedures.

C. MAIN ISSUES INVESTIGATED

1. INNs, Products and Patents

(396) This section describes the sample of 219 INNs (pharmaceutically active molecules) selected for the in-depth investigation in the sector inquiry and on the related products. The second section gives information on patent applications, patent portfolios and patent life cycles, both in general and for the 219 INNs covered by the sector inquiry.

1.1. Products and INNs

(397) In this report medicines are referred to by their international non-proprietary name (INN), a public nomenclature overseen by the World Health Organisation (WHO). The INN is often known as a "generic name", which is not protected by trademarks and is used next to the brand name in the international medical community.³⁰⁷

(398) "Products" are defined as products for which a marketing authorisation has been granted and which are placed on the market. Different dosages or different forms of administration of the same prescription medicine have been considered as different products.

(399) For a number of issues relevant to the sector inquiry, stakeholders were asked to provide information on a sample of 219 INNs, which were selected as follows:³⁰⁸

- A first group of INNs was selected by taking, in three Member States (France, Germany and the United Kingdom), the 75 top-selling INNs that had faced loss of exclusivity (e.g. expiry of their patent, SPC, IP or data exclusivity) over the period from 2000 to 2007. In each Member State, this list of 75 INNs represented, in value terms, well over 90% of sales of all INNs that faced loss of exclusivity from 2000 to 2007. The list of the top 75 molecules in each of these three Member States were combined. This produced a final list of 128 INNs. This list is referred to as "E75". The INNs on this list were particularly relevant for gathering information on the originator/generic relationship.
- A second group of INNs contains the 50 top-selling INNs (whether protected or not) in each of the three above-mentioned Member States. This led to identification of a total of 90 INNs (of which 61 were not already on the E75-list). This list is referred to as "T50". These ensured that information on the most remunerative INNs would be collected in the inquiry.

³⁰⁷ For further information on INNs, see <http://www.who.int/medicines/services/inn/en/>.

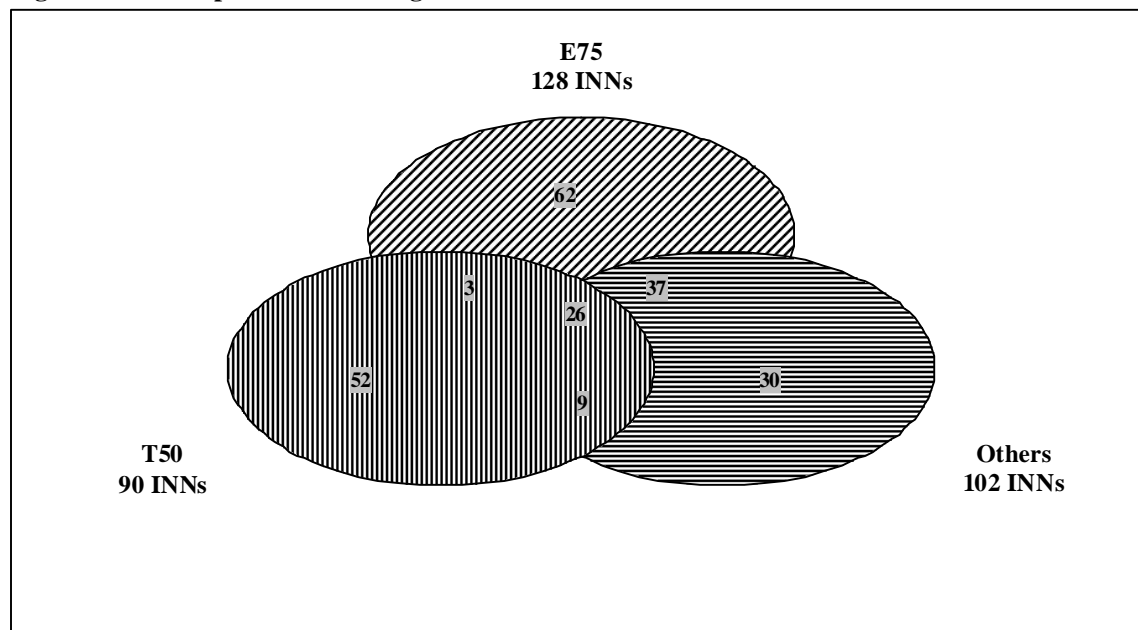
³⁰⁸ For further details see Annex Methodology and list of 219 INNs (Annexes to Chapter A).

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- A third group of other INNs was selected by considering the 50 top-selling INNs which had faced (possible) first generic entry in each of the countries selected. This gave a total of 95 INNs (30 of which were new in comparison with the E75 and T50 lists). This group of INNs was also potentially relevant to the originator/generic relationship. Finally, the list contained some INNs that might be of interest in view of other market information available to the Commission.

(400) Figure 37 illustrates the overlap between the three universes. It indicates that 26 INNs were present in all three subgroups.

Figure 37: Overlap between investigated INNs universes



Source: Pharmaceutical Sector Inquiry

(401) This section will describe some broad characteristics of the sample of 219 INNs on which stakeholders were asked to provide information.

1.1.1. INNs in Relation to Companies and Products

(402) As indicated in Table 17, usable information on INNs and products was received from 43 originator companies and 24 (out of a total of 27) generic companies.

(403) Out of the 219 INNs considered, the originator companies were active on 215³⁰⁹ and the generic companies on 216. On average in the period 2000 to 2007 the generic companies were active on 214 INNs per Member State and the originator companies on 161. Looking at the E75 list of INNs, in the period 2000 to 2007 the generic and the originator companies were, on average, active on 121 and 90 INNs per Member State

³⁰⁹ Relevant information for this section was received on 215 INNs (out of the 219 investigated).

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respectively. In the T50 universe, the generic and the originator companies were active on an average of 85 and 77 INNs per Member State respectively.³¹⁰ These averages hide substantial differences between Member States.

Table 17: Overview of INNs and companies³¹¹

Company type	Number of companies analysed	Number of INNs on which companies were active (EU27)	Average number of INNs per MS (219 INNs)	Average number of INNs per MS (E75)	Average number of INNs per MS (T50)
Originator companies	43	215	161	90	77
Generic companies	24	216	214	121	85

Source: Pharmaceutical Sector Inquiry

- (404) Figure 38 illustrates the average number of products per INN and per type of company in the E75 sample plus the number of originator and generic companies per INN. It is based on data concerning all the generic and originator³¹² companies active in fifteen EU Member States³¹³ in the period 2000 – 2007.
- (405) As can be seen, originator companies have a higher average number of products per company and INN (2.88) than generic companies (2.22), which indicates that generic companies focus on a few selected products for a given INN, while originator companies offer a broader product range. At the same time, in general, the average number of originator companies active on each INN (1.64) is significantly lower than the number of generic companies (4.47).

³¹⁰ In the case of the E75 list, Table 11 indicates the average number of INNs per Member State. This does not necessarily mean that those E75 molecules sold in a given Member State also already faced loss of exclusivity in that particular Member State in the reference period 2000-2007. For further details see the Methodology Annex (Annexes to Chapter A).

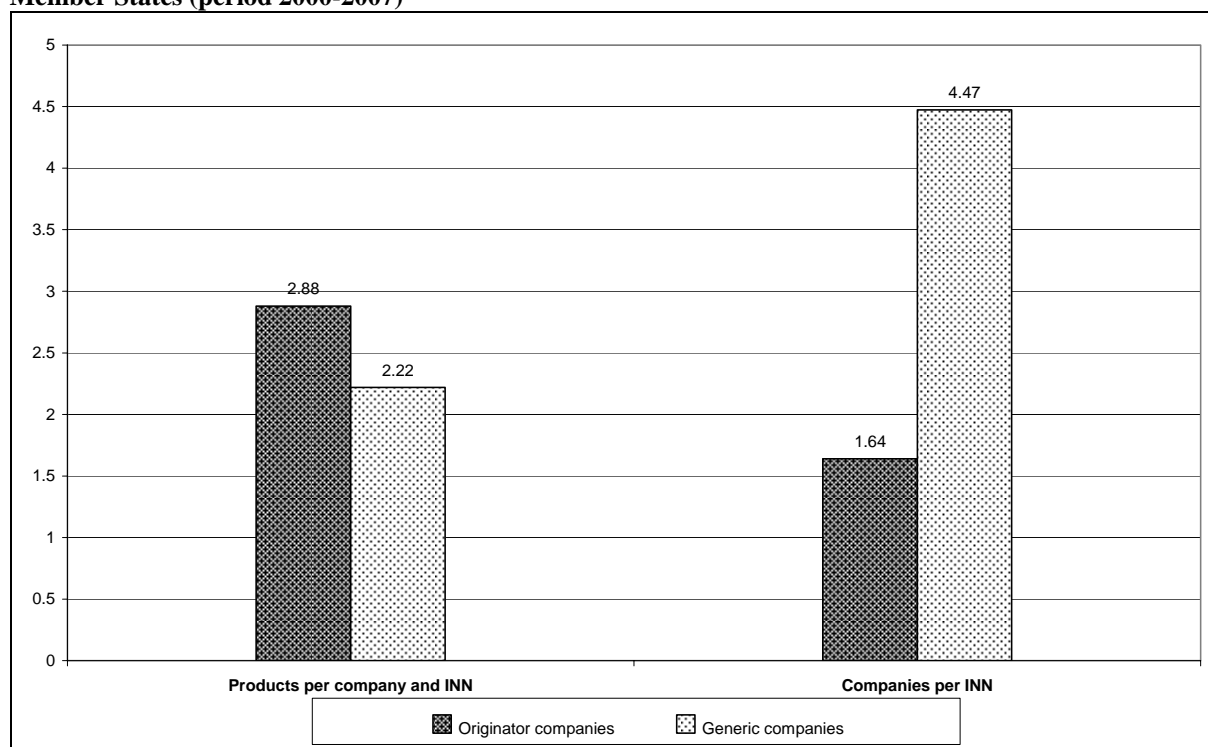
³¹¹ During public consultation the reliability of data concerning the exact number of companies per INN was questioned. However, the information included in Table 17 has shown the data as submitted by originator and generic companies concerning their activities in EU27.

³¹² In Figure 38 and Figure 39 the category of originator companies includes the originator company itself and/or the companies which have obtained a licence to produce and sell the INN concerned. Information provided by companies about expiry dates was complemented with information received from IMS. Some molecules originally selected, including some biotechnological products, have been excluded because it was not possible to identify an exact expiry date.

³¹³ The Member States selected are Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Portugal, Spain, Sweden and the United Kingdom.

PHARMA SECTOR INQUIRY – MAIN ISSUES INVESTIGATED

Figure 38: Average number of originator and generic products and companies per INN in fifteen EU Member States (period 2000-2007)



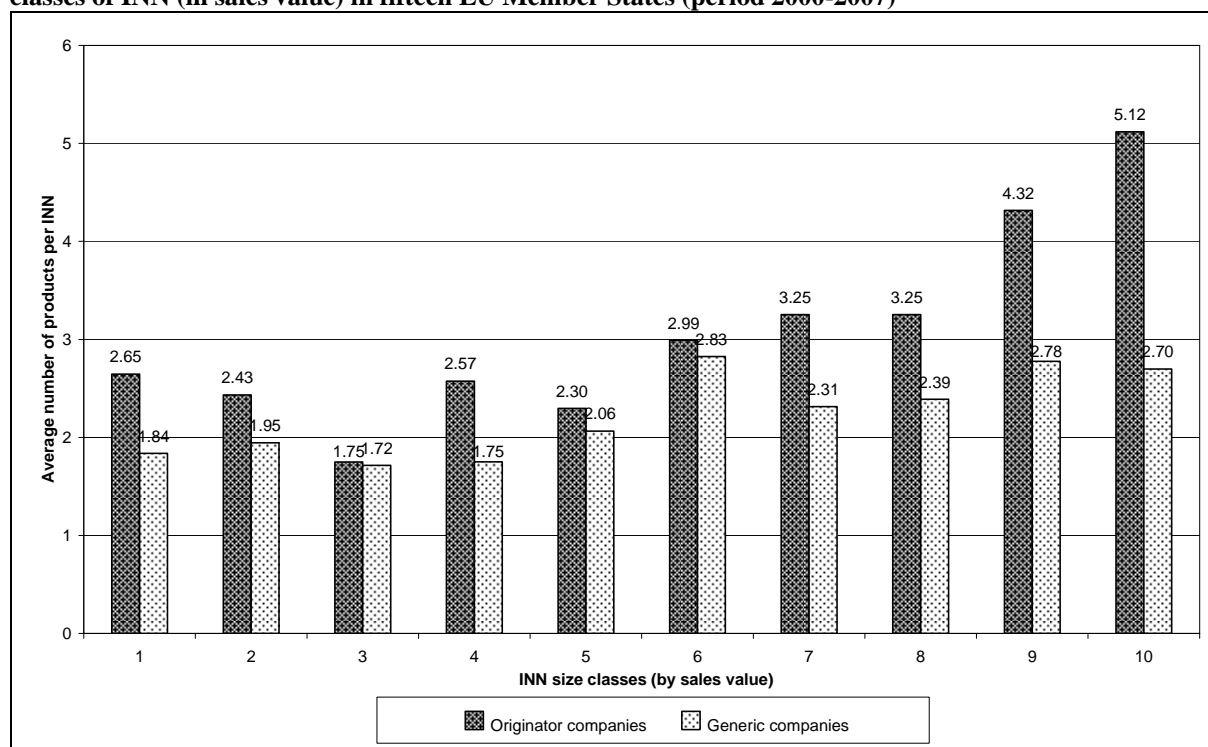
Source: Pharmaceutical Sector Inquiry (based on IMS data) (E75)

(406) Figure 39 illustrates, for the period 2000 – 2007, the average number of products of generic and originator companies per INN for ten size classes of INNs ordered by sales (in terms of value in the year prior to expiry). The size classes are based on the E75 sample and rank INNs into groups, starting from the INNs with the lowest sales (class 1) and moving up to those with the highest (class 10). As expected, the average number of products per group of INNs varies substantially as a function of the sales generated by each INN. The average number of products per INN in the first class (lowest selling) is 2.65 and 1.84 for the originator and generic companies respectively. The figure shows that originator companies have a higher number of products per company and INN in all the INN classes than the generic companies. The difference between the two types of companies is more significant for the INNs with high sales value. The originator companies have, on average, 5.12 products per company and INN in the class of best-selling INNs, whereas the generic companies have an average of 2.70 products per INN. All in all, Figure 39 confirms that originator and generic companies have a more diversified product portfolio for the best-selling INNs.³¹⁴

³¹⁴ During public consultation it was argued that Figure 39 does not take into account the fact that some INNs and products could have been introduced more recently than others, i.e. future blockbusters which do not show important sales yet. However one should consider that the graph is based on the E75 list which, by definition, includes well-selling INNs. Moreover, quintiles are established considering the sales of the first product in the INN one year before the expiry (value sales of the originator product) and not in consideration of recently introduced products. For further details see the Methodology Annex (Annexes to Chapter A).

PHARMA SECTOR INQUIRY – MAIN ISSUES INVESTIGATED

Figure 39: Average number of originator and generic products per company and INN, over different size classes of INN (in sales value) in fifteen EU Member States (period 2000-2007)



Source: Pharmaceutical Sector Inquiry (based on IMS data) (E75)

1.1.2. Overview of INNs where a Product Was Launched or Lost Exclusivity

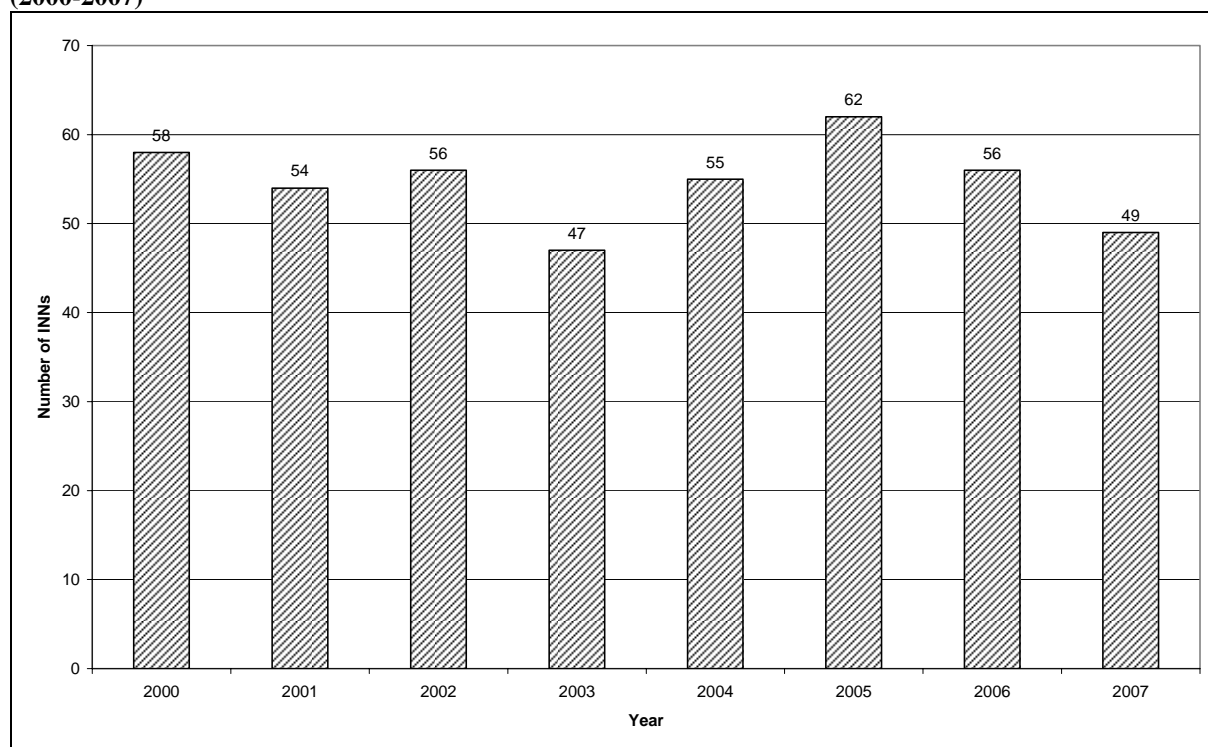
(407) Figure 40 shows the number of INNs on the T50 list³¹⁵ in which respondent originator companies launched at least one product in at least one Member State over the period 2000 – 2007. It shows the large number of INNs under which originator companies launched products during the period considered, confirming the relevance of this universe to the sector inquiry. For the sake of completeness, it must be added that the results are similar when considering the E75 list.

(408) Note that the same INN can be counted in several years in cases where a product from the same INN was launched in more than one year. At the same time, each INN is counted only once if more than one product is launched within the same year by one or more originator companies in at least one EU Member State.

³¹⁵ In order to analyse the originator companies' product launch activity, the most remunerative INNs were selected.

PHARMA SECTOR INQUIRY – MAIN ISSUES INVESTIGATED

Figure 40: Number of INNs under which originator companies launched at least one product in the EU (2000-2007)



Source: Pharmaceutical Sector Inquiry (T50)

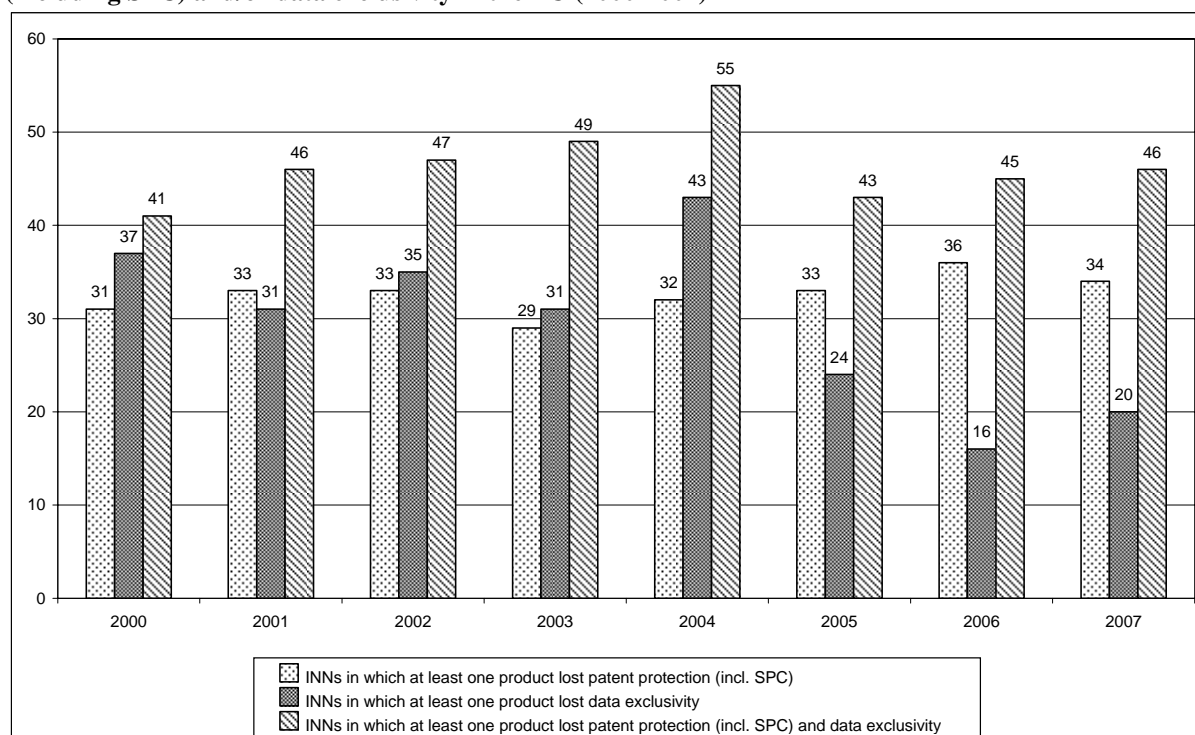
(409) Figure 41 shows the number of INNs on the E75 list³¹⁶ for which a product lost patent protection including SPC, data exclusivity or both in at least one Member State in the period 2000 – 2007. It shows a significant number of INNs offering possible opportunities for generic companies to prepare more imminent entry, which confirms the importance of this universe for the sector inquiry. Note that in Figure 41 the same INN can be counted in several years in cases where a product related to that INN lost protection in more than one year.³¹⁷

³¹⁶ In order to analyse the potential opportunities for generic companies to launch a product, the INNs facing loss of protection were selected.

³¹⁷ At the same time, each INN is counted only once if more than one product is launched within the same year by one or more originator companies in at least one EU Member State. Moreover, since a given product can lose patent protection in one year and data exclusivity in another, the column indicating the INNs where at least one product lost patent protection and data exclusivity is not simply the sum of the other two columns for the same year.

PHARMA SECTOR INQUIRY – MAIN ISSUES INVESTIGATED

Figure 41: Number of INNs in which at least one product of originator companies lost patent protection (including SPC) and/or data exclusivity in the EU (2000-2007)



Source: Pharmaceutical Sector Inquiry (E75)

(410) Figure 42 indicates the number of INNs in the T50 list³¹⁸ under which originator companies launched a product or lost patent protection including SPC and data exclusivity on a product in at least one Member State in the period 2000 - 2007. This information is also grouped by ATC 1 class.³¹⁹ Hence, this figure illustrates the main therapeutic areas in which the originator companies investigated launched products or lost patent protection and/or data exclusivity for their products, providing an initial indication of therapeutic classes in which the market interaction between originator and generic companies could have been more or less effective in the period considered.

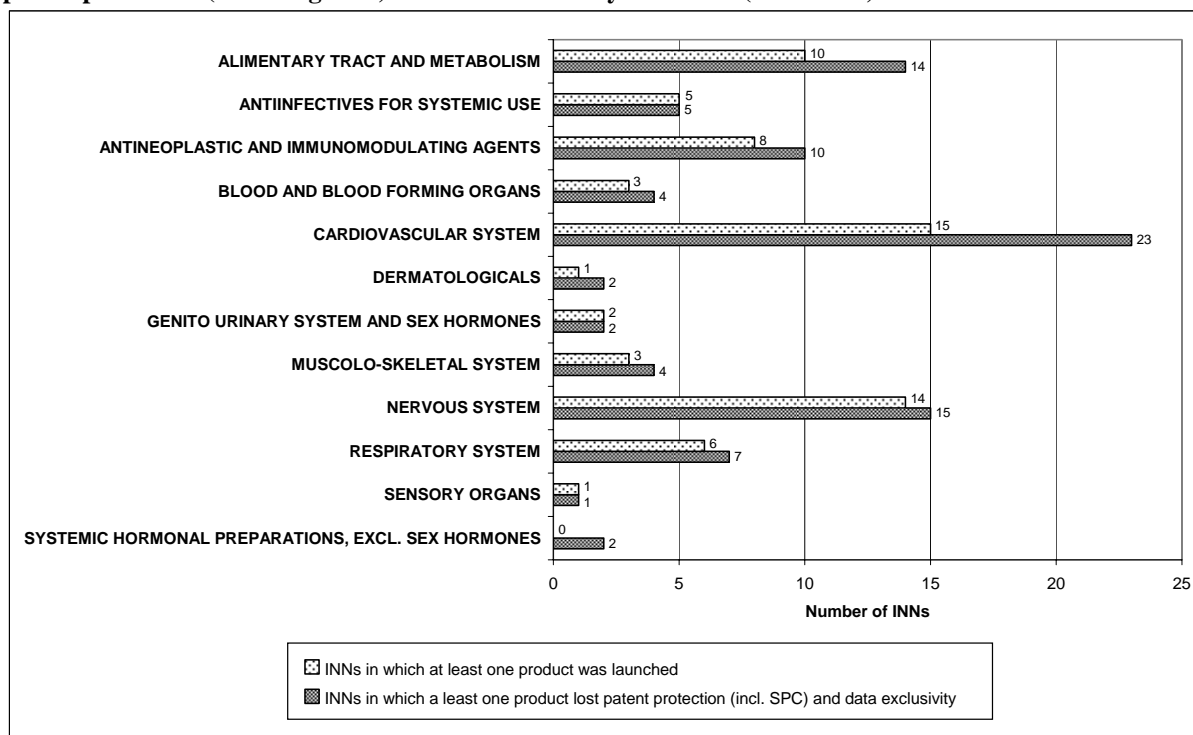
(411) Figure 42 shows that for the sample of INNs on the T50 list, the originator companies launched the highest number of products in the following ATC 1 classes: cardiovascular system (15), nervous system (14), and alimentary tract and metabolism (10). These are also the classes in which the highest number of INNs lost patent protection and data exclusivity. For the sake of completeness, it must be added that the results are similar when considering the E75 list.

³¹⁸ For this figure, the T50 universe was chosen, as it comprises the most remunerative INNs whether protected or not on which originator companies focus their activity.

³¹⁹ "ATC" stands for Anatomical Therapeutic Chemical classification, i.e. an international standard for classifying medicines. Class 1 of the ATC system provides indication on the general therapeutic group to which a medicine belongs.

PHARMA SECTOR INQUIRY – MAIN ISSUES INVESTIGATED

Figure 42: INNs per ATC 1 class in which originator companies launched at least one product or lost patent protection (including SPC) and data exclusivity in the EU (2000-2007)



Source: Pharmaceutical Sector Inquiry (T50)

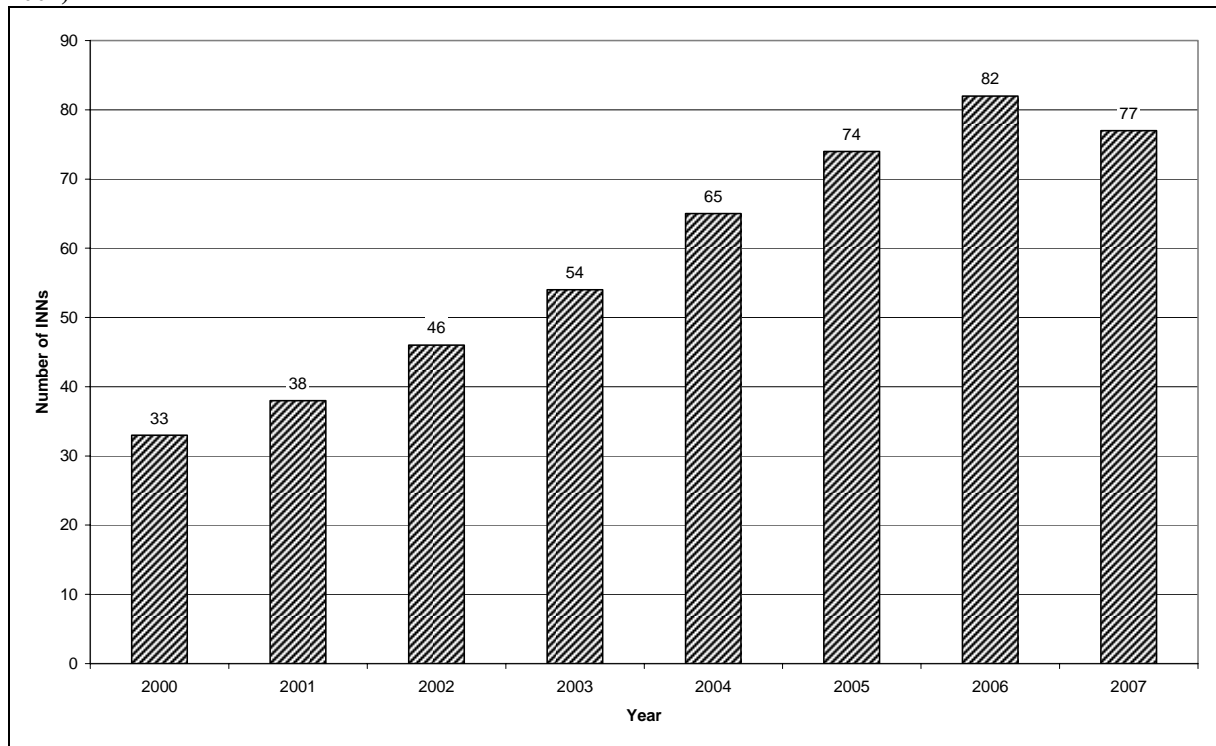
(412) Figure 43 illustrates the number of INNs on the E75 list³²⁰ where generic companies launched at least one product in a Member State in the period 2000 – 2007. It shows that generic companies became active on a significant number of INNs each year. Further analysis demonstrated that mainly the same INNs are concerned each year. In general terms, this could be because additional generic companies began selling products under that INN and/or the same generic companies launched additional products for a given INN.³²¹ The figure provides an initial indication of INNs where market interactions between generic and originator companies could have taken place during the period considered.

³²⁰ In order to analyse generic product launch activity, the INNs facing loss of protection were selected.

³²¹ Note that the same INN can be counted in several years in cases where a generic product for the same INN was launched in more than one year. At the same time, each INN is counted only once if more than one product was launched within the same year by one or more generic companies in at least one Member State.

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Figure 43: Number of INNs for which generic companies launched at least one product in the EU (2000-2007)



Source: Pharmaceutical Sector Inquiry (E75)

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Summary

For the purpose of the sector inquiry a representative sample of 219 molecules (also referred to as INNs, i.e. the international non-proprietary name) was selected for the in-depth analysis. The INNs chosen include products which faced loss of exclusivity in the period 2000 – 2007 (E75 list) as well as bestselling medicines (T50 list).

The sector inquiry confirmed that generic companies brought fewer versions of a medicine to market than originator companies for the same INN. Medicines with a higher turnover were characterised by a higher degree of product differentiation.

1.2. Patents

- (413) In the pharmaceutical industry, patent protection has a huge bearing on the commercial success of a company. By providing exclusive rights to the holder, patents offer a pharmaceutical company the opportunity to reap financial reward for investment made in the development of new medicines, and thus provide incentive for further innovation. At the same time, patents affect market entry by a company's competitors, both originator and generic alike, in that they can prevent other parties from exploiting the invention for a set period.
- (414) In the context of the sector inquiry, it is therefore important to provide an overall picture of pharmaceutical companies' activities in the patent arena, before looking further into the information available and drawing any conclusions on the use of patents to support commercial activities. Since originator companies have traditionally been those which have sought patent protection for their inventions, this group was asked to provide information on their patents and patent applications.
- (415) This section of the report provides a general overview of the geographical scope of patenting, patent applications by originator companies and their outcomes, and of originator companies' patent portfolios. These aspects are addressed with particular reference to the 27 Member States and the information gathered on the 219 INNs covered by the sector inquiry. Application data from the European Patent Office (EPO) are provided for all patent applications in all sectors, a proxy for the pharmaceutical sector and organic chemistry for general comparative purposes. The section further considers patent portfolios in terms of applications made over the lifetime of the primary patents for different INNs. Finally, some brief observations are made on the filing of patent applications by generic companies.

1.2.1. Geographical Scope of Patenting

- (416) As explained previously,³²² patent rights are limited with respect to their geographical scope and can only be enforced in those countries where a valid patent exists. Accordingly, companies must decide where they require patent protection. In the absence of a community patent, companies active in the EU must decide for which Member States they wish to obtain protection, either at individual national patent offices or centrally via the EPO. As the filing of patent applications and indeed the maintenance of granted patents bear significant costs, low though they may be compared to the revenues earned from blockbuster medicines.³²³ Individual companies may decide to set priorities in the selection of countries where they wish to obtain patent protection.

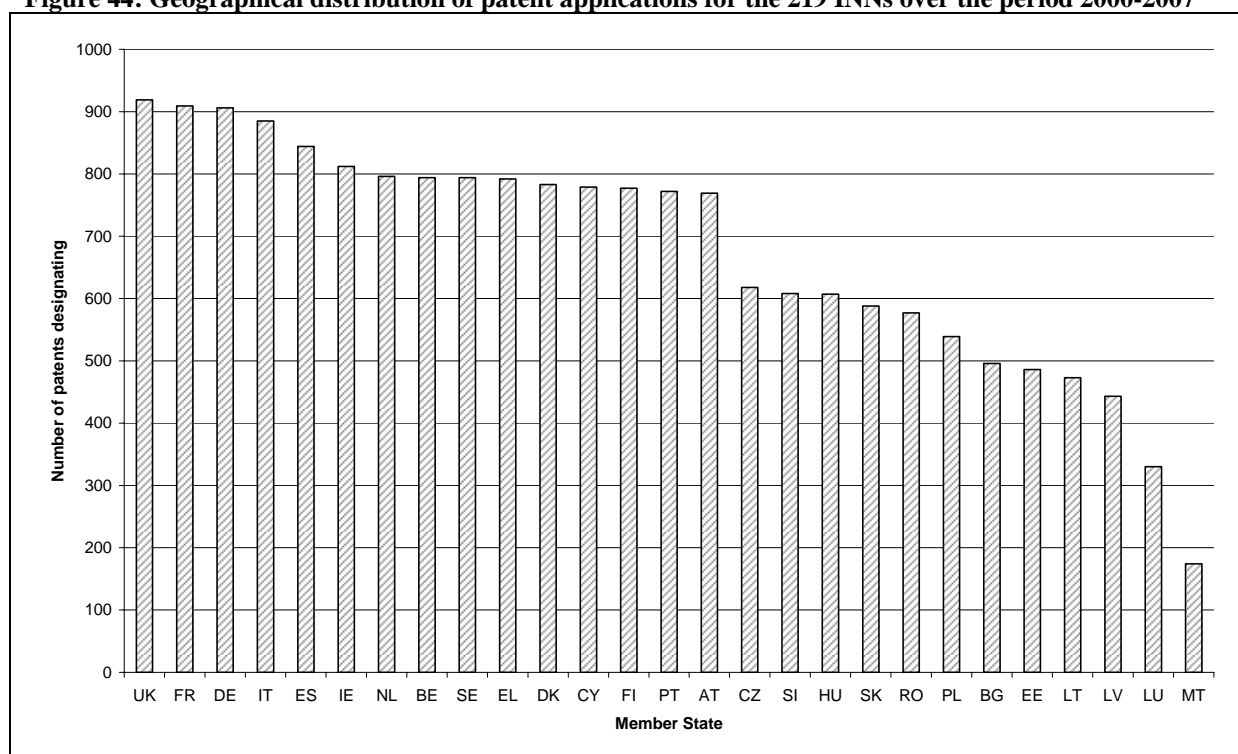
³²² For further details see Chapter B.2.1.

³²³ For further details see Chapters B.2.1. and D.1.1.

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- (417) In fact, more than a third of the originator companies (15 out of 43) submitted patent strategy documents indicating that they employ a 3- to 5-tier system which groups patent applications according to their geographical importance. The tier regarded by the companies as being the most important covers the most extensive geographical scope, *viz.* all PCT member states plus some non-PCT members, whereas the least important tier contains only a few strategically-important areas, usually the USA, the EPC contracting states (or a selection thereof) and Japan. The analyses in this section focus on patenting in the EU.
- (418) Analysis of the responses to the sector inquiry showed that, in respect of the 219 INNs, an average 14.8 states (of the 27 Member States) were designated for each patent or application at the EPO. The distribution of patents and applications for the 219 INNs across the 27 Member States for the period 2000 – 2007 is shown in Figure 44.

Figure 44: Geographical distribution of patent applications for the 219 INNs over the period 2000-2007



Source: Pharmaceutical Sector Inquiry

1.2.2. Patent Applications

- (419) The period 2000 – 2007 saw a markedly greater increase in pharmaceutical-related patent applications. A proxy for pharmaceutical applications, based upon the IPC³²⁴ classification A61K and termed A61K* in this report, was used to give a general idea

³²⁴ The International Patent Classification (IPC) system is used to classify patent applications by subject-matter and is currently in its eighth version (IPC8) with version 9 (IPC9) planned to be introduced on 1 January 2009. For further information on the IPC, see <http://www.wipo.int/classifications/ipc/en>.

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of this trend.³²⁵ Applications with classifications falling within the definition of A61K* were taken as the closest proxy for pharmaceutical applications. As a comparison, data is presented for organic chemistry³²⁶ and all sectors (represented by the overall EPO figures).³²⁷

- (420) Table 18 shows the numbers of pharmaceutical patent applications filed at the EPO in A61K*, organic chemistry and all sectors. Thus, whilst an increase of around 40% was seen in the total number of patent applications filed at the EPO from 2000 to 2007, the increase in A61K* doubled between 2000 and 2007, corresponding to an average 10.2% increase *per annum* compared to 4.9% for all sectors. In organic chemistry the number of applications rose by 61%, corresponding to an average 7% increase *per annum*.

Table 18: Total European and Euro-PCT (regional phase) filings at the EPO for all sectors, organic chemistry and A61K*

Year of Filing	2000	2001	2002	2003	2004	2005	2006	2007
All Sectors	100,702	110,115	106,341	116,832	123,761	128,724	135,425	140,882
Organic Chemistry	5,435	6,022	6,311	6,622	6,817	7,193	8,203	8,743
A61K*	2,876	3,650	3,762	4,515	4,988	5,110	5,562	5,687

Source: European Patent Office

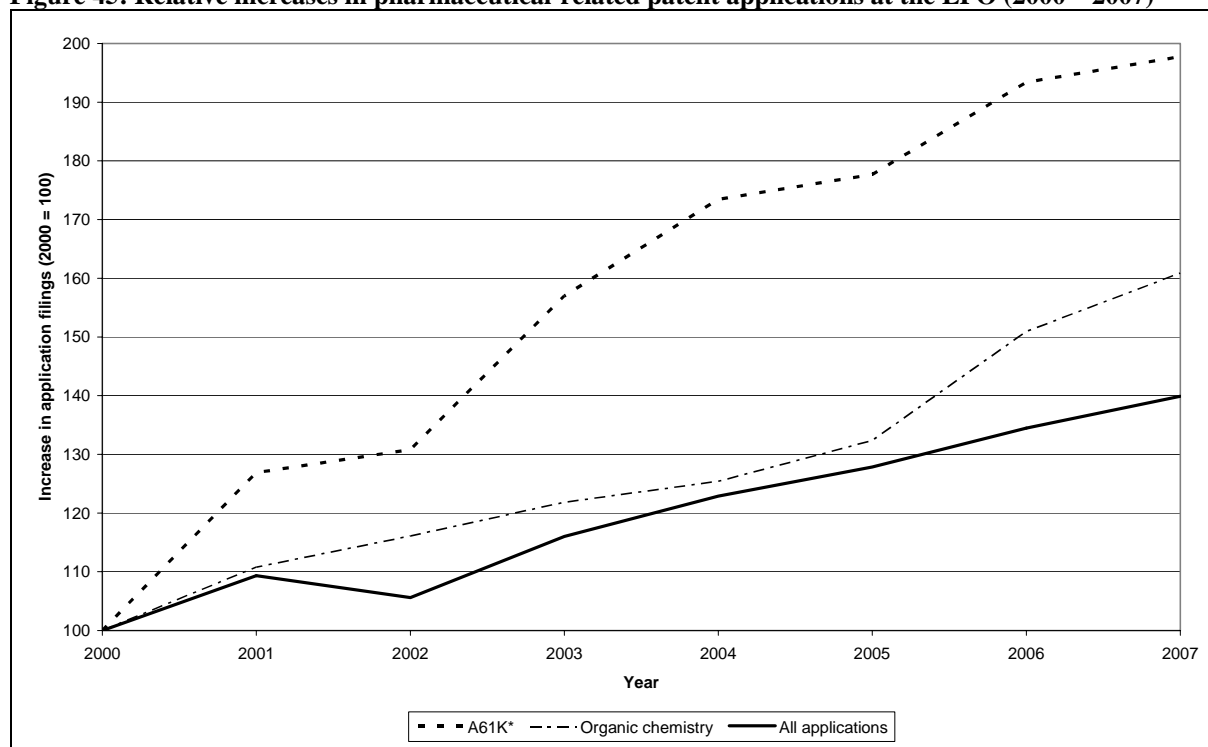
- (421) The divergence in patent application rates is brought out visually in Figure 45, which shows the relative increases in applications based on year 2000 = 100.

³²⁵ The IPC classification A61K relates to 'Preparations for Medicine, Dentistry and Toiletry'. This was restricted to give A61K*, which comprises all A61K sub-classifications with the exception of those classified as A61K6 - 'Preparations for dentistry' - and A61K8 (A61K7 under IPC7) - 'Cosmetics or similar toilet preparations'. The sub-classification A61K36 - 'Medicinal preparations of undetermined constitution containing material from algae, lichens, fungi or plants, or derivatives thereof, e.g. traditional herbal medicines' - was first introduced into the IPC on 1 January 2006 with version 8 and was also disregarded.

³²⁶ The technical unit 'organic chemistry', found in the EPO Annual Reports, covers the IPC classifications C07 and A01N.

³²⁷ Whilst applications for new pharmaceutical chemical entities are normally classified in one of the classifications of Section C of the IPC, it is recognised that these classifications also comprises organic molecules for purposes other than pharmaceuticals (e.g. agrochemicals). Within the context of the sector inquiry it was, however, not possible to separate applications classified as organic chemistry into those directed to pharmaceutical products and those directed to non-pharmaceutical products. Nevertheless, the field organic chemistry is presented for general comparative purposes.

Figure 45: Relative increases in pharmaceutical-related patent applications at the EPO (2000 – 2007)



Source: Pharmaceutical Sector Inquiry (based upon European Patent Office data)

- (422) The sector inquiry asked companies to provide details of granted patents (both expired and still in force) and pending applications in the EU Member States in relation to the 219 INN of the inquiry. These were not restricted to applications prosecuted at the EPO, but also covered direct applications to national patent offices. Responses showed that during the period 2000 – 2007, originator companies filed over 28,750 patent applications at the EPO concerning prescription medicines for human use.³²⁸ In total, including also patents pre-dating year 2000, nearly 40,000 patents or patent applications related to the 219 INN were reported/filed as further elaborated below.
- (423) Originator companies were also asked at which stage of development of a drug candidate (R&D, pre-clinical, clinical phases 1-4 or other) they file their patent applications. Many respondents said that they do not keep records of that nature. As a general rule, companies stated that they mostly file patent applications during the research phase. For those companies which were able to offer information on this subject, the majority of their applications (84%) were indeed filed during the research phase. However, on an aggregate sample of top 20 INNs by total sales as analysed below, it appears that patenting steadily continues throughout all stages of development and after the first launch of a product.

³²⁸ The expression "prescription medicines" was defined as including not only substances or medicines which are already available on prescription but also those which have the potential to become prescription medicines.

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- (424) The originator companies were asked to give details for the period 2000 – 2007 of all patents in force and those granted, as well as applications pending, in the 27 Member States for the 219 INNs. In order to determine the potential effect on competitor companies, each application filed at the EPO and still pending was taken as being an application for a patent in each designated State (if one of the 27 Member States). Hence, a pending European Patent application which designated five Member States was counted as five individual applications, one for each designated Member State.
- (425) It was submitted in the public consultation that this method multiplied the total number of patents by all the national validations and designations. However, given that European Patent applications, when granted, led to a bundle of national patents, and absent an EU-wide judiciary (with the exception of opposition and appeal proceedings at the EPO), per country counting is more representative of the patent situation potential entrants into R&D and product markets are facing. Frequently, entry strategies may need to diverge from one Member State to another in view of divergent patent positions owing to patents possibly being upheld in litigations in certain Member States and annulled in others. Looking from a commercial perspective, if a company has a patent annulled in front of one national court this may influence litigation strategies but does not change the patent situation as such in any of the other 26 Member States. Accordingly, the challenger may need to analyse the sum of all national patents in all those Member States where it intends to launch a product and confront those which are potentially problematic. This is further exacerbated by the existence of patents filed nationally and various patterns of designating Member States in the EPO patent applications or renewing validated national patents. In the same vein, even certain originator companies and associations thereof contend that the markets in EU are fragmented due to this and thus e.g. do not allow generic companies to develop economies of scale. However, to convey the full picture, analysis based on the number of patent bundles has been added where it was deemed necessary to address the comments.
- (426) As indicated above, the responses of the originators revealed that for the 219 INNs nearly 40,000 patents had been granted or patent applications (as defined above) were still pending. Just over three quarters (78%) of these cases were filed directly with the EPO (count based on around 2,000 reported EPO applications) and 22% with national patent offices.³²⁹
- (427) Of the nearly 40,000 cases, some 87% were classified by the companies as involving secondary patents, giving a primary:secondary ratio of approximately 1:7.³³⁰ Of the

³²⁹ It should be noted that a direct application at a National Patent Office could, in principle, still be filed at the EPO within the priority year for search and examination by the EPO. In such cases, national application filings are often simply used to establish a priority right.

³³⁰ This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying intentions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

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applications still pending, 93% were classified as secondary (a primary:secondary ratio of approximately 1:13), whilst 84% of the patents granted were classified as secondary (a primary:secondary ratio of approximately 1:5).

- (428) Certain submissions received during the public consultation pointed out that the terms 'primary' and 'secondary' patent are not known in patent law. This is not questioned by this report, which however gives recognition to the fact that these terms are commonly used by originator companies themselves as evidenced in their internal documents. For the purpose of the present analysis, patents have been therefore divided into primary patents protecting the active ingredient, and secondary patents, protecting all other aspects relating to a pharmaceutical product³³¹. It needs to be underlined that this categorisation does not suggest that secondary patents are as such of inferior importance, quality or legitimacy.
- (429) The subject-matter of the secondary patent applications filed in respect of the 219 INNs was largely concerned with claims to products, processes and second/further medical uses. Table 19 gives details of the four most frequent categories of claim in secondary patents.

Table 19: Subject-matter of secondary patents or patent applications as classified by the companies

Subject-matter claimed	% with at least one claim to subject-matter
Products	81%
Processes	38%
Second/further medical uses	24%
First medical uses	6%

Source: Pharmaceutical Sector Inquiry

- (430) A further breakdown of the product claims in Table 20 shows a significant tendency to file claims to formulation products,³³² with 57% of all product claims being directed to such products. Different physical forms of an INN (polymorphic forms, salts, hydrates, particles and solvates) accounted for a further 13% of product claims.

³³¹ See Chapter B.1.2.

³³² The term "formulation products" covers those claims classified by companies as 'formulations', 'dosage forms' or 'tablets'.

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Table 20: Break-down of product claims³³³ in secondary applications

Category of product claim	% of all product claims
Formulations	57%
Devices	7%
Combinations	7%
Polymorphic forms	5%
Salts	4%
Intermediates	4%
Substances	4%
Product by-process	4%
Unspecified	3%
Hydrates	2%
Particles	1%
Solvates	1%
Others	1%

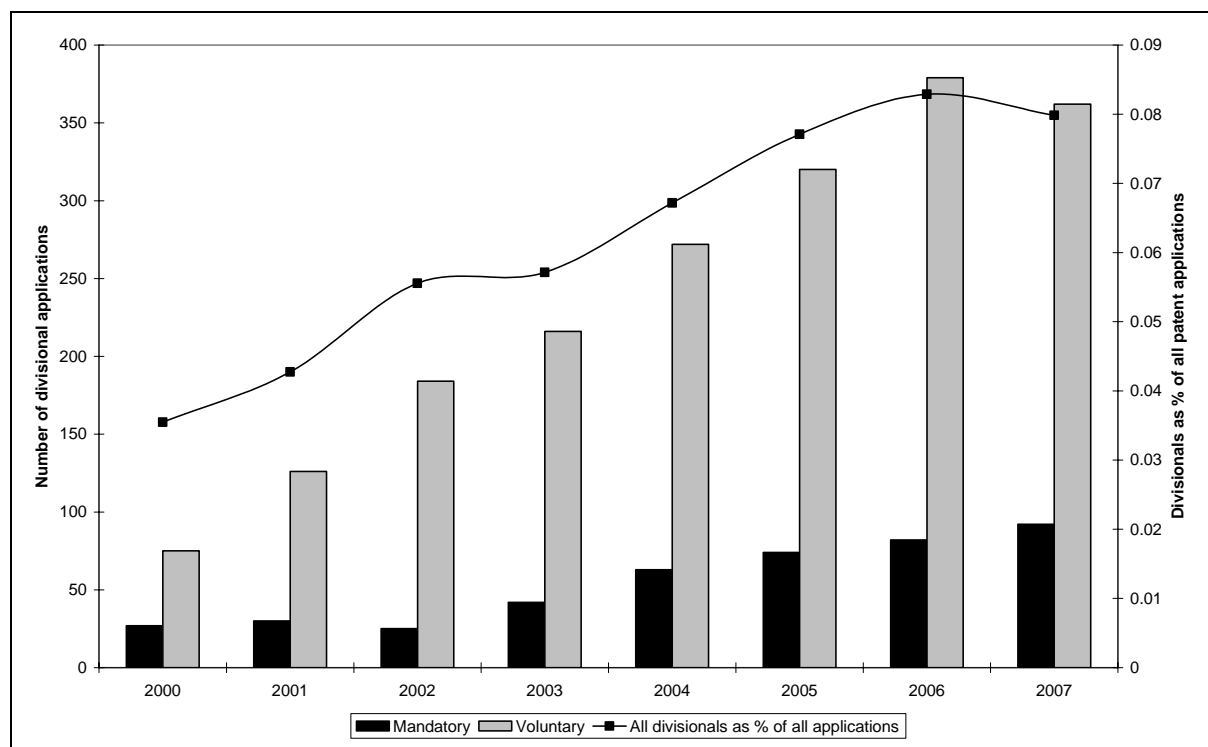
Source: Pharmaceutical Sector Inquiry

- (431) A divisional patent application is created where the applicant, either voluntarily or at the request of the examining office, divides out from a patent application ("parent patent application") one or several (identical or narrower) patent applications ("divisionals"). Such a divisional application can only be undertaken as long as the parent patent application is still pending.
- (432) According to the information provided by EPO, the incidence of filing of divisional applications has significantly increased in the period 2000 – 2007 within the A61K* universe, as Figure 46 shows. For A61K*, the total number of divisional applications rose from 102 in 2000 to 470 in 2007. Compared to the number of overall application in A61K*, the relative share of divisional applications rose from 3.5% in 2000 to 8% in 2007. The percentage of divisional applications within all EPO applications has grown in a parallel manner, from 2.3% in 2000 to 4.9% in 2007, yet remains, in relative terms, on a lower level than in A61K*.

³³³ For a brief explanation of these types of claims, see Annex: Claim Types (Annexes to Chapter B).

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Figure 46: Number of divisional applications in A61K* by year of receipt, type and as percentage of all patent applications in A61K*



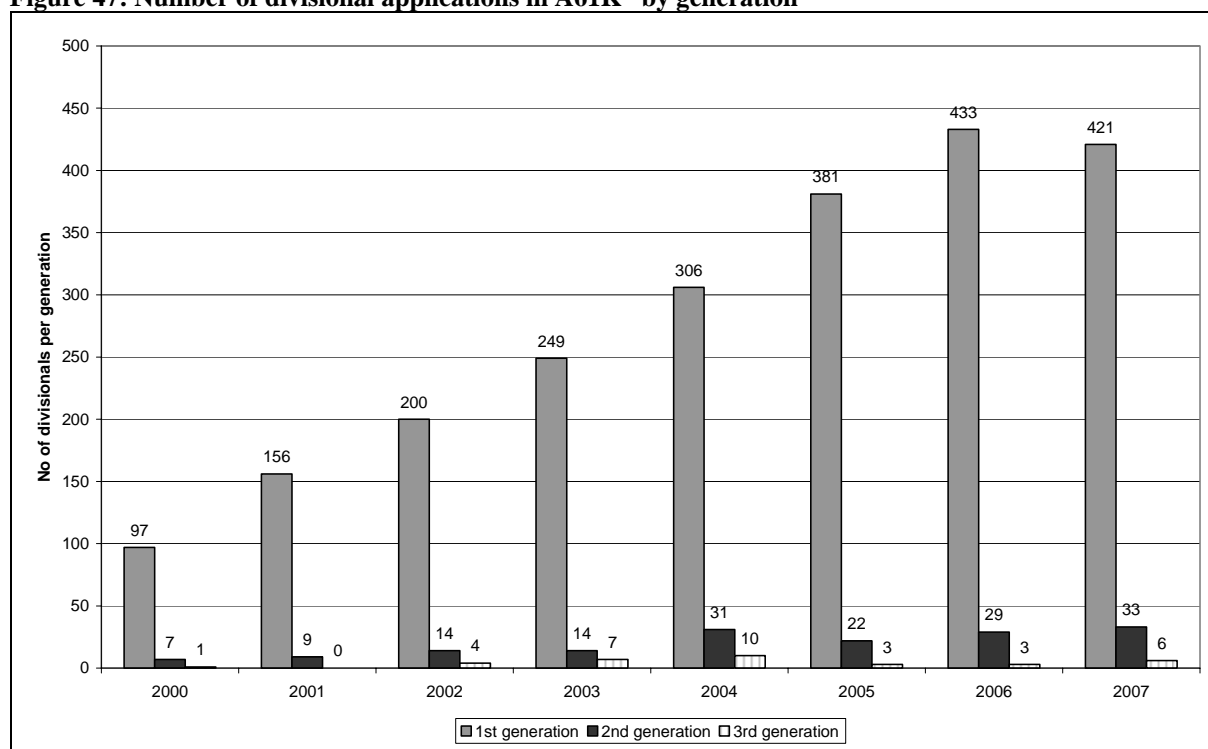
Source: Pharmaceutical Sector Inquiry

- (433) Figure A61K* also makes a distinction between mandatory divisional applications, i.e. those filed at EPO's request, and voluntary divisional application, filed on applicant's own motion. The figure shows that a large majority of divisional patent applications are done on a voluntary basis by patent applicants themselves. In 2000, 73.4% of divisional applications were voluntary, and by 2007, this percentage has stabilised in the region of 80%.
- (434) A divisional application may serve as the basis for further divisional applications. Thus, an initial patent application may be followed by one or more generations of divisional applications. Figure 47 provides an overview of divisional filings per generation for A61K*. Throughout the period, second and further generation divisionals account for around 8% of all divisionals.³³⁴

³³⁴ A recent change to the EPO rules has introduced limitations on the period within which voluntary divisional filings can be made, as described in Chapter D.1.

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Figure 47: Number of divisional applications in A61K* by generation



Source: Pharmaceutical Sector Inquiry

1.2.3. Outcomes of Patent Applications

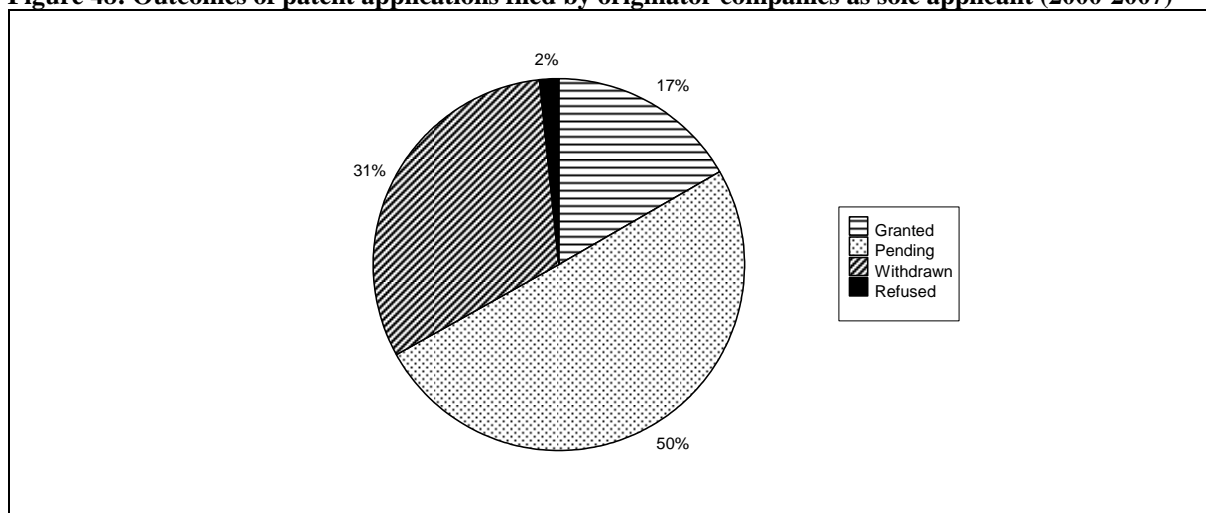
- (435) Companies were asked to comment on the source and fate of patent applications made over the period 2000 – 2007. From the data received, it emerged that the vast majority (95%) of patent applications filed at the EPO by originator companies are made with the company as sole applicant.³³⁵
- (436) Figure 48 shows the fate of the patent applications for prescription medicines for human use filed at the EPO between 2000 and 2007 with the originator company as sole applicant. In 50% of the cases, no decision has yet been reached, 17% were granted a patent, 31% of applications were withdrawn and 2% were refused. For the cases decided in the sample as defined, this translates into 34% granted and 66% refused/withdrawn.³³⁶

³³⁵ A preference for being the sole applicant also emerged from the responses to questions on patent applications at the EPO concerning prescription medicines.

³³⁶ No further breakdown between refused and withdrawn patent applications was possible since a considerable number of originator companies reported that they did not keep separate statistics for withdrawals and refusals.

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Figure 48: Outcomes of patent applications filed by originator companies as sole applicant (2000-2007)



Source: Pharmaceutical Sector Inquiry

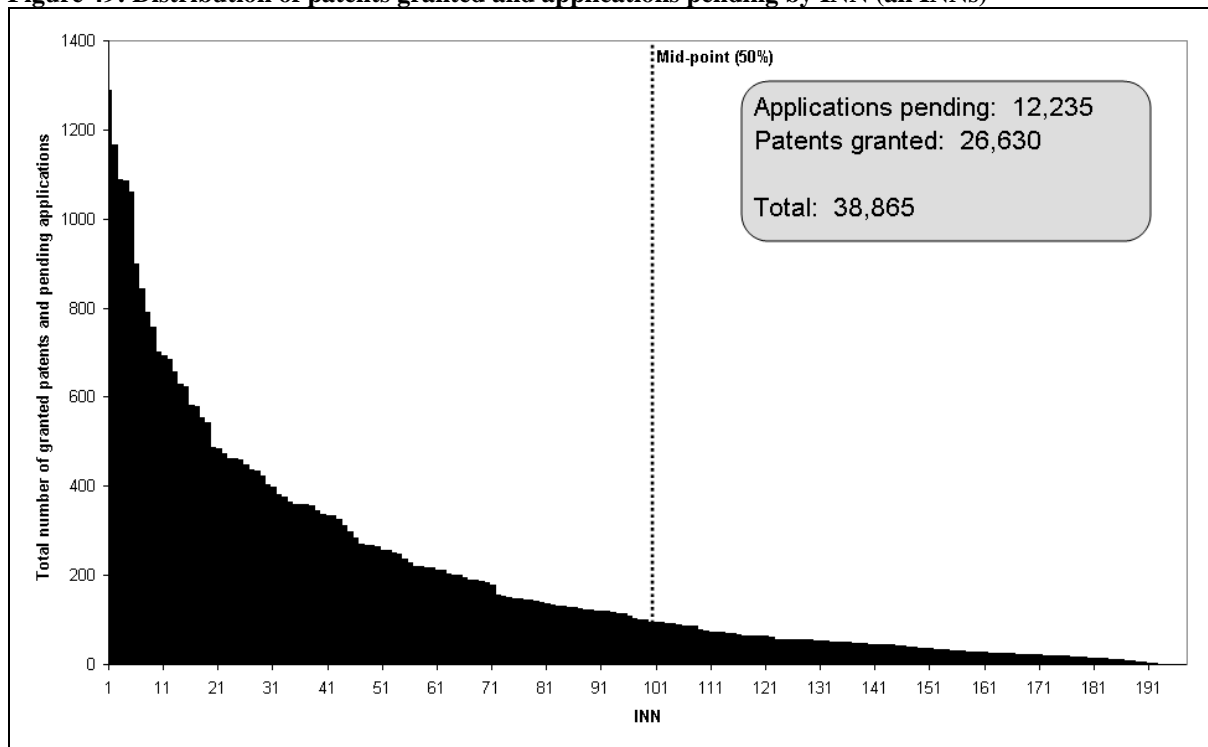
(437) The situation for cases where the originator company was a co-applicant (5% of applications) was similar to that presented in Figure 48.

1.2.4. Patent Portfolios

(438) This sub-section considers patent applications and patents granted together as a whole in order to give a more general picture of the use of patents by originator companies.

(439) The data provided by respondent companies concerning their patent portfolios in relation to the 219 INNs were analysed for trends in distribution. Figure 49 shows the distribution of patents and patent applications based on the information available on 219 INNs in the 27 Member States (relevant information on 22 INNs was incomplete or missing). The number of granted patents and pending applications can be as high as 1,300 per INN. It should be noted once again that the number of patents and patent applications relates to the number of Member States where a patent has either been validated or has the potential to be validated (because the application designates the Member State).

Figure 49: Distribution of patents granted and applications pending by INN (all INNs)



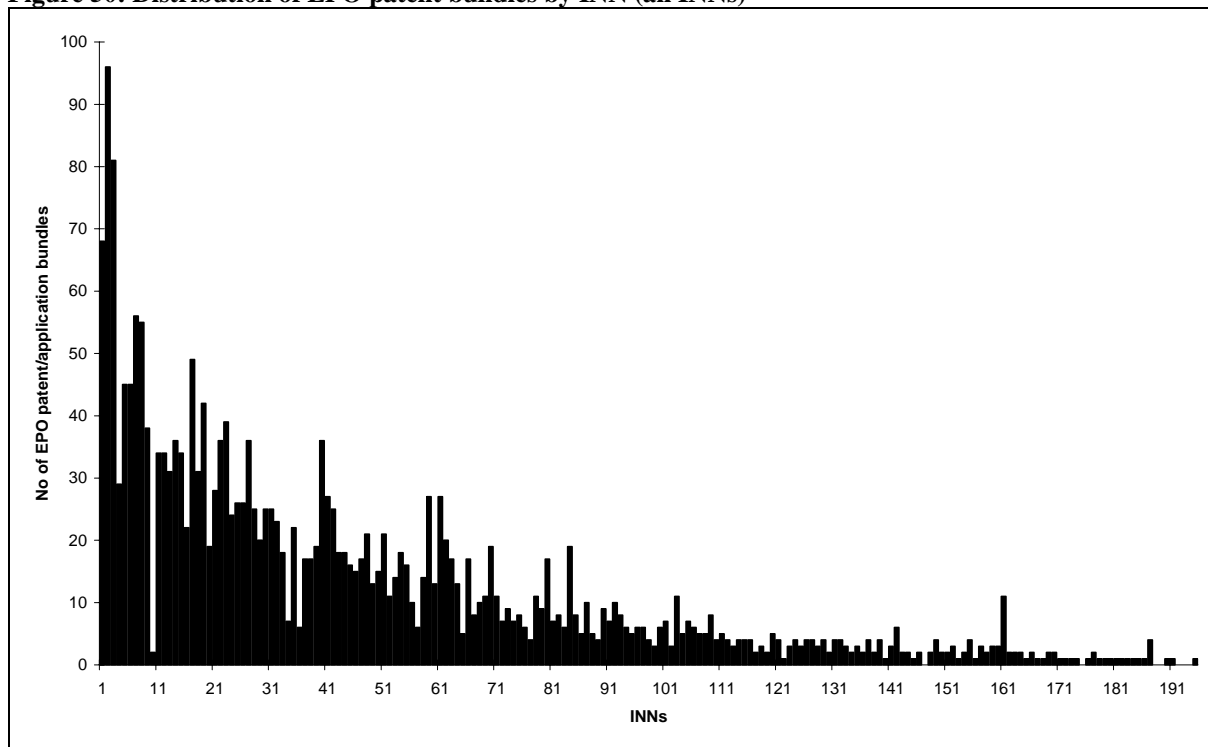
Source: Pharmaceutical Sector Inquiry

- (440) It is also clear from Figure 49 that the majority of granted patents (or applications) held are for a small proportion of the 219 INNs. For example, the top 20% of INNs (by total number of patents granted and pending applications) account for 60% of all patents and applications, whilst the top 50% account for 90%.³³⁷
- (441) The number of patents and patent applications may also be analysed from a strictly patent law perspective, as suggested by a number of respondents during the public consultation. This can be done by aggregating all national (granted or potential) patents stemming from a single EPO patent application. As mentioned above, this would disregard that EPO applications lead to a bundle of national patents, which have an independent existence as they need to be litigated and renewed separately. Figure 50 shows the distribution of EPO patent bundles and applications related to a single INN and Figure 51 shows national patents/patent applications filed nationally, per INN.

³³⁷ A small number of patents granted (or applications pending) was found to cover more than one INN. In these cases, the patent (or application) in question was counted in the total for each INN to which it relates.

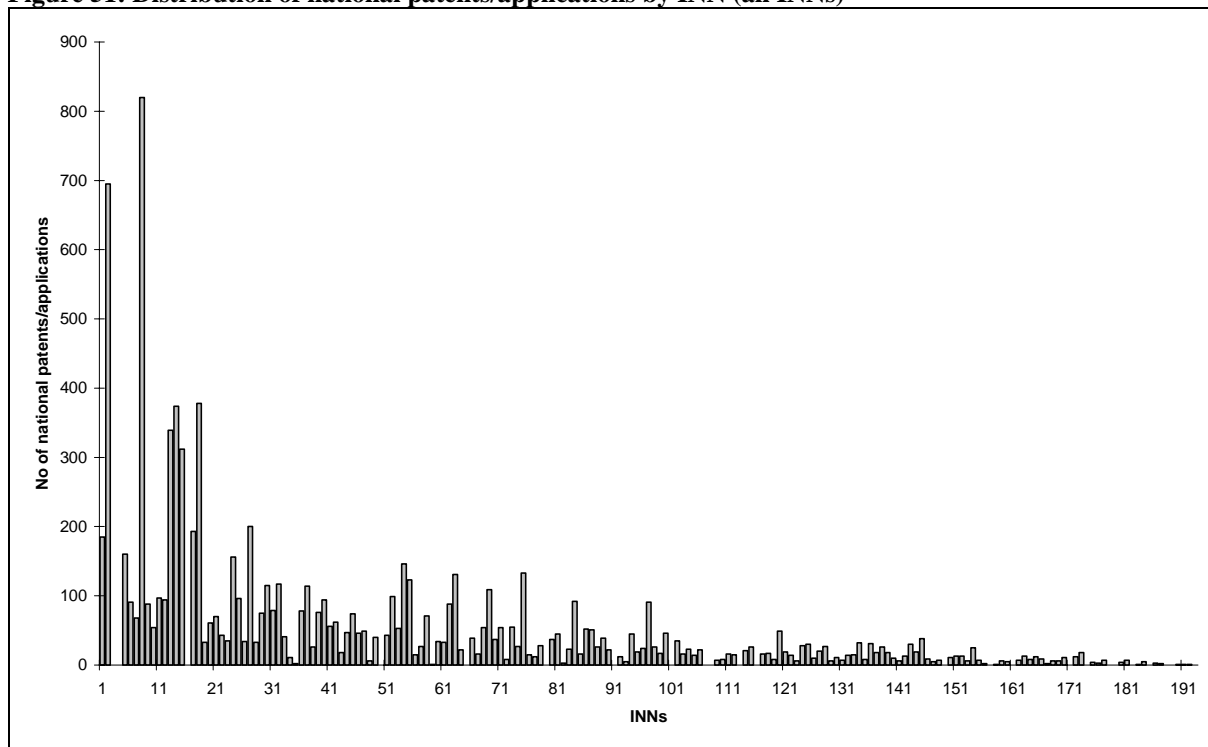
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Figure 50: Distribution of EPO patent bundles by INN (all INNs)



Source: Pharmaceutical Sector Inquiry

Figure 51: Distribution of national patents/applications by INN (all INNs)



Source: Pharmaceutical Sector Inquiry

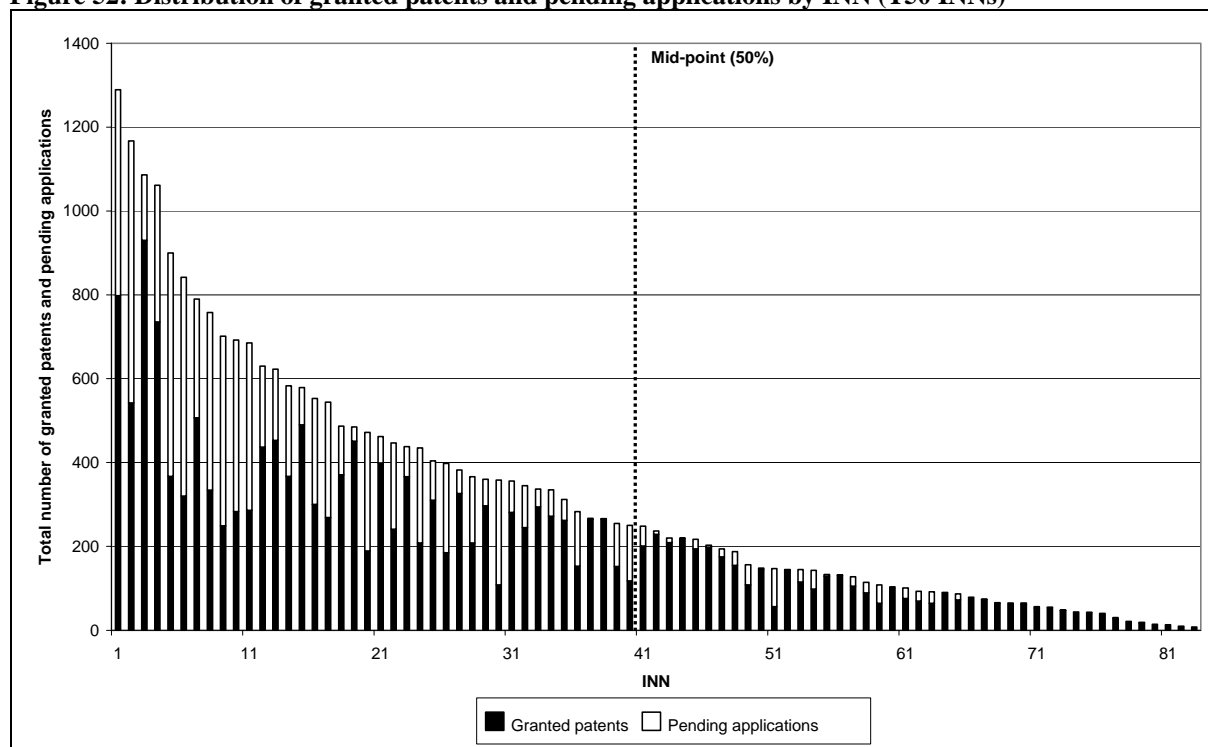
(442) Figure 50 and Figure 51, where INNs are represented in the same order as in Figure 49, show the distribution of EPO patent families and national patents/application per INN. As expected, Figure 50 shows a much lower number of patent families, with maximum 96 patent families for a single INN. The graph also shows that top third

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INNs in terms of patent protection are on average protected by almost 30 patent families. Having said this, it follows from Figure 51 that the number of national patents/applications remains very elevated for some top INNs and reached around 800 and around 700 counts in two INNs, respectively. Such high numbers of national patents/applications are observed notably among INNs with the most numerous patents which however only feature a low number of EPO patents/patent applications.

- (443) Based on the methodology underlying Figure 49, i.e. counting each member of a patent family as one entry, Figure 52 shows a similar distribution pattern for the T50 INNs. It also draws a distinction between patents granted and patent applications per INN. As is clear from the figure, the upper half of the INNs sorted by number of granted patents and pending applications reveals a high degree of ongoing patenting activity, with a significant number of patent applications pending. Patent applications account for 38% of the aggregate number of granted patents and applications for the upper half of the INNs, which stands in stark contrast to only 12% of applications in the aggregate number for the lower half. Another noteworthy observation which arises from the comparison of Figure 49 and Figure 52 is that the median number of patents held in the T50 group (see Figure 52) is 237, whereas that of all INNs (see Figure 49) is only 98.5.

Figure 52: Distribution of granted patents and pending applications by INN (T50 INNs)



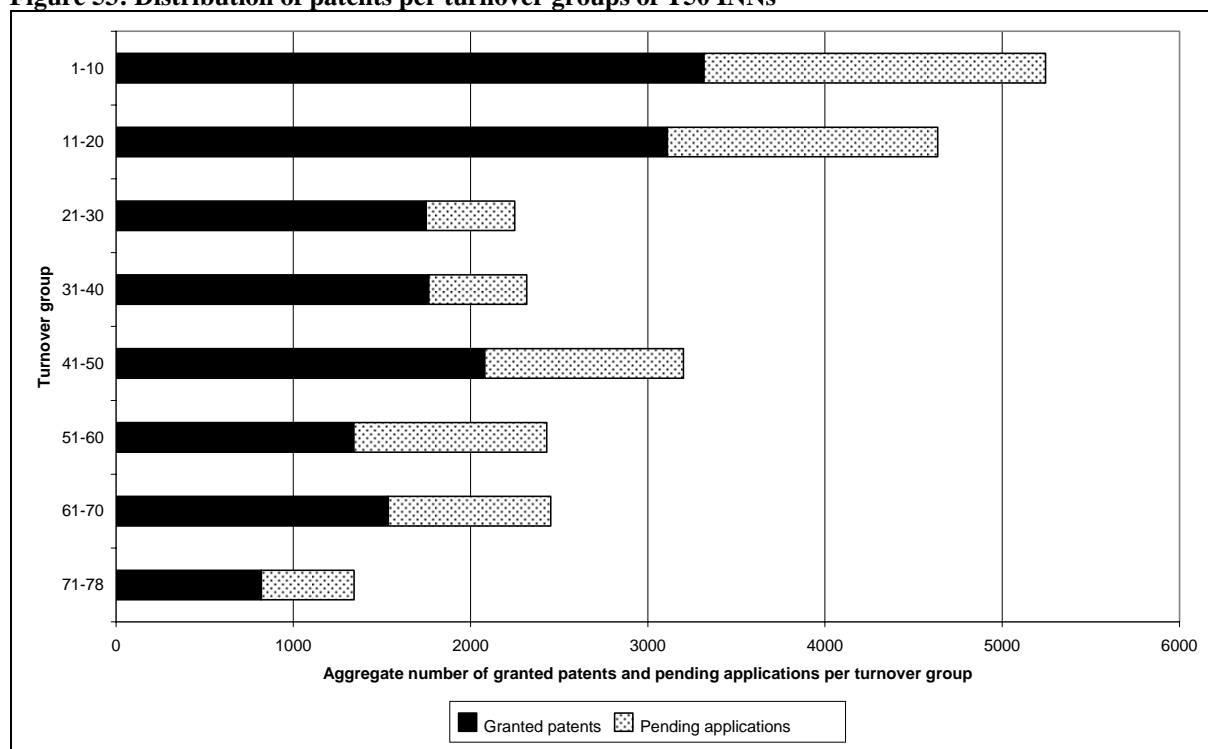
Source: Pharmaceutical Sector Inquiry

- (444) Figure 53 shows the distribution of granted patents and pending applications as a function of the market value of INNs from the T50 group. For this purpose, INNs were divided into groups based on average sales values for the period 2000 – 2007 in the EU (where this information was available). Overall, Figure 53 shows that the number of granted patents and pending applications increases with the value of the INN, in particular for the top-selling INNs in the T50 group. The figure also clearly demonstrates that the twenty top-selling INNs, i.e. groups 1-10 and 11-20, have by far the largest numbers of granted patents and pending applications. More specifically, the top ten INNs have more than 5,000 granted patents and pending applications, whilst

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INNs 11-20 have around 4,500. The mid-tier groups of INNs (in terms of sales) show a fairly even distribution of patents and applications, with between 2,000 and 2,500 per group, with the exception of INNs 41-50, which have more than 3,000. The last group (INNs 71-78) has a significantly lower number of granted patents and pending applications; however, this cannot be explained solely by the fact that it consists of two INNs fewer than the other groups.

Figure 53: Distribution of patents per turnover groups of T50 INNs



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

1.2.5. Patent Portfolio Life Cycles of Some Important INNs

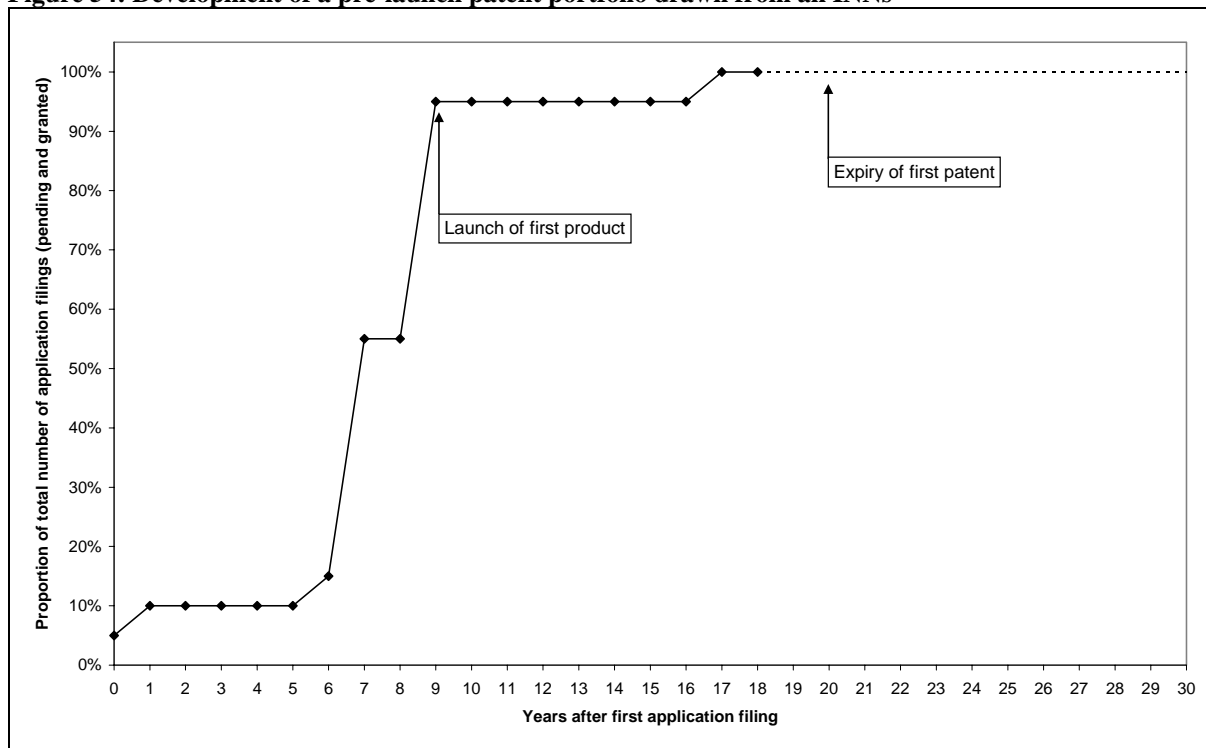
- (445) Patent portfolio life cycles were determined in terms of development of the patent portfolio over time by looking at patent applications filed for each INN in the years following the filing of the first (primary) patent. In almost every case, one or more applications filed in the first year ("year 0") for a basic patent are typically followed by filings for formulations, processes and the like in subsequent years. In contrast to the previous subsection, for this analysis applications at the EPO were counted only once. Moreover, only granted patents or pending applications were counted in the analysis. No account was taken of applications which had been filed, but subsequently refused or withdrawn, since these no longer present obstacles to competitors.
- (446) It has been submitted that patent portfolios tend to develop over time,³³⁸ with many applications filed in the years immediately following the first application for a given INN. It has also been said that these subsequent applications, or "secondary patents",

³³⁸ EFPIA: Intellectual Property and Pharmaceuticals. June 2008, Section 2.11 and Figure 2.

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can be filed before the first launch of a product containing the INN. This pattern could be described as a "pre-launch patent portfolio". Indeed, a number of examples were found amongst the 219 INNs analysed in the inquiry. One such case, for which 19 years' data were available, is presented in Figure 54.

Figure 54: Development of a pre-launch patent portfolio drawn from all INNs



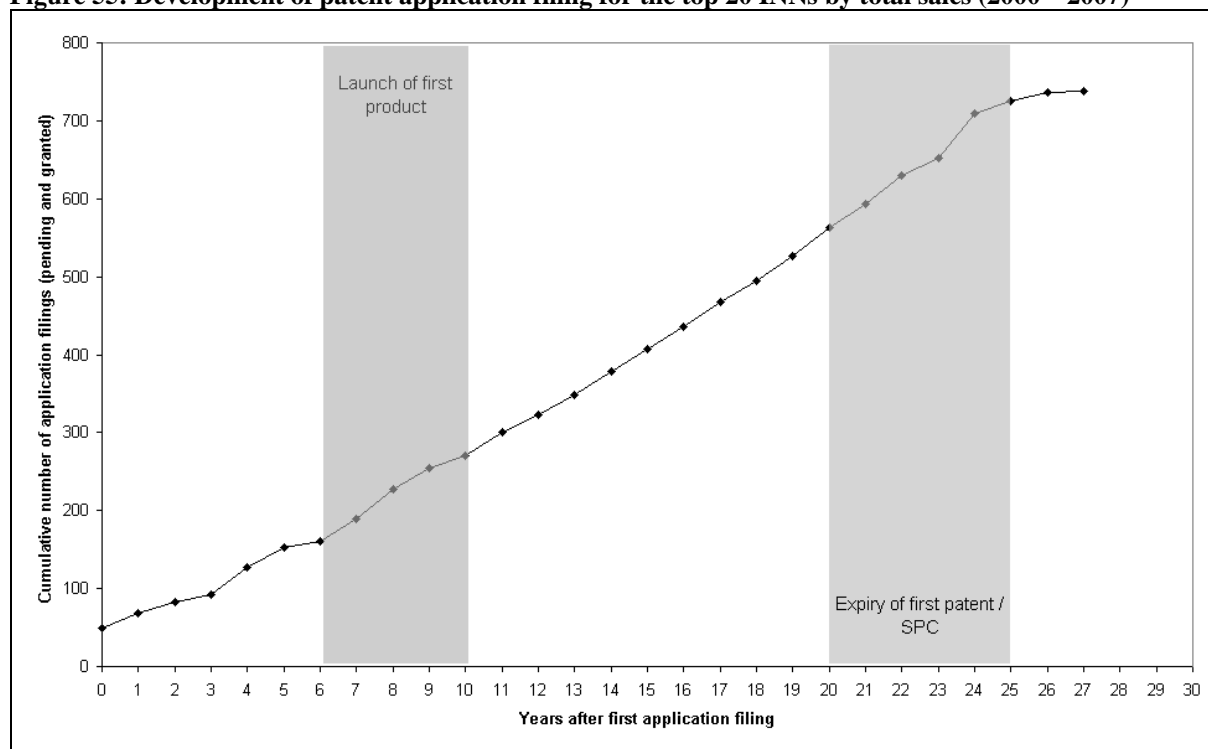
Source: Pharmaceutical Sector Inquiry

- (447) Figure 54 clearly demonstrates that the majority of patent applications for inventions involving this particular INN were filed in the years prior to the launch of the first product.
- (448) Figure 55 shows the cumulative development of patent portfolio life cycles for the top twenty INNs from the E75 group in terms of their total sales over the period 2000 – 2007. The graph shows the aggregate number of patents filed per year by the first originator company for each INN following the filing of the first application(s). Thus, Year 0 is the year when the first applications were filed and Year 17 is the eighteenth year following the first application. The graph further shows the periods during which the first product was launched for the twenty INNs (this ranged from six to ten years after the first patent application was filed) and when the first patent, and any related SPCs,³³⁹ might be expected to expire. It should be noted, however, that an SPC does not necessarily exist for each INN.

³³⁹ Supplementary Protection Certificates (SPCs) are discussed in Chapter B.2.1.

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Figure 55: Development of patent application filing for the top 20 INN by total sales (2000 – 2007)

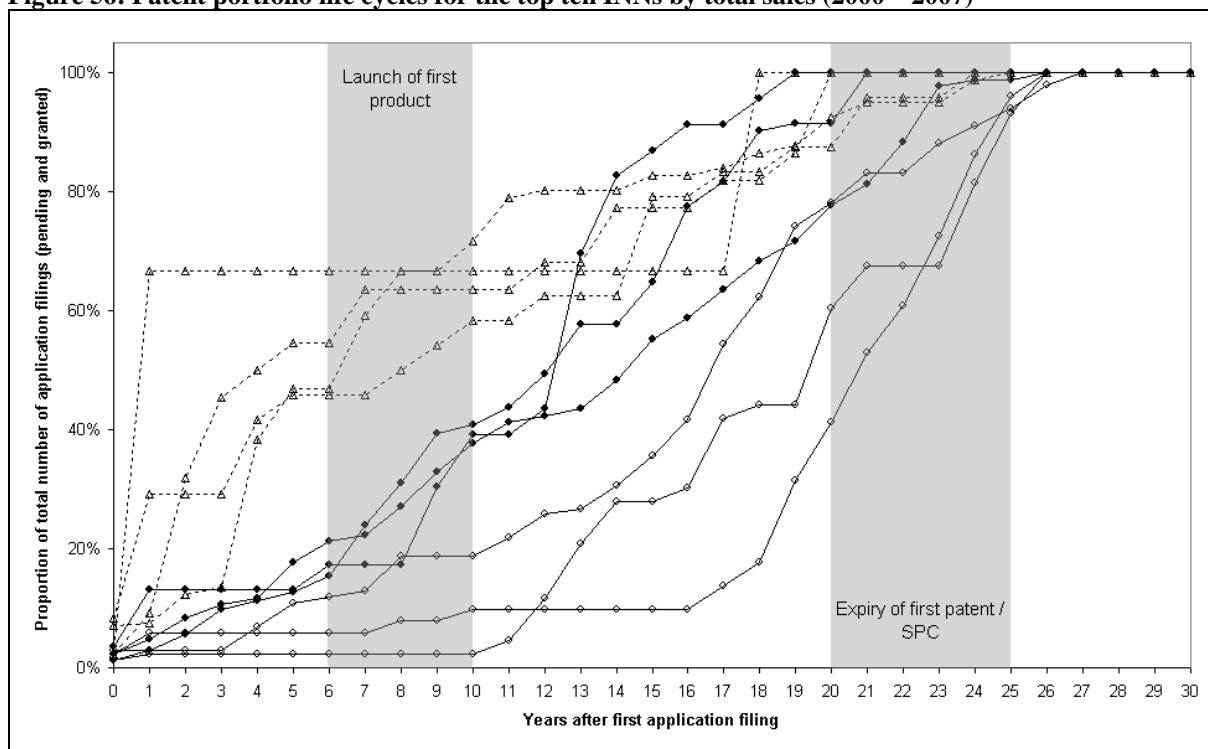


Source: Pharmaceutical Sector Inquiry

- (449) Figure 55 shows that, on an aggregate level, very few of the total number of patent applications were filed before the first product launch. Instead it suggests a steady increase in the number of applications over the whole lifetime of the primary patent, with a decline in the years immediately after the patent and/or SPC expires. This being said, it needs to be borne in mind that these findings relate to the sample of 20 top-selling INN, and are not necessarily representative for all INN.
- (450) The situation looks rather different when INN are examined on an individual basis. Figure 56 shows the development of the patent portfolio life cycles for each of the top ten INN from the E75 group (in terms of their total sales over the period 2000 – 2007) as a percentage of the total number of applications filed for each INN. The graph also indicates the period during which the first products for each INN were launched and the period over which the first patent for the INN, including any supplementary protection certificate (SPC), might be expected to expire. At least six of the top ten INN, shown as open (-○-) and filled (-●-) circles, display patent portfolios where under 50% of the total number of patents are filed before the first product is launched and where the majority of the applications are made well after that date. The remaining applications, shown as open triangles (-Δ-), are more in keeping with the "pre-launch patent portfolio" (see Figure 54).
- (451) Figure 56 depicts a clear trend in the case of the top ten INN for companies to file significant numbers of patent applications well after the first product launch, in particular immediately before or after the primary patent in the portfolio expires.

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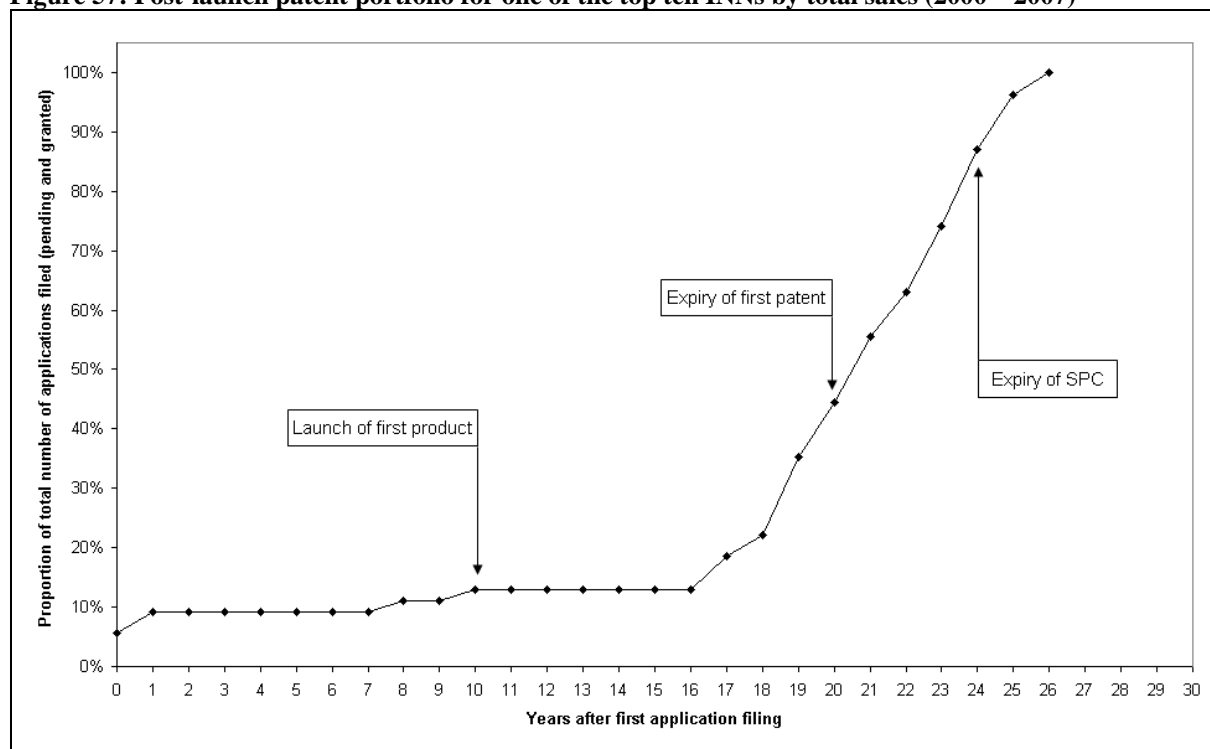
Figure 56: Patent portfolio life cycles for the top ten INN by total sales (2000 – 2007)



Source: Pharmaceutical Sector Inquiry

(452) Figure 57 depicts a patent portfolio, where the large majority of patent applications related to an INN were filed after the patent launch and which could be described as post-launch patent portfolio. This post-launch patent portfolio is drawn from the top ten INN by total sales, which shows a surge of patent application in the years immediately preceding loss of exclusivity. This is in stark contrast to the pre-launch patent portfolio shown in Figure 54.

Figure 57: Post-launch patent portfolio for one of the top ten INN's by total sales (2000 – 2007)



Source: Pharmaceutical Sector Inquiry

- (453) During the public consultation, originator companies and associations thereof submitted that there is no such thing as a "conventional life cycle" as any life-cycle will be determined by concrete factual and technical circumstances. This comment is corroborated by Figure 56, which depicts a variety of patenting life-cycles. Some respondents also contended that Figure 55, showing the average development of patent applications filing would be a more typical example, as "innovator companies permanently keep on innovating and improving their products and processes". However, this does not explain why, in the above samples of top-selling INN's, this continuous development is suddenly discontinued shortly upon loss of exclusivity as shown in Figure 56 and Figure 57, even more so in cases of patent life-cycles with intense patenting activities in the years preceding loss of exclusivity. Moreover, Figure 56 shows that, for the top selling INN's, such cases of continuous development are fewer than the post-launch patent portfolios.
- (454) In the public consultation, an association of originator companies also contended that, in relation to Figure 57, none of the patents based on applications filed after the market launch could possibly prevent competition in respect of products marketed before these applications were filed. This would, according to the association, be "for the simple fact that, to the extent that they covered such products, they would be invalid for lack of novelty".
- (455) In order to consider this claim, further analysis has been undertaken in order to verify whether patents with applications post-dating the market launch of the initial product and the primary patents are enforced against companies attempting to launch a generic version of that initial product. To that effect, information on patents invoked in litigation cases, information on whether the generic versions at the source of litigation copied the essential elements of the initial product (e.g. as regards API, salts, process,

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formulation) or not, and information on initial entry per INN was compared. The comparison led to a narrower sample of litigations involving generic products copying the essential elements of the originator product in general and for which all relevant information from originator companies was available: 23 INNs and around 150 instances of litigation.³⁴⁰

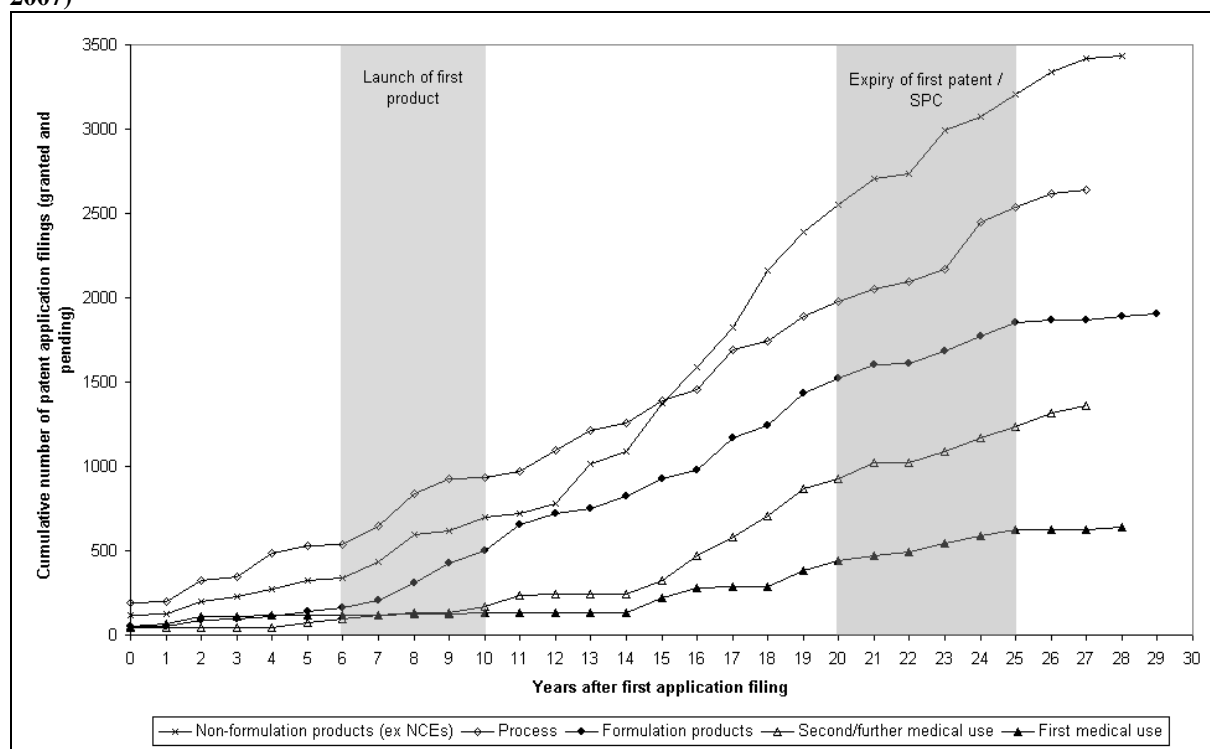
- (456) Contrary to the statement by the association, patents which were filed for after the initial product had already been launched were invoked in relation to attempted entry of generic versions of the initial product copying the essential elements of the latter in about one third of the cases (both in terms of INNs and individual litigation cases).³⁴¹
- (457) A final insight into patent portfolio life cycles is presented in Figure 58. In view of the tendency of companies to file secondary applications for five main categories of claims (see Table 20), each patent for each of the top twenty INNs by total sales was analysed to see which types of claims it contained. Claims were divided into the following categories: non-formulation products, which include products such as salts, polymorphic forms, particles, solvates and hydrates but exclude NCEs; formulation products, including those classified by respondents as 'tablets' and 'dosage forms'; processes; first medical use claims; and second/further medical use claims. Figure 58 plots the cumulative number of patents with claims in each of the five categories as a function of time (calculated as the number of years following filing of the primary patent).

³⁴⁰ As compared to approximately 700 litigation cases analysed in Chapter C.2.2.

³⁴¹ Data available did not allow for further analysis.

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Figure 58: Patent portfolio life cycles as a function of claim types for the top 20 INN by total sales (2000 – 2007)



Source: Pharmaceutical Sector Inquiry

- (458) The results in Figure 58 show, once again, the trend for companies to continue to file patent applications as the expiry date of the first (primary) patent approaches. Figure 58 also indicates a marked preference for non-formulation product-related claims towards the end of the patent portfolio lifetime. In particular, the filing of claims to non-formulation products increases substantially after the 15-year mark.
- (459) Since more than one category of claim can be present in any given application, the sum of the figures in Figure 58 exceeds 100% of the total number of patents filed for these INNs. Interestingly, the number of product claims excluding formulations is much higher for the top ten INNs (where the ratio of non-formulation product:formulation product claims is approximately 2:1) than for the average of the 219 INNs covered by the inquiry (which have a non-formulation product:formulation product ratio of around 1:1 — see Table 20).

1.2.6. Patent Applications Filed by Generic Companies

- (460) Primarily, the sector inquiry sought to collect information on patents relating to the list of 219 INNs identified as being of greatest significance to the investigation. In view of the definition of "originator company" for the purposes of the sector inquiry, such patents are *ipso facto* held by originator companies. However, generic companies are also frequently involved in filing patent applications. Consultation of EPO public

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databases³⁴² reveals that many of the generic companies questioned in the inquiry were increasingly more active in filing applications for patents over the period 2000 to 2007. In particular, the information in the databases reveals that many of the generic companies regularly file applications for secondary patents on many of the INNs covered by the inquiry. Moreover, these secondary patent applications relate, *inter alia*, to manufacturing processes, formulations, polymorphic crystalline forms, salts, particle sizes and tablet forms of INNs for which the primary patent is held by an originator company.

- (461) It was submitted during public consultation that the statistics on patent portfolios should not only relate to patenting by originator companies, but should also investigate further the growing trend of secondary patents by generic companies. However, as explained in Chapter A, the main focus of the sector inquiry was on competition between originator and generic companies on the one hand, and, on the other, amongst originator companies. It should also be noted that throughout the investigation, there have been no indications that patenting activities by generic companies, which are unlikely to hold a dominant position, would have negatively affected the possibility for generic or originator companies to enter the market. Likewise, only a limited number of cases reaching litigation have been reported where a generic company claimed infringement of its own patents by an originator company, be it as a counterclaim or in its own separate action.³⁴³

Summary

The pharmaceutical sector is one of the main users of the patent system. The number of pharmaceutical-related patent applications before the EPO nearly doubled between 2000 and 2007. Patents concerning the active substances are also referred to by the industry as "primary patents" because they relate to the first patents for their medicines. Further patents for such aspects as different dosage forms, the production process or for particular pharmaceutical formulations are referred to by the industry as "secondary patents".

In general, blockbuster medicines' patent portfolios show a steady rise in patent applications throughout the life cycle of a product, also after product launch. Occasionally they show an even steeper increase at the end of the protection period conferred by the first patent. In patent litigation cases originator companies often rely on patents that were not yet filed when their product in question was launched.

³⁴² Register Plus on EPOLine® allows free on-line public inspection of all EPO patent application files. Register Plus was searched using generic company names as the applicant. For further information see: <http://www.epoline.org>.

³⁴³ In view of the stress on the importance of incremental innovation, patenting activity by generic companies can be equally considered a welcome trend.

2. Competition Between Originator and Generic Companies – The Issues

- (462) The present chapter examines the competitive relationship between originator and generic companies which market pharmaceutical products in the European Union. As explained in Chapters B.1.1., B.1.2. and C.1., originator companies produce and sell pharmaceutical products developed during a lengthy and costly research and development (R&D) process, involving substantial commercial risks. The resulting originator products are protected by intellectual property rights (in particular by patent rights), which give the originator company the opportunity to recoup investment costs and provide incentives to originator companies to continue innovating, which can make important contributions to meet interests patients need.
- (463) This chapter does not question the value of (incremental) innovation. Neither does it aim to provide guidance on whether certain types of practices could be considered compatible or incompatible with the EC competition law. Such an assessment would require in-depth analysis of the individual practice taking into account the factual, economic and legal background. The Commission will further investigate whether individual company behaviour may have fallen foul of the competition rules.
- (464) Originator companies compete with other originator companies (see Chapter C.3.) as well as with generic companies. In principle, generic companies produce and market an equivalent version of the originator medicine once patent protection of the medicine has expired. However, competition between generic and originator companies may begin before patent expiry if the generic company finds a way of entering the market without infringing the patent protecting the originator product, or if the patent relied upon by the originator company is not valid, in particular if it is annulled prior to the formal patent expiry date.³⁴⁴
- (465) As explained in Chapter B.1.3., the prices of generic medicines are substantially lower than those of originator products. The entry of a competing generic product on the market inevitably results in a significant decline in the price and market share of the corresponding originator product. Therefore, originator companies may seek to protect their market position using various means ranging from strategic patenting around the product to patent litigation and interventions before national regulatory authorities.
- (466) The purpose of the present chapter is to examine to what extent originator companies employ instruments of the "tool-box"³⁴⁵ to delay or block the entry of competing generic products on the market. Therefore, the following issues are examined:

³⁴⁴ As explained above, protection can also stem from SPC and/or data/market exclusivity. (The latter does not however provide legal exclusivity.)

³⁴⁵ The analysis of general strategy documents of originator companies confirmed that this terminology is commonly used in the industry. It should not be misunderstood to mean that all companies use all instruments for the protection of their products. Nor does the use of the term in this report suggest that the individual instruments would be illegal.

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Patent strategies of originator companies: the first section examines the various patent strategies employed by originator companies with the aim of maximising profit derived from their patented products and shielding them from competition. The section focuses in particular on patent strategies involving patent clusters³⁴⁶ and divisional application and their intended effects.

Patent-related contacts, disputes and litigation: the second section examines the patterns and the outcome of patent enforcement by originator companies both in patent-related exchanges out of court (such as contacts and disputes) with generic competitors and in patent-related litigation cases before national courts. The section also looks, in greater detail, at costs related with patent litigation, divergence of decisions and interim injunctions.

Opposition and appeals: the third section studies the patterns and outcome of patent opposition procedures and appeals filed by generic companies at the European Patent Office (and at national patent offices), in order to establish whether this provides an alternative route for generic companies to secure their market entry.

Settlements and other agreements: the fourth section analyses the various types of agreements concluded between originator and generic companies. It focuses on settlements of patent disputes, litigation and opposition procedures, and other agreements (such as licence and distribution agreements) and examines companies' considerations for entering into such agreements. This section also contains a brief overview of the established patent settlement practise in the USA as compared with the EU.

Other factors affecting generic entry: the fifth section examines strategies and actions of originator companies aimed at national regulatory bodies (such as marketing authorisation and pricing and reimbursement bodies), other stakeholders (e.g. doctors and pharmacists) as well as distributors and API producers. This section examines pre-litigation contacts and disputes as well as litigation in which originator companies are involved.

Life cycle strategies for follow-on products: the sixth section analyses the relevance of follow-on products and the mechanisms employed by originator companies to switch patients from an earlier generation to follow-on products. In particular, the practices which may facilitate such patient switches are examined.

Cumulative use of practices: the seventh section examines various life cycle tools which may be used cumulatively by originator companies and may affect the entry of the generic product into the market.

³⁴⁶ This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying intentions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

2.1. Patent Filing Strategies

- (467) For the purpose of this section the term "patent strategies" should be understood to encompass all strategies of a company concerning the use of the patent system to the benefit of the company in relation to generic competition.³⁴⁷ The term includes strategies on the timing and scope of filing as well as the manners in which patents are applied for.
- (468) As already mentioned, in addition to the primary functions of exclusion/protection and information, patents have a multitude of other functions such as creating "freedom to operate", bargaining, standardisation, and company image. Furthermore in some cases originator companies might also have incentives to maintain and use patents for their effect of blocking or delaying the development of a generic product.
- (469) In fact, patent strategies can form part of a company's tool-box³⁴⁸ which are used in order to protect continuous revenue streams from pharmaceutical products by preventing or delaying generic entry.
- (470) This section will look at different scenarios that may entice an originator company to employ patent strategies with the aim of preventing or delaying generic market entry.³⁴⁹ It will then examine the use of patent clusters and the use of divisional applications. Thereafter it will examine the intended effects of this strategy, including litigation strategies in the context of patent enforcement.
- (471) For the purpose of illustration a number of quotes have been added, which form only a part of those obtained in the course of the sector inquiry. They may be taken from general policy documents or concrete instructions for individual cases. Most of the quotes were taken from documents obtained during the unannounced inspections by the Commission in January 2008.
- (472) It is not the purpose of this sector inquiry to provide guidance as to the compatibility of certain practices with EC competition law. The Commission will further investigate whether individual company behaviour may have fallen foul of the competition rules.

³⁴⁷ In so far as patent strategies specifically aim to prevent other originator companies from developing or marketing products competing with a product of an originator company, they will be analysed in a separate section, see below Chapter C.3.1.

³⁴⁸ For the different elements of life cycle strategies see above: Chapter B.1.2. During the public consultation the use of the term "tool-box" in the preliminary report has been criticised as giving it a "pejorative" meaning. This term however has not been invented for purposes of this report. Rather it has been found to be used by several originator companies within their strategy documents. Moreover, the use of various instruments varies from company to company and from product to product. In the present chapter, the instruments most observed were analysed.

³⁴⁹ During the public consultation it has been submitted that terms, such as "delaying" and "blocking" were used for certain practices of originator companies, which would discredit their behaviour. These terms, however, have not been invented for purposes of the report. Rather they have been found to be used by originator companies within their strategy documents as can be seen in the quotes shown in the subsequent subsections.

2.1.1. Scenarios of Generic Market Entry Addressed by Patent Strategies

(473) Information and data gathered in the course of this inquiry, in particular from companies' strategy documents, indicate that the ultimate aim of protecting the market share of a product is pursued by some major originator companies by obtaining the most efficient, broadest and longest possible patent protection for this product and variations thereof.

(474) An originator company issued internal guidelines as how to draft applications with regard to generic competitors:

"The description should include sufficient specific reproducible examples to make the scope of claim a reasonable generalisation of the examples. Our primary objective is to obtain claims that will be effective against generic competitors."

(475) Two scenarios seem to be particularly noteworthy in this context.³⁵⁰

- How can an originator company ensure that its (blockbuster) pharmaceutical product enjoys exclusivity at least until the end of the patent protection period of the base patent³⁵¹ in cases where generic companies threaten the base patent by challenging its validity?
- How can an originator company prolong the exclusivity period beyond the expiry of the base patent? This may serve to simply preserve continuous revenue streams, where no follow-on product has been developed or to bridge a gap between the loss of exclusivity and the market launch of a follow-on product which is intended to take over market shares of the old product (for life cycle strategies for follow-on products, see also Chapter C.2.6.).

(476) To ensure exclusivity at least until the end of the patent protection period of the base patent, originator companies may file for a multitude of patent applications (on process, reformulation, etc.) protecting the product in addition to the base patent with the aim of creating several layers of defence. Such a multitude of patents is often referred to as a "patent cluster"³⁵². Thus where generic companies might manage to

³⁵⁰ This section focuses on patent strategies employed by originator companies. Patenting strategies may also be employed in the context of life cycle management, i.e. a commercial switch to a follow-on product, yet this aspect will be looked at in more detail in Chapter C.2.6. While generic companies tend to file for patent applications nowadays as well, in particular for different salt forms of a particular substance when its base patent expires, the majority of patents are obviously being held by originator companies; see above Chapters B.1.2. and C.1.2.

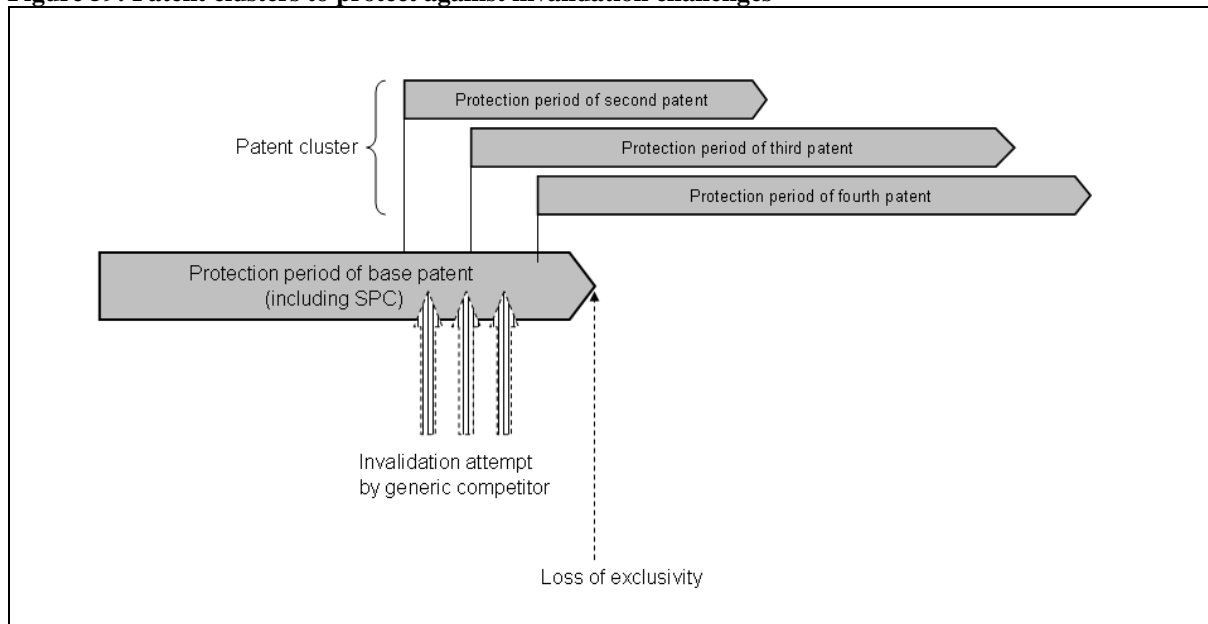
³⁵¹ While such base patents, usually claiming the invention of a new active substance, often constitute the first patent to protect a product, there are also cases where a secondary patent turns the active substance into a medicine.

³⁵² This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive

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invalidate the base patent before its regular expiry they still cannot enter the market, if the originator company has succeeded in creating what some originator companies call "a multilayered defence" by other patents for such aspects as different dosage forms, the production process or for particular pharmaceutical formulations. This is illustrated in Figure 59:

Figure 59: Patent clusters to protect against invalidation challenges

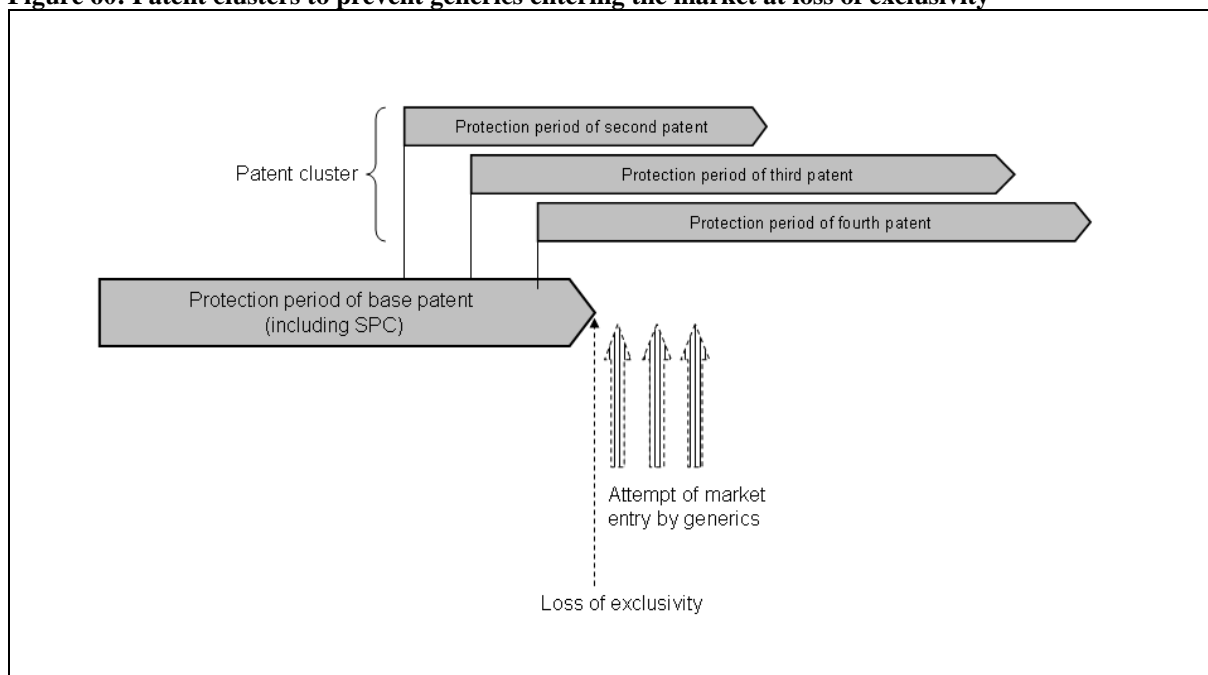


Source: Pharmaceutical Sector Inquiry

(477) The second scenario shows a situation where an originator company obtains a multitude of patents (on process, reformulation, etc.) protecting the product, i.e. a patent cluster, during and towards the end of the protection period of the base patent, with the aim of keeping generics off the market beyond expiry of the first patent. This is illustrated by the following figure:

step and (3) industrial application. The underlying intentions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

Figure 60: Patent clusters to prevent generics entering the market at loss of exclusivity



Source: Pharmaceutical Sector Inquiry

- (478) It has been submitted by a UK based research body dealing with all aspects of intellectual property law that the more likely scenario of the two would be the latter one as generic companies would wait until the expiry of the base patent before contemplating launch which is also supported by the fact that patent litigation mainly concerns secondary patents^{353 354}.
- (479) It goes without saying that for both scenarios a company can rely on the same patents constituting the patent cluster surrounding the base patent. Thus, the scenarios overlap to the extent that the same set of patents may (i) disable generic entry before the end of the protection period stemming from the base patent, while they may also (ii) postpone generic entry after the base patent expired.³⁵⁵

³⁵³ Patent law does not make a distinction between "primary" and "secondary" patents, and patents need to be evaluated on the basis of the statutory patentability criteria, not on the basis of the stage in which applications are made. The notion of "secondary patent" should not be understood to mean that these patents are of a lower quality or value, but merely that – from a time perspective – follow the primary patents. Yet the term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices, see also Chapter A. Introduction of this report.

³⁵⁴ For further details see Chapter C. 2.2.

³⁵⁵ During the public consultation it has been submitted that a later patent cannot extend the protection period or scope of an earlier patent as each patent is for a different invention. This, however, has never been claimed in the preliminary report. It is rather extending the exclusivity period of a product that the filing of patent applications towards such aspects as a different production process or for particular pharmaceutical formulations can be aimed at as the quotes from strategy documents below show. Furthermore, contrary to a statement made by an originator companies' association, subsequent patents

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- (480) Under certain circumstances the patent strategy might also pursue a more specific objective, namely to facilitate the switch to follow-up inventions or second generation products, criticised as "evergreening" by the generics industry, which will be analysed in more detail in Chapter C.2.6. below.
- (481) A patent cluster may consist of granted patents as well as pending applications. Under certain circumstances, originator companies may also multiply the number of pending applications by filing for divisional patent applications dividing out from a parent patent application one or several (narrower) applications, which, after that division, all have a procedural life of their own, however, without extending the protection period of the parent application.
- (482) Furthermore, according to Article 67 of the EPC in connection with Article 64 thereof, an application can from the date of its publication provisionally confer upon the applicant the protection of a patent, including damage claims, if provided for under national law. This is also applicable for divisional applications.
- (483) In the following, patent cluster and divisionals are analysed, before their intended effects are examined.

2.1.2. Patent Clusters

- (484) It can be observed that originator companies' patent applications may be very broad in scope and claim a multitude of different innovations surrounding the original compound, including e.g. formulations, dosage regimes, processes etc.³⁵⁶
- (485) Such patents may signify an increase of incremental innovation, which can be of significant importance. Following the filing of a basic patent application, further research into a particular development candidate (or series of candidates) can give rise to the need for further patent protection for improvements of the basic active agent such as salt forms, metabolites or polymorphs. Similarly, problems with the administration of a therapeutic agent might lead to the need for formulation patents, whilst clinical trials may reveal new medical uses.

(which were filed for after the initial product had already been launched) were invoked in relation to attempted entry of generic versions of the initial product copying the essential elements of the latter in about one third of the cases examined (both in terms of INNs and individual litigation cases). For further details see Chapter C.1.2.

³⁵⁶ This corresponds with findings of an OECD study that patenting has increased in the last ten years in particular in the sectors of ICT, pharmaceuticals and chemicals, where companies reported that they now patent inventions that they would not have sought to patent 10 years ago. This trend was most pronounced in chemicals industry followed by the pharmaceuticals and ICT industry, see OECD pp. 91, 92., see: Patents, Innovation and Economic Performance: OECD Conference Proceedings, Science & Information Technology 2004, vol. 2004, no. 13, at: <http://massetto.sourceoecd.org/vl=1083396/cl=28/nw=1/rpsv/ij/oecdthemes/99980134/v2004n13/s1/p11>. For the different types of patents in the pharmaceutical sector see Chapter B.2.1. and Annex: Claim Types (Annexes to Chapter B).

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- (486) For some companies the trend towards broader and more patents aiming at protecting a product constitutes a change, as the following quote of an originator company illustrates:

*"Before end 80s: Products mainly NCEs which were protected by the one patent- [...]
Late 80s – early 90s[...] Expansion of the portfolio to cover lifecycle initiatives, to extend protection time for product and the breadth of the protection trying to keep competition further away."*

- (487) Of the 43 originator companies asked, seven stated that they did not have specific patenting strategy documents. The remaining 36 submitted such documents indicating that as a general policy they filed for a multitude of patent applications surrounding the first patents of a successful compound and its product in order to protect their position. The use of patent clusters is illustrated in a strategy document from an originator company:

"Clustering – protecting the companies (sic) products and processes...Clustering involves three components

- Broad Scope*
- Maximizing Patent Term through innovation*
- Layered protection"*

- (488) As the analysis of patent portfolios in Chapter C.1.2. confirmed, many INNs, in particular the commercially important ones, are surrounded by a multitude of patents and patent applications. The analysis showed that the number of granted patents and pending applications significantly increases with the value of the INN, in particular as regards the 20 top-selling INNs. In fact, blockbuster medicines can even be protected by up to nearly 100 INN-specific EPO patented bundles and applications (sometimes also referred to as patent families), which in one particular case lead to 1,300 patents and applications across all the EU Member States.³⁵⁷ Despite the lower number of underlying patent families based on EPO applications, looking from a commercial perspective, a challenger may need to analyse and possibly confront the sum of all existing patents and pending patent applications in those Member States in which the generic company wishes to enter.

- (489) The ratio of primary to secondary patents³⁵⁸ (and their applications) is 1:7. As mentioned earlier, as regards to the top 20 INNs by total sales, claims of their

³⁵⁷ During the public consultation it has been submitted the number of 1,300 patents should be reviewed to remove the so-called "Member State" effect avoiding double counting of patents being part of the same patent family.

³⁵⁸ During the public consultation it has been submitted that the distinction between primary and secondary patents is irrelevant under patent law. Whilst this is acknowledged it has to be underlined, however, that this distinction has not been invented for the purposes of the preliminary report. Rather, it has been found

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secondary patents mostly concern formulations, processes and non-formulation products (excluding NCEs), such as salts, polymorphic forms, particles, solvates and hydrates.

- (490) During the public consultation it has been submitted that the distinction between primary and secondary patents is irrelevant under patent law. Whilst this is acknowledged it has to be underlined, however, that this distinction was not invented for the purposes of the preliminary report. Rather, it has been found to have been employed by several originator companies in their strategy documents as e.g. quotes in the subsequent paragraphs show (see also Chapter C.1.2.). Thus, the term is being used by the report, as it constitutes part of the terminology and concepts employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices.³⁵⁹
- (491) In this context, another originator company explained:

"To maximize patent coverage on our commercial products, patent applications will also in general be filed to cover any novel potentially commercially important aspect of products such as processes, formulations, additional pharmaceutical or other indications and salts/solvates/physical forms (so called 'secondary' or 'subsidiary' patent protection)."

- (492) The consequence of maximising patent coverage in such a way is the creation of a web of patents. In such a situation any attempt to develop a generic version of the medicine in form of a salt, a crystalline or amorphous form would inevitably infringe a patent (for example a patent for the relevant salt, crystalline or amorphous form of the medicine).
- (493) Originator companies could thus use their web of patents to prevent or delay generic entry, as illustrated by the following originator company's quote:

"We were recently successful in asserting the crystalline form patent in [name of country], where we obtained an injunction against several generic companies based on these patents by 'trapping' the generics: they either infringe our crystalline form patent, or they infringe our amorphous form process patent when they convert the crystalline form to the amorphous form. [...] The availability of 'trapping' strategy will be evaluated on an on-going basis."

- (494) In a similar way the following quote of an originator company demonstrates how salts and intermediates are used in order to create such blockades:

"I suppose we have all had conversations around "how can we block generic manufacturers". [...] Don't play games in patenting new salt forms too late, the

to have been employed by several originator companies in their strategy documents as e.g. quotes in the subsequent paragraphs show. See also Chapter C.1.2.

³⁵⁹ See also Chapter A on the use of terminology.

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generics are starting earlier and earlier. Get claims on key intermediates that cover a number of routes. Process patents are not the biggest block but can put generics off if a superior chemistry job is done."

- (495) This quote also confirms that timing is of crucial importance. As shown above, many patent applications are filed in the period prior to lapse of patent protection of the existing product, possibly in an attempt to prolong the originator's term of protection. Typically, such patent applications are filed in anticipation of imminent generic entry. This is evidenced by the following quote of an originator company:

"Our intelligence reveals that [generic company name] is developing a [salt form] of [patented pharmaceutical]. [...] Fortunately we had anticipated the possibility of such a threat and last year filed several applications to alternative salts, including two for the [salt form]."

- (496) In fact, the analysis in Chapter C.1.2. confirms that patent applications are filed at regular intervals over a 20-year period following the first filing of an application for a given INN. Many of the top-selling INNs, i.e. those which generate substantial revenues, do not have a traditional patent portfolio life cycle. Instead, a significant increase in the number of patent applications filed is seen towards the end of the lifetime of the first patent in the portfolio.
- (497) Incremental innovation can be of significant importance, e.g. when developing new administration routes, dosages or revealing new medical uses, as already explained above. Such innovation can lead to an increase in secondary patents.
- (498) However, generic companies their associations and consumer associations have submitted that the filing of numerous patent applications in order to create patent clusters around one product can also lead to "weak patents".³⁶⁰
- (499) Generic companies maintained that originator companies obtain "weak patents" since in their opinion novelty and inventive step requirements, in particular for secondary patent applications, were too easily considered to be met by the EPO, an argument which was also reiterated during the public consultation.³⁶¹
- (500) In this context it needs to be pointed out that certain types of prior art may be "unsearchable" and thus not easy to detect for the EPO. Furthermore, examination by the EPO does not include any experiments to verify applicant allegations.³⁶²

³⁶⁰ The use of the term "weak patent" in this context has been criticised by originator companies, their associations and intellectual property associations, claiming that a patent once granted cannot be described as weak or strong but only as valid or invalid if declared so by the relevant office or court.

³⁶¹ For further details see Chapter D.1

³⁶² See Chapter B.2.1.

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- (501) As later shown the final outcome in 60 % of opposition and appeal procedures against originator company's patents examined in this report was a revocation of the disputed patent. In addition to this, the scope of the patents was reduced in another 15%.³⁶³ These procedures almost exclusively concerned secondary patents. Furthermore in 55 % of the patent litigation cases between originator and generic companies that involved a question of the disputed patent's validity and that reached a final judgement, the patents were annulled (43 of 78 cases).³⁶⁴
- (502) Originator companies and their associations have submitted that these outcomes do not give any substantial indication on the quality of patents in patent clusters, in particular secondary pharmaceutical patents, as generic firms will only tackle those patents that they consider to be most contentious and that are protecting commercially viable and interesting products. In this context, it has to be said that existing patent litigation is the only tangible parameter of assessing the validity of such pharmaceutical patents.³⁶⁵ Furthermore most patent clusters, in fact, concentrate on commercially viable, i.e. successful products such as blockbusters.³⁶⁶ Thus it is only logical that these patents are disputed through litigation by originator companies eager to protect their products and generic companies that are eager to enter the market. Furthermore the commercial success of the products in question points to an important patient demand that has been met. Thus from society's viewpoint if numerous patents protect such products their validity is of particular importance.³⁶⁷
- (503) Remarks by originator companies themselves indicate doubt as to the inventiveness and strength of their patents and suggest that the purpose of obtaining secondary patents was to keep generic competitors off the market, as is illustrated by the following quote taken from an inspection document:

³⁶³ For further details see Chapter C.2.3.

³⁶⁴ See Chapter C.2.2.

³⁶⁵ Also, it must be noted that even if only a limited number of cases reach final judgement, it is interesting to record their outcome as they can provide insights into the current situation. Furthermore, it must also be noted that the fact that certain patents have not been challenged in court does not necessarily provide certitude as to their ultimate solidity.

³⁶⁶ For further details on numbers of patents protecting blockbuster medicines see Chapter C.1.2.

³⁶⁷ For further details see Chapter C.2.2.

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"Late 80s – early 90s [...]"

- Some of those patents are inevitably more vulnerable and more likely to be challenged [...]

- Strategy – better to have patent which might not be "rock solid" than no patent.

All patents and applications create a hurdle/problem for a competitor [...]"

- (504) The originator company goes on to specify that nowadays the weakness of patents is taken into account when seeking to extend the protection period:

"Today [...]"

Inevitably there will be patents covering products on the market that can be, and will be challenged [...] The strategy today is to try and provide a solid protection for the substance (has a limited time though) and a portfolio protecting different aspects of product providing extended protection both in brea(d)th and time but inevitable less solid and robust."

- (505) In general, originator companies will be very discreet about the relative strength or weakness of their patents and urge their employees not to commit any evaluation of their patents on paper, as the following quote from internal communications of an originator company shows:

"I am sure you are aware that we prefer to communicate opinions regarding the strength of our patent property verbally, rather than in writing, which can result in an overly wide circulation, and no doubt you will bear this in mind when advising your regulatory colleague."

- (506) Generic companies increasingly view the practice of broad patenting of secondary patents around the basic product, which they often describe as "patent thickets"³⁶⁸, as an obstacle, which is only being pursued in order to *de facto* extend the exclusive position of the originator in respect of the active ingredient.³⁶⁹

³⁶⁸ This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying interventions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology."

³⁶⁹ For further details see Chapter D.1.

2.1.3. Divisional Patent Applications

- (507) The increased use of filing of divisional patent applications, in particular before the EPO, has been an object of complaints by the generic industry as a potential instrument to prevent or delay generic entry.
- (508) Therefore, this section does not want to question the legitimacy of divisional patent applications as such which are foreseen under patent law. It rather seeks to examine in how far the use of the application procedure for such divisional patents may under certain conditions affect generic entry.
- (509) As already explained,³⁷⁰ a divisional patent application is created where the applicant, either voluntarily or at the request of the examining office, divides out from a patent application ("parent patent application") one or several (narrower) patent applications ("divisionals"). Such a division must be undertaken as long as the parent patent application is still pending. However, once created, a divisional has a life of its own, i.e. even if the parent patent application is refused or revoked, the divisional would still be pending. The divisional will have the same priority and application date as the parent patent application. In other words, if granted, a divisional will, in principle, provide the same duration of patent protection as the parent application. Furthermore the divisional application cannot go beyond the scope of the parent application.³⁷¹
- (510) As shown above, the vast majority of divisional applications before the EPO in 2008 for A61K*, the closest proxy for pharmaceutical patents, were created voluntarily by the patent holders whereas only about 20% were divisional applications requested by the EPO. The increase of voluntarily created divisional applications also seems to reflect a new trend within the pharmaceutical sector.³⁷²
- (511) Of the 43 originator companies addressed, eleven companies declared that in the period 2000 to 2007 they had filed for divisional patent applications where the corresponding parent application had subsequently been refused or withdrawn. The numbers of individual divisionals varied between 1 and 30.
- (512) The sector inquiry unearthed a number of situations, where stakeholders claimed that originator companies insisted on pursuing the grant procedure for divisional patents, even if the parent patent application was subsequently refused or withdrawn.
- (513) For example, for some originator companies, the divisional appeared to be a means to expedite prosecution for certain more unproblematic or interesting claims, while other claims of the parent application might still be questioned by the EPO or be of less scientific or commercial interest to the applicant.

³⁷⁰ For further details see Chapter C.1.2.

³⁷¹ For further details see Chapter B.2.1.

³⁷² For further details see Chapter C.1.2.

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- (514) One purpose of divisional patent applications, namely to protect the existing product, is illustrated by the following reflection of an originator company in one of its strategy documents:

"Secondary patents

What can be done apart from extending the basic patent on the active compound (API)? File divisionals or new applications relating to the specific API - narrower claims are easier to defend and enforce."

- (515) Another reason given by some companies for using divisionals where parent applications were subsequently refused or withdrawn was to gain more time to answer objections made by the patent office examiners to claims in the parent application. Thus one originator company explained:

"The divisionals were filed because the time granted by the examiner to reply to the objections against the patentability of the respective parent applications was not sufficient. Filing a divisional application in these cases gives more time for preparing the answers adequately."

- (516) Similarly another originator company explained:

"The divisional was filed in order to reset the acceptance deadline clock and allow more time for prosecution."

- (517) Generic companies pointed out that divisionals may be filed to prolong the period of legal uncertainty, since an applicant could use this procedure to "reset the clock" and gain more time for patent examination, thus extending the period where applications are pending. Also, as pointed out during the public consultation, each divisional application has to be assessed individually. Thus a successful challenge of a parent application will not create legal certainty as long as several other divisional applications are still pending.
- (518) Generic companies emphasised that in such cases it is virtually impossible for them to predict when which divisional application will possibly be granted. As a consequence they are unsure as to what they can reproduce without infringing any patents, even if the parent patent application has been refused or revoked. This is particularly pertinent, as a divisional application, as already explained, can confer claims for reasonable compensation on the applicant and under certain conditions lead to damages claims.³⁷³
- (519) Of the 27 generic companies 16 claimed that they have had problems with divisional filings (12 of which inter alia referred to the same INN) as one generic company claimed:

³⁷³ It has been submitted during the public consultation that divisionals neither extend the duration nor the scope of patent protection. It should be noted that this has never been stated in the preliminary report.

"[...] mainly, because they are creating additional uncertainties on our projects."

- (520) Another generic company agrees with the assessment that divisionals mainly serve to create uncertainty in this context:

"Filing of divisional applications also enables the originators to maintain the uncertainty generated by parent patent application Multiple divisional patent applications combined with abusive patent litigation and preliminary injunctions hinder the development of generic medicines."

- (521) Other stakeholders that frequently deal with IP law issues have confirmed the potential of using divisionals to create legal uncertainty in the context of the public consultation. Thus, an intellectual property law firm stated that

"Filing as many divisional patent application(s) as wanted by the applicant, at any time during the pendency of a parent application, generates legal uncertainty and unpredictability for third parties facing the pending patent application(s)."³⁷⁴

- (522) Also in this context the EPO in its submission explained that it considered the preliminary report

"... interesting for the Office as it gives further insight into certain patterns of applicant behaviours which may increase legal uncertainty, some of which are already under careful scrutiny within the EPO. In particular, internal policy discussions are ongoing with respect to a tightening of the rules governing the filing of divisional applications."

2.1.4. Intended Effects of Patent Clusters and Divisionals

- (523) The intended effects of both patenting strategies as analysed above are identical: in some case both patent clusters and divisionals seemingly serve to prevent or delay generic entry. While this, during the period of exclusivity, is generally in line with the underlying objectives of patent systems, it may in certain cases only be aimed at excluding competition and not at safeguarding a viable commercial development of own innovation covered by the clusters.³⁷⁵

³⁷⁴ This firm also pointed to cases where the EPO's Enlarged Board of Appeal had approved the practice of filing multiple divisional patent applications, including divisional patent applications from a divisional patent application, all using at their respective filing dates the exact same description and the exact same claims as for the parent patent application. An institute dealing with issues of IP Law acknowledged in its submission that there may be potential scope of misuse of the system.

³⁷⁵ During the public consultation the EPO has rightly pointed out that the purpose for which an application has been filed is not relevant to the decision-making process within the European patent system and that this should remain so. The EPO would have neither a mandate nor the resources to analyse such intentions. It goes however, without saying that the description of the underlying intentions is relevant to understand how companies use existing legislative framework for their purposes. The intention can also be taken into account in competition law assessments.

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- (524) In this context, it has to be pointed out that from a patent law perspective the intention behind companies' use of these patenting strategies is and should not be of relevance.³⁷⁶
- (525) The denser the web created by the patent clusters and/or the divisionals is, the more difficult it will be for a generic company to bring its generic version of the original pharmaceutical to the market. That is to say, even though the main patent protecting the product, e.g. the basic substance patent, may have expired, the generic version may still infringe one of the multiple patents surrounding the original pharmaceutical. This can occur either because patents cover all economically interesting or viable salt forms, enantiomers or formulations of the compound or all efficient ways of its manufacturing. In other words patent clusters and divisionals seem to be aimed at creating legal uncertainty for generic competitors, as the following quote from a generic company illustrates in relation to patent clusters:

"The entire point of the patenting strategy adopted by many originators is to remove legal certainty. The strategy is to file as many patents as possible on all areas of the drug and create a 'minefield' for the generic to navigate. All generics know that very few patents in that larger group will be valid and infringed by the product they propose to make, but it is impossible to be certain prior to launch that your product will not infringe and you will not be the subject of an interim injunction."

- (526) An originator company's quote confirms this purpose:

"Purpose: Establish an effective barrier to generic competition by extending the term of the existing compound patent and by filing patents on further inventions that last beyond the expiry of the compound patent...The objective [of scope of patent claims] is to secure an optimal competitive position for [our company's] products in the market by blocking competitors."

- (527) Another originator company specifically emphasises the delay function of secondary patenting:

"Secondary patents will not stop generic competition indefinitely but may delay generics for a number of years, at best protecting the originator's revenue for a period of time."

³⁷⁶ During the public consultation the EPO has rightly pointed out that the purpose for which an application has been filed is not relevant to the decision-making process within the European patent system and that this should remain so. The EPO would have neither a mandate nor the resources to analyse such intentions. It goes however, without saying that the description of the underlying intentions is relevant to understand how companies use existing legislative framework for their purposes. The intention can also be taken into account in competition law assessments.

2.1.4.1. Limitations of Generic Entry as an Immediate Consequence of Patenting

- (528) As shown above, patent strategies can lead to significant uncertainty concerning the possibility of a legitimate and commercially viable generic entry. Patent clusters and/or divisionals may without further enforcement action by originator companies, thus delay generic entry until the patent situation is clearer or even discourage more risk sensitive generic companies from entering altogether.
- (529) An originator company explained how it expected the use of its secondary patents to reduce generic uptake (and consequently to slow originator decline) over a relatively long period post-patent expiry:

"Key factors resulting in slow decline:

Patent factors: secondary manufacturing process patent or patent formulations result in limited (2-3) generic competitors over 2-3 years. [...]

Key factors resulting in medium decline:

confusing or unclear molecule patent position combined with robust defence results in 2-3 generic competitors in first year."

- (530) The impact such patent strategies can have on generic entry could also be observed in a case study based on the findings of the sector inquiry where an originator company had filed for more than 30 patent families translating into several hundreds patents in the Member States in relation to one product. More than a quarter of these patent applications were, in fact, filed after the launch of the product. These applications interfered with several generic companies' plans to develop and/or bring their generic versions of the original product to the market, led to several opposition procedures and subsequent legal disputes and in one case to abandoning the development of the generic product.
- (531) In one of its latest working papers the EPO has assessed the abuse of divisional applications in the following way:³⁷⁷

"There is a trend for applicants to abuse these procedural possibilities by using the divisional application procedure to achieve a "duplication" of the proceedings ... This is detrimental both to legal certainty for third parties and to patent office workloads."

- (532) As a consequence the Administrative council of the EPO, composed by its contracting states has agreed on a reform proposal of the EPO to introduce time limits for the filing of divisional applications.³⁷⁸

³⁷⁷ EPO paper CA/145/08 Rev. 1, subject: Divisional applications, Munich, 15.01.2009; <http://www.sipf.se/admin/photo/big/hearinginbjudan/CA14508Rev.1.pdf>. For further details see Chapter C.2.1.

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- (533) The statement of a generic company below illustrates the possible delays if the use of divisionals creates uncertainty:

"The three divisional applications are identical or practically identical to each other. It can be expected that they will be held pending and – if possible be brought to issuance – one by one so there is a constant threat and uncertainty to generic companies over years. Several opposition proceedings are pending against the [number of divisional] patent. The opposition proceedings can be expected to take about four to five years. Thereafter, nullity proceedings before the [...] Court are possible [...], which can be expected to take another two to four years."

- (534) A second generic company pointed out:

"Obviously, [originator]'s strategy is to file numerous identical or practically identical divisional applications from one basic application – which has been found invalid by the EPO! – and keep them pending. Should the grant of one of them be denied, the other still pending applications are such a threat to the generic companies that many of them are extremely reluctant to enter the market. [...] The grant [meant is: EPO decision on the patent application] can be delayed for years by [originator]."

- (535) Apart from causing delays, generated uncertainty may also lead to abandonment of development of generic versions as shown in the following testimony by a third generic company:

"The filing of divisional patent applications by another company has interfered with our plans to develop a generic pharmaceutical composition... On [date], the European Patent Office ("EPO") granted to [originator company] the European patent [number] related to the use of [INN] for treating [condition] in a [details of dosage], despite the fact that [earlier] an Opposition Division of the EPO revoked its parent patent related with the same dosage regime. The divisional European Patent EP [] is currently being opposed at the EPO by [...] companies [...]. The uncertainty generated by the decision granting European patent [number of patent above] forced our company to abandon the development project related to [originator's product name] generic drug [...]."

- (536) Originator companies, their associations, IP law firms and bodies dealing with IP law issues have submitted that generics are not necessarily forced to abandon their projects due to perceived legal uncertainty. Rather they claim that there exist several ways to clear the way such as the opposition procedure as well as litigation procedures. As explained in the respective chapters of this report these are time consuming and costly.

³⁷⁸ As of 1 April 2010, voluntary divisional applications will need to be filed within a period of two years from the first communication by the EPO examining division in respect of the parent or an even earlier (in case of a "chain" of applications) application. For further details see the Decision of the Administrative Council of 25 March 2009 amending the Implementing Regulations to the European Patent Convention (CA/D 2/09) under: <http://www.epo.org/patents/law/legal-texts/decisions/archive/20090325.html>.

2.1.4.2. Procedural Enforcement of Patent Rights

- (537) Patents are proprietary, exclusive rights and enforcing one's patents against parties infringing them is a legitimate procedural dimension of the material right granted to the patent holder. It furthermore is part of the fundamental right to a fair hearing before court as manifested in Article 7 of the European Convention of Human Rights (ECMR).
- (538) The preceding subsection showed that the use of patent clusters and divisionals by some companies may deter or delay generic entry merely by their existence. In other cases, companies may proceed with the development of generic versions with a view to enter the market at risk. In such cases, patent clusters and also divisionals are an indispensable asset for originator companies' implementation of their procedural enforcement strategies. These strategies will typically lead to patent litigation, but can also result in settlements, as discussed in subsequent chapters.³⁷⁹ Such patent positions may also be an argument originator companies raise in their interventions vis-à-vis the marketing authorisation, pricing and reimbursement bodies etc.³⁸⁰
- (539) The present subsection focuses on litigation as the most immediate aspect of procedural enforcement of patent clusters, as well as divisionals. Patenting strategies appear to be coupled with assertive effort of judicial enforcement.
- (540) Originator companies, in their strategy documents and internal communication emphasise the necessity to enforce patents wherever they perceive an infringement by third parties, such as the following quote shows in an exemplary manner:

"We defend our patent rights vigorously against third party challenge with respect to validity and enforceability."

- (541) Another originator company put it more bluntly by saying:

"[...] we will legally exploit all opportunities to get generics out of the market."

Patent litigation as signal to the generic companies

- (542) An important part of this patent enforcement through litigation is signalling to the generics industry that patent infringements will not be tolerated by the patent holding originator company. As one originator company declared in its internal communication:

"We should as a matter of principle defend our intellectual property. Failure to do so will not only impact on sales of current generic products but will create a perception of weakness which may damage future patent expiries".

³⁷⁹ For further details see Chapter C.2.4.

³⁸⁰ For further details see Chapter C.2.5.

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- (543) Sending such a signal relating to patent defence of the original product can be particularly important to an originator company where a second generation product is about to be launched, as follows from this internal communication at another originator company:

"My view is that we ask for interlockatory [sic] injunctions for two reasons: 1) [...] 2) we send a strong signal to the generics that we haven't softened which is important for possible IP issues with [name of second generation product] in beginning [year]."

Consequences of patent litigation for generic companies

- (544) For generic companies patent litigation with an originator company can in itself create obstacles to market entry namely by creating costs and by using interim injunctions, preventing the sale of the generic product. As described above, sometimes the threat of incurring substantial litigation cost or issuance of an interim injunction can in itself deter entry.
- (545) While larger generic companies may have the financial resources for long and costly litigation – in fact some of the latter have reserved a significant part of their overall budget for litigation and damages – smaller companies may be affected more substantially by litigation.³⁸¹ In fact, patent enforcement litigation can aim at financially overburdening them, in particular where a big originator company obtains interim injunctions against the generic product being put on the market. This creates an uphill struggle for the generic firm, as its litigation costs rise without mirroring revenues from its generic pharmaceutical whereas the originator company will continue to collect revenues from its product.
- (546) In certain cases, when enforcing patent clusters and/or divisionals, an originator company may bring numerous patent infringement actions against a generic company in several Member States on each supposed infringed patent, even where the originator company does not believe to have a chance of being successful. An illustrative example pointing in this direction, in particular with respect to obtaining an interim injunction, is the following internal communication at one originator company:³⁸²

"Our strategy is clear. We want to send a signal (by applying for interim injunctions well knowing that we will not be granted a ban) that we do not accept early [generic] entry and then later we withdraw everything."

³⁸¹ This is of course no particularity of the pharmaceutical sector, however, as explained in the introduction the originator companies subject to this inquiry were typically significantly larger than even their larger generic companies.

³⁸² In this context it is interesting to note that concerning the sample examined in the sector inquiry the ultimate success rate of cases where such interim injunctions were granted was not in clear favour of the applicants. For further details see Chapter C.2.2.

Summary

The findings of the inquiry suggest that in recent years originator companies have changed their patent strategies. In particular, strategy documents of originator companies confirm that some of them aimed at developing strategies to extend the breadth and duration of their patent protection.

Filing numerous patent applications for the same medicine (forming so called "patent clusters" or "patent thickets") is a common practice. Documents gathered in the course of the inquiry confirm that an important objective of this approach is to delay or block the market entry of generic medicines.

In this respect the inquiry finds that individual medicines are protected by up to nearly 100 product-specific patent families, which can lead to up to 1,300 patents and/or pending patent applications across the Member States. Despite the lower number of underlying patent families based on EPO applications, looking from a commercial perspective, a challenger may, in the absence of a Community patent, need to analyse and possibly confront the sum of all existing patents and pending patent applications in those Member States in which the generic company wishes to enter.

When the number of patents and in particular of pending patent applications is high (patent clusters), this can lead to uncertainty for generic competitors – affecting their ability to enter the market. Statements in internal documents collected in the context of the sector enquiry point at the awareness by patent holders that some of their patents might not be strong.

A second instrument used by originator companies could be identified as filing voluntary "divisional patent" applications, most prominently before the EPO where most patent applications in the pharmaceutical sector are filed. Voluntary divisional patent applications, which are foreseen in patent law as a legitimate way to split an (initial) parent application, cannot extend the content of the original application nor the protection period. But they can extend the examination period of the patent office, as the examination of divisional applications continues even if the parent application is withdrawn or revoked, which, under certain conditions, can add to the legal uncertainty for generic companies. Enforcing patent rights in court is legitimate and a fundamental right guaranteed by the European Convention on Human Rights: it is an effective means of ensuring that patents are respected. Like in any other industry the inquiry's findings show, however, that litigation can also be an efficient means of creating obstacles for generic companies, in particular for smaller ones. In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants.

2.2. Patent-Related Exchanges and Litigation

- (547) The purpose of this section is to describe practices of enforcing and challenging patent rights before and out of court without drawing any conclusions as to their compatibility with EC competition law. This section first examines contacts and disputes between originator and generic companies out of court and then looks at patent litigation before the EU Member States' courts.
- (548) It should be noted from the outset that enforcing patent rights in court is legitimate and constitutes a fundamental right guaranteed by the European Convention of Human Rights.³⁸³
- (549) However, the inquiry's findings show that, like in any other industry, litigation can also be an efficient means of creating obstacles in particular for smaller companies. In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants.
- (550) It is not the purpose of this section to provide guidance as to the compatibility of certain practices with EC competition law. The Commission will further investigate whether individual company behaviour may have fallen foul of the competition rules.

2.2.1. Patent-Related Exchanges between Originator and Generic Companies out of Court

- (551) This section examines the enforcement of patent rights by originator companies through patent-related exchanges out of court. In particular, originator and generic companies were asked to report on all contacts and disputes³⁸⁴ in which they were involved across the EU in the period 2000 to 2007 and which had not ended in litigation.³⁸⁵
- (552) Classifying a given exchange between an originator and a generic company as a contact or dispute is not always straightforward and can be open to interpretations.
- (553) Contacts and disputes between an originator and a generic company may have an impact on the decisions of the generic company regarding the launch of a competing product. Although not (always) leading to court proceedings, such patent-related exchanges can have a dissuasive effect and thus affect planned generic entry, in

³⁸³ See Chapter C.2.1.

³⁸⁴ For the purpose of the sector inquiry, disputes are defined as referring to any exchange of views between an originator and a generic company in which, in particular, the actual or potential infringement, non-infringement or invalidity of one or several patents concerning a specific INN have been raised and which has not (yet) ended in litigation, whereas contacts refer to all out of court patent-related exchanges reported, which respondent companies did not classify as disputes.

³⁸⁵ The data provided by respondent companies are based on the records available at the date of companies' replies to the requests for information.

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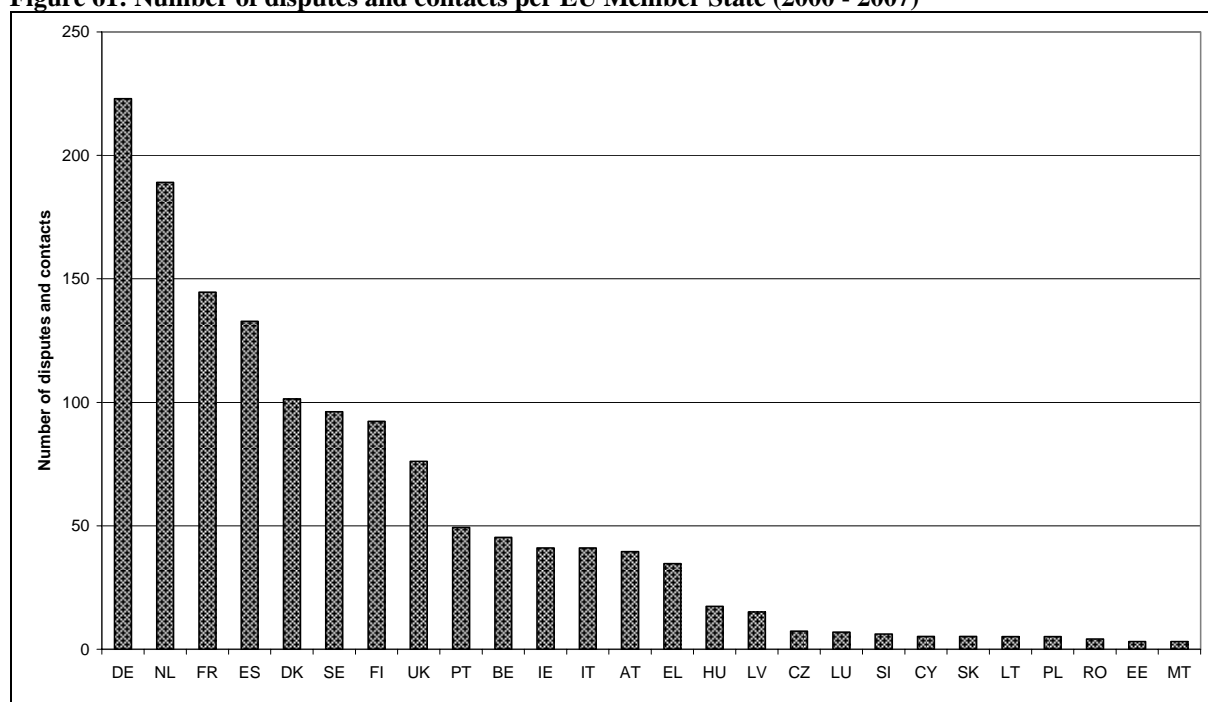
particular as a result of the threat of costly litigation and the risk of the grant of interim injunctions and, eventually, damages.

- (554) The present section will therefore examine the number of contacts and disputes concerning market entry of generic products which were initiated by originator and generic companies in EU Member States in the period 2000 to 2007 and the INNs most often invoked in such patent-related exchanges. The section goes on to look at the number of disputes started in the EU by category and type of the patent in dispute, and the percentage of disputes ending in settlement. Finally, an overview of the percentage of patent disputes in relation to the date of expiry of the disputed patent is provided.

2.2.1.1. Number of Contacts and Disputes between Originator and Generic Companies in the EU and INNs Most Often Concerned by Contacts and Disputes

- (555) Figure 61 provides an overview of the number of contacts and disputes (patent-related exchanges) initiated by originator and generic companies per EU Member State in the period 2000 to 2007. Respondent companies reported a total of 1,337 disputes and contacts initiated in the EU in the period under review.³⁸⁶

Figure 61: Number of disputes and contacts per EU Member State (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

- (556) As shown above, the highest number of disputes and contacts concerned Germany (223 or 16% of the total), followed by the Netherlands (189 patent-related exchanges

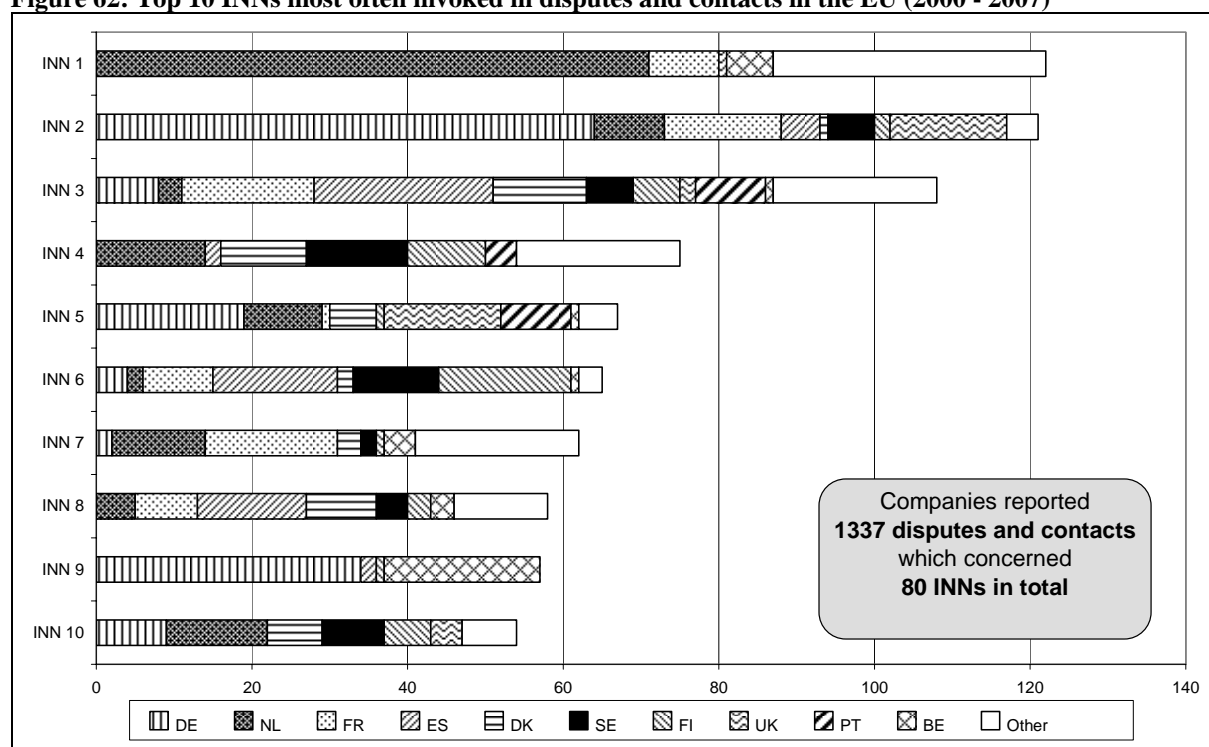
³⁸⁶ The total number of disputes and contacts shown on Figure 52 above is slightly higher (1390) since the disputes and contacts reported by respondent companies as concerning EU-27 were equally added to all the Member States.

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or 14%), France (145 exchanges or 10%) and Spain (133 exchanges or approximately 10%). After these countries come Denmark, Sweden, Finland and the United Kingdom, with roughly 5 to 7% (70 to 100) of patent-related exchanges.

- (557) Figure 62 presents an overview of the top 10 INN_s which were most often the object of contacts and disputes between originator and generic companies in the EU in the period 2000 to 2007. Respondent companies reported a total of 1,337 disputes and contacts which concerned 80 INN_s.

Figure 62: Top 10 INN_s most often invoked in disputes and contacts in the EU (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

- (558) It should be noted that contacts and disputes relating to the top 10 INN_s listed in Figure 62 above accounted for 59% of all contacts and disputes between originator and generic companies reported during the period examined.
- (559) Contacts and disputes concerning INN_s 1 and 2 were the most frequent, each accounting for 9% of all patent-related exchanges. INN_s 3 and 4 were the object of 8% and 6% of patent exchanges, respectively. INN_s 5 to 7 were invoked in 5% of patent-related exchanges, compared to 4% for INN_s 8 to 10.
- (560) On the major national markets, INN_s 1 and 3 were among the best-selling medicines (T50) and among the best-selling medicines which faced loss of exclusivity (E75).³⁸⁷ Overall, each of the top 10 INN_s belonged to at least one of the two aforementioned groups.

³⁸⁷ For more information on the T50 and the E75 lists, please refer to the Annex: Methodology (Annexes to Chapter A).

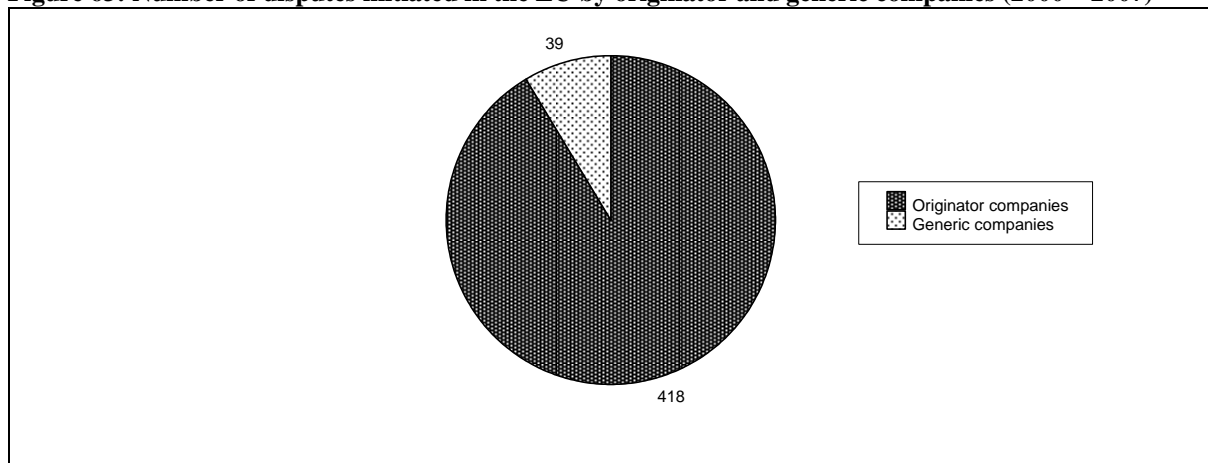
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- (561) As shown on Figure 62, contacts and disputes concerning INN 1 and relating to the Netherlands accounted for the majority (71%) of all patent exchanges for this INN. Furthermore, most of the patent exchanges concerning INN 2 involved Germany (53%), France and the United Kingdom (12% for each). INN 3 was the subject of a substantial number of contacts and disputes concerning France and Spain (18-21%), while most patent exchanges concerning INN 4 involved the Netherlands, Sweden and Denmark (19, 17 and 15% respectively). A similar pattern of unequal geographical distribution is also seen for the remaining INNs.
- (562) All of the top 10 INNs were the object of contacts and disputes in at least four Member States (and most often in more than seven Member States). The reasons for which a dispute on any given INN was initiated in a specific Member State appeared to be case-specific.
- (563) Thus, for the same INN, one observed a significant number of (often parallel) contacts and disputes between originator and generic companies concerning various Member States. This multiplication of contacts and disputes across Member States is a direct consequence of the current European patent system which lacks a unified Community-wide patent and is instead based on a bundle of national patents.

2.2.1.2. Number of Disputes Initiated in the EU by Originator and Generic Companies

- (564) Figure 63 provides an overview of the number of disputes initiated by originator and generic companies in the EU in the period 2000 to 2007. Companies reported a total of 457 disputes initiated in the EU in the period examined. Data provided shows that nearly all disputes (91%) were initiated by an originator company, whilst generic companies launched only 9% of all disputes.

Figure 63: Number of disputes initiated in the EU by originator and generic companies (2000 – 2007)

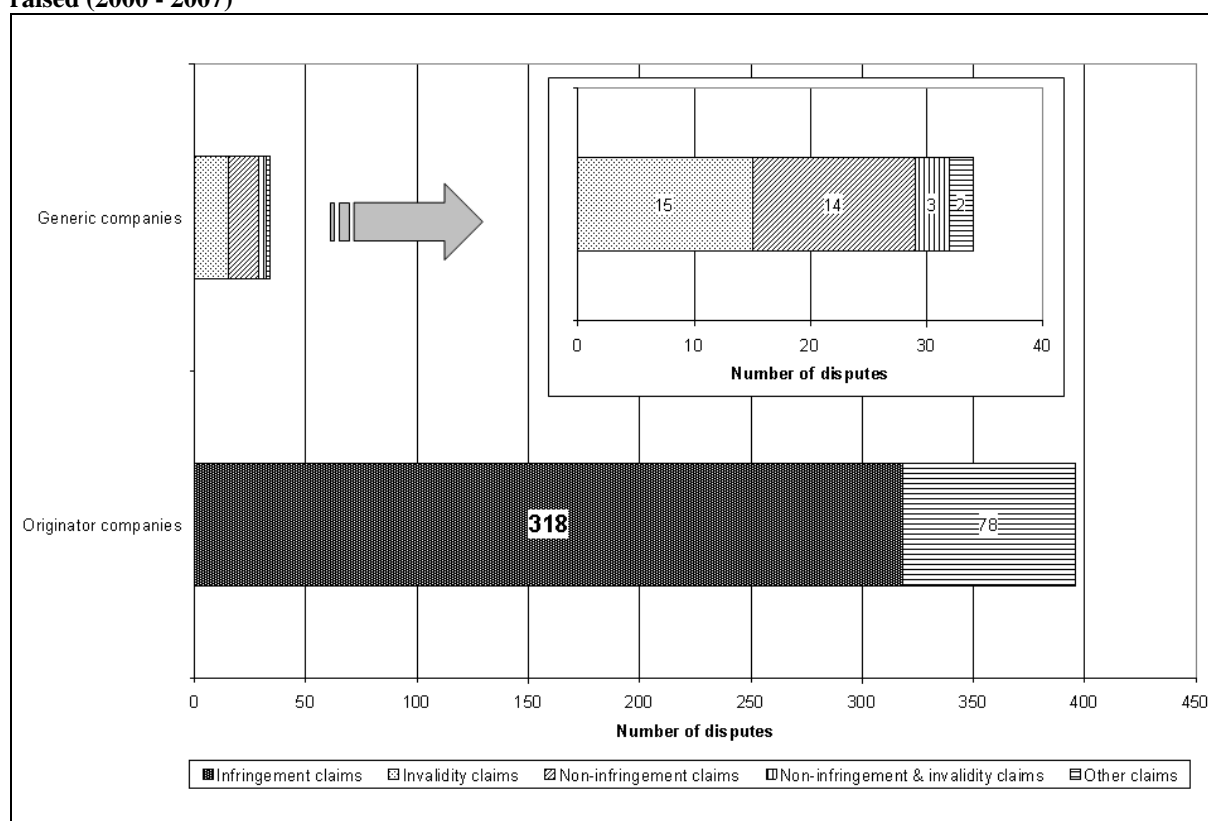


Source: Pharmaceutical Sector Inquiry

- (565) Figure 64 illustrates the number of disputes initiated by originator and generic companies in the EU in the period 2000 to 2007 by type of claim raised (infringement, invalidity, non-infringement, non-infringement and invalidity, and other).

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Figure 64: Number of disputes initiated in the EU by originator and generic companies by type of claim raised (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

- (566) As already indicated above, nearly all reported disputes (91%) were initiated by an originator company.³⁸⁸ This high percentage could be explained in terms of originator companies' strategies aimed at protecting patent rights and initiated at the point when an originator company becomes aware of the planned entry to the market by a generic company (e.g. by informing the generic competitor of its patent rights, the consequences of patent infringement and demanding that the generic product be withheld from the market). In 74% of disputes initiated by an originator company, the originator company claimed that the generic company was infringing its valid patent rights. The remaining 26% of disputes dealt with other claims.³⁸⁹
- (567) In contrast, only about 9% of all reported disputes were started by a generic company. Those disputes raised claims of invalidity (15 instances), non-infringement (14 instances), non-infringement combined with invalidity (3 instances) and other claims (2 instances).

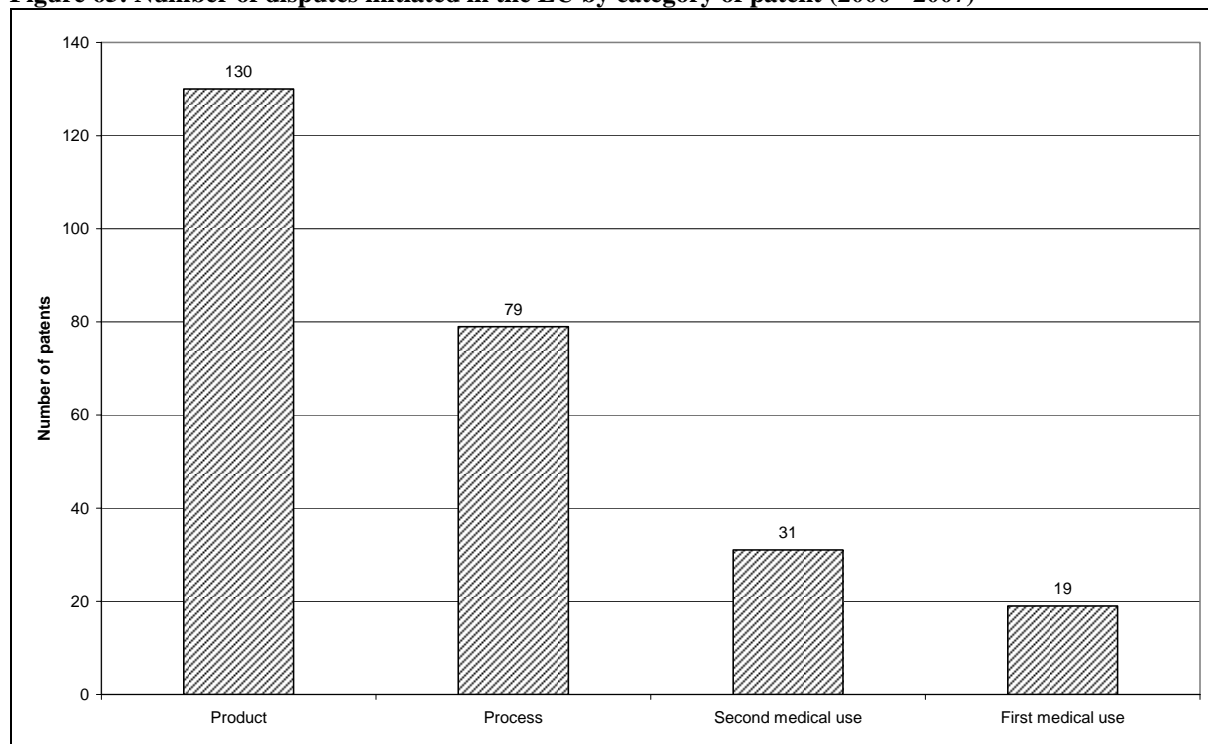
³⁸⁸ The total number of disputes initiated by originator and generic companies in the EU in the period 2000 to 2007 as shown on Figure 64 above is slightly lower than the one indicated on Figure 63. This may be explained by the lack of indication, for some of the disputes reported, of the type of claim raised.

³⁸⁹ Respondent companies have indicated that such other claims raised in disputes concerned *inter alia* letters drawing the attention of the generic company to the existence of the relevant patent.

2.2.1.3. Number of Patents in Dispute by Category of Patent

(568) Figure 65 illustrates, by category of patent, the number of patents which were the object of a dispute in the EU in the period 2000 – 2007.³⁹⁰

Figure 65: Number of disputes initiated in the EU by category of patent (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

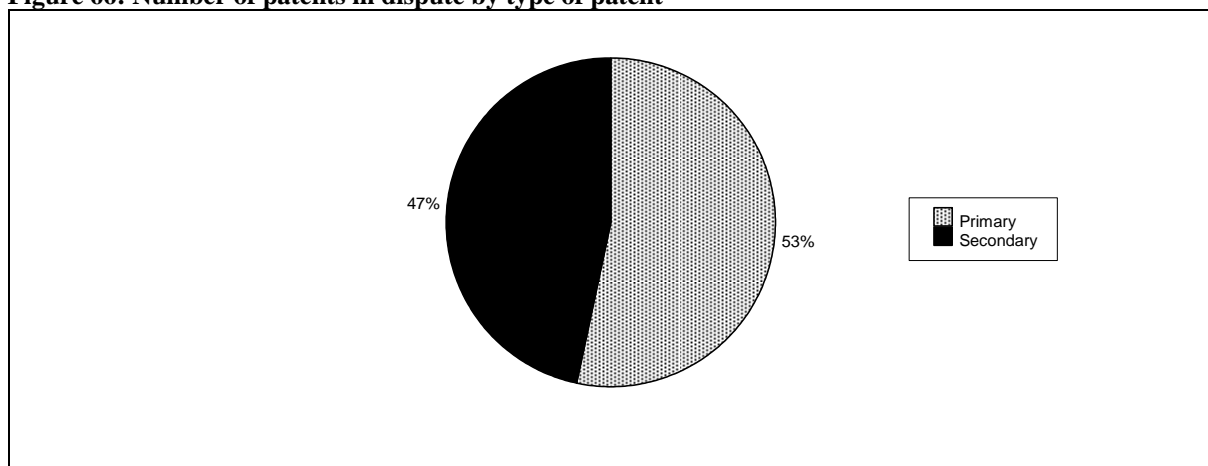
(569) Companies reported a total of 187 patents which were concerned by disputes in the period under review. As Figure 65 shows, more than two-thirds of disputed patents were product patents (70% or 130 patents). Process patents represented the second most disputed category of patents (42% or 79 patents). The percentage of first and second medical use patents in dispute was significantly lower (10% and 17% respectively). A similar pattern, described further on in this chapter (see Figure 76), was also observed in relation to litigated patents.

(570) As Figure 66 shows, primary patents were the object of disputes between originator and generic companies in over half (53%) of all disputes reported whilst the remaining 47% of all disputes involved secondary patents.³⁹¹

³⁹⁰ For more information on patent categories see Annex: Claim Types (Annexes to Chapter B). It should be noted that one patent may fall under one or more different patent categories. Hence, due to multiple counting, the aggregate number of disputed patents, if added across the four patent categories as listed in Figure 65, will exceed the total number of disputed patents reported by respondent companies.

PHARMA SECTOR INQUIRY – MAIN ISSUES INVESTIGATED

Figure 66: Number of patents in dispute by type of patent

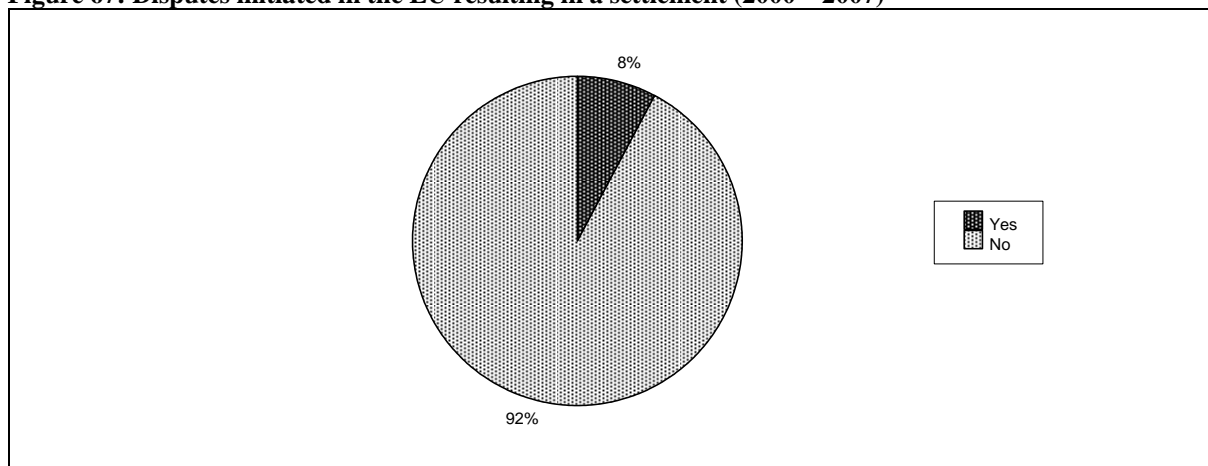


Source: Pharmaceutical Sector Inquiry

2.2.1.4. Disputes Resulting in Settlement

(571) Figure 67 shows that only 8% of disputes between originator and generic companies ended in a settlement. This can be seen as one illustration of the fact that, even without reaching the stage of litigation, patent-related disputes may have effects on generic entry.

Figure 67: Disputes initiated in the EU resulting in a settlement (2000 – 2007)



Source: Pharmaceutical Sector Inquiry

³⁹¹ This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying interventions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

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- (572) The disputes, reported in this section, which did not lead to a settlement, were either not further pursued by originator companies (e.g. no legal action was brought to court) or may have led to litigation or ended with a settlement after 1 January 2008.³⁹²
- (573) An originator company may decide not to further pursue a dispute because the generic company has refrained from entering the market. Even if there is generic entry, an originator company may still discontinue the dispute it has initiated if the lack of infringement has been established, or if it is not convinced of the existence of an actual infringement or of the strength of its patent.
- (574) In the example given below, an originator company initiated a patent dispute when it became aware of the marketing of a competing generic product.

"It has come to the attention of our client that you [generic company] have received a marketing authorisation for [originator's product] and [originator's product]. [...] At the request and on behalf of our client [originator company], we seek your confirmation in writing that you [generic company] will refrain, for the duration of [the originator company's] industrial property rights from producing, offering and placing on the market or using [originator's product] and [originator's product]. We should receive your written confirmation by [date]. Our client explicitly reserves the right to initiate patent litigation in the future in relation to unlawful patent use."

- (575) However, the originator company did not pursue its claim further, even though the generic product remained on the market. Even if many disputes are not further pursued by originator companies, they can have a strong dissuasive effect on the entry of generic products on the market, in particular as a result of the threat of costly litigation and the risk of the granting of interim injunctions and, possibly, damages.³⁹³ The data reported by respondent companies on patent litigation show that over half of litigation proceedings were preceded by prior disputes and/or contacts. This illustrates the strength of the link between patent-related exchanges and patent litigation.

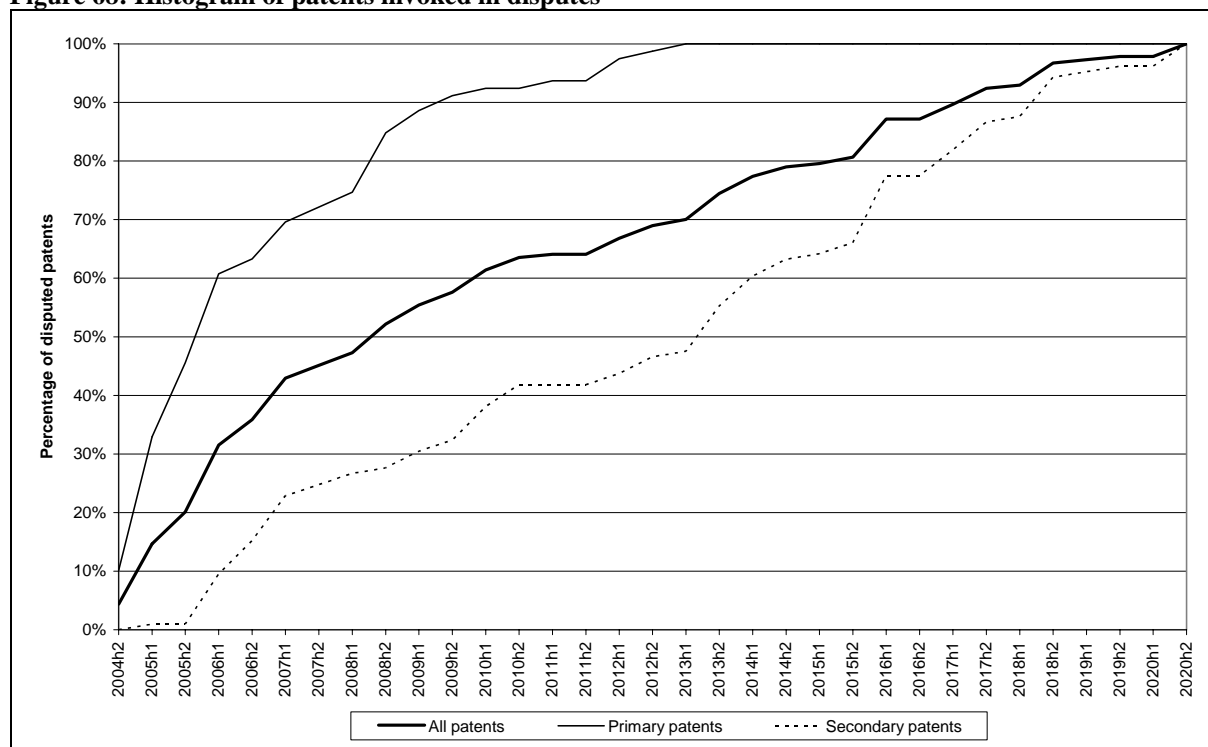
2.2.1.5. Histogram with Patent Expiry Dates of Patents in Dispute

- (576) Figure 68 provides a histogram of patents in dispute in the EU in the period 2000 to 2007 relative to patent expiry dates. It distinguishes between primary and secondary patents. The vertical axis shows expired patents as a percentage of the total number of disputed patents, while the horizontal axis lists the semesters in which individual patents were or are about to expire.

³⁹² In the requests for information, companies were asked to report the disputes between originator and generic companies, which had led to litigation, in the section concerning patent litigation.

³⁹³ The findings of the sector inquiry show, with regard to all disputes reported by respondent companies for which an outcome to the dispute was indicated, that in nearly half of disputes, the generic company decided not to launch its product prior to the expiry of the originator company's patent.

Figure 68: Histogram of patents invoked in disputes



Source: Pharmaceutical Sector Inquiry

(577) Figure 68 shows that primary patents, which were the object of a dispute, have an earlier expiry date than secondary patents in dispute. For example, 92% of disputed primary patents will have expired by the first half of 2010 which stands in contrast to the 38% of secondary patents in dispute that were reported by originator companies to expire by the same time. This would indicate that secondary patents are the object of disputes much earlier in the process when the relevant expiry dates are relatively further away. The latest expiry date of an individual secondary patent reported in the section on disputes by respondent companies falls in the second half of 2020. Hence, it appears that originator companies tend to invoke secondary patents which were granted relatively recently.³⁹⁴

2.2.2. Litigation

(578) This section examines the enforcement and challenge of patent rights through litigation before EU Member States' courts. More specifically, originator and generic companies were asked to report on all patent-related litigation, to which they were a party, and which was launched in the EU in the period 2000 – 2007.

(579) The questionnaires that were sent to companies defined patent-related litigation as covering any type of court proceedings or other formal adversarial proceedings with

³⁹⁴ For further information on patent strategies used by originator companies see Chapter C.2.1.

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the exception of patent opposition proceedings.³⁹⁵ In particular, questions were asked concerning the main patent-related legal actions such as the action for infringement, the action for declaration of non-infringement and the action for annulment³⁹⁶ (also sometimes referred to as "invalidity action").

- (580) The action for infringement is launched by an originator company with the aim of having the court find that the generic product is (imminently or actually) infringing the originator's patent and prohibit its production and commercialisation until the date of patent expiry. The action for a declaration of non-infringement is brought (independently or as a counter-action) by a generic company seeking a declaration by the court that its product does not infringe the originator company's patent (e.g. because of the difference between the two products, processes etc.). This allows the generic product to enter or remain on the market free of patent claims.
- (581) Generic companies may also bring an action for annulment of the originator company's patent, which would allow them to enter the market unless the product is protected by other patents which have not been invalidated.³⁹⁷ The grounds for nullity most often invoked by generic companies concern the lack of novelty and/or inventive step of the originator product. If the patent is annulled, it is considered retroactively to be abolished *erga omnes*.
- (582) A variety of scenarios of litigation may take place. Either the originator or the generic company may initiate litigation against the other party, bring a counter-action or merely defend themselves.³⁹⁸
- (583) Patent litigation can influence the commercial decisions of generic companies. In particular, the threat of lengthy and costly patent litigation across EU Member States can dissuade smaller generic companies from launching a competing product, hence avoiding burdensome court procedures, before patent expiry, even if they consider the patent to be invalid or not to have been infringed. Even if generic companies are not put off by patent litigation and are willing to go to court, litigation can have an impact on bringing to market a generic version of the originator product. Most importantly, interim injunctions can oblige generic companies to withdraw their product from the market and refrain from further production and commercialisation until the main action

³⁹⁵ For further information on patent opposition proceedings see Chapter C.2.1. and 2.3.

³⁹⁶ For further details see footnote 207.

³⁹⁷ For more information on the regulatory framework see Chapter B.2.1.

³⁹⁸ For instance, the generic company may bring an action for a declaration of non-infringement and/or an action for annulment and launch its product once generic entry has been cleared (or the patent has been annulled by the court). The generic company may also launch at risk while its action for non-infringement and/or annulment is still pending or launch its product without filing any action at all. In the event of a generic launch at risk before patent expiry, the originator company may seek to defend its patented product by bringing an action for infringement (and possibly requesting that interim injunctions be granted).

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is decided.³⁹⁹ It goes without saying that interim injunctions can also be a necessary and legitimate tool allowing patent-holders to effectively enforce their patent rights. However, the grant of interim injunctions can become particularly relevant when examined in the light of originator companies' overall patent and life cycle strategies which are aimed at maximising profit and shielding their products from competition.

- (584) For the sake of example, it can be useful to refer to anonymised but real-life situations. In one of them an originator company started infringement proceedings and successfully obtained interim injunctions on one of the main national markets. That originator company lost subsequently its case which in turn allowed for generic entry many years before the patent expiry dates claimed in the court proceedings. Another originator company started infringement proceedings and successfully obtained interim injunctions on another national market just in order to subsequently settle the case, allow for generic entry many years before the patent expiry dates claimed in the court proceedings and on top of that transfer a substantial sum to its generic competitor. In each of these cases, the originators' involvement in litigation translated into an extended period during which no generic competition was present.
- (585) The present section will examine the patterns of patent litigation in relation to generic entry (e.g. the total number of litigations initiated in the EU per launching party and per Member State, the duration of litigation, the types and categories of litigated patents etc.) and the INNs which were most often the object of litigation. It will also analyse the final outcome of patent litigation on the merits and the patterns of interim injunctions. Finally, this section will look at the cost of external legal advice in patent matters.⁴⁰⁰

2.2.2.1. Number of Patent Litigations Initiated in the EU and per EU Member State

- (586) As illustrated in Figure 69, companies reported a total of 698 separate⁴⁰¹ cases of patent litigation which were initiated⁴⁰² in the EU in the period 2000 to 2007⁴⁰³. Of the

³⁹⁹ Or until the patent expiry date (if it precedes the final judgement) or until such time as the judge may decide.

⁴⁰⁰ It is not the purpose of this section to provide a comparative analysis of the data on patent litigation as reported by pharmaceutical companies and data on patent litigation relating to other industrial sectors. Such a comparison would require the collection of extensive data through the use of investigative powers which do not fall within the Commission's current mandate relating to the pharmaceutical sector inquiry.

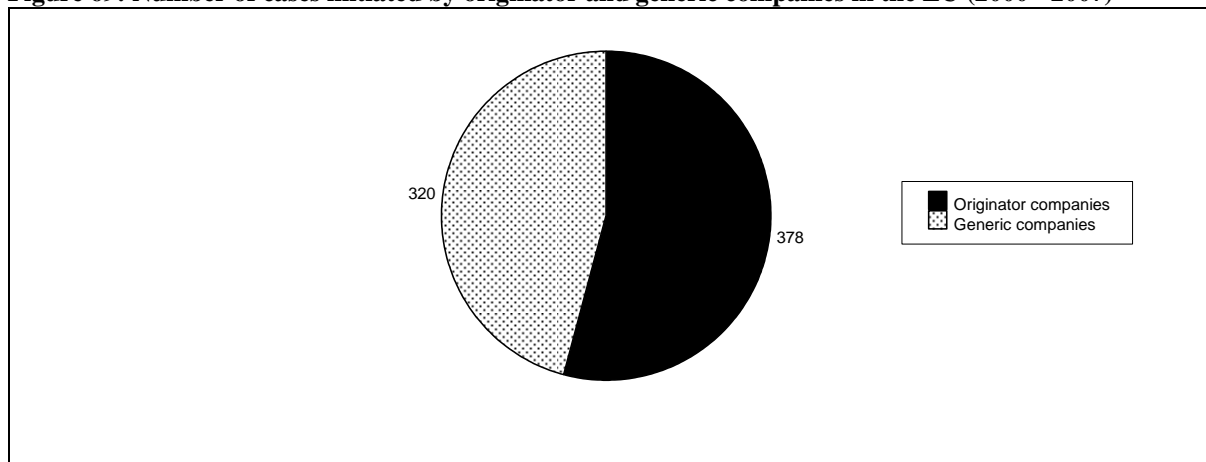
⁴⁰¹ The term "separate litigation" refers to patent litigation cases in one Member State identified by a single court reference number independently of the number of patents concerned or parties and instances involved. Hence, a legal action brought in one Member State against several different defendants concerning several patents and examined by several instances is counted as one separate litigation if it is identified by the same, unique court reference number. Throughout this chapter, all references to patent litigation denote separate litigation cases.

⁴⁰² Throughout this chapter, "initiation of litigation" refers to the first legal action started by a party which is the one taken into account for statistical purposes, independently of the existence of a counter-action (not included in the calculations).

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total reported, the cases initiated by originator companies accounted for 54% (378 cases) as against 46% (320 cases) launched by generic companies.

Figure 69: Number of cases initiated by originator and generic companies in the EU (2000 - 2007)



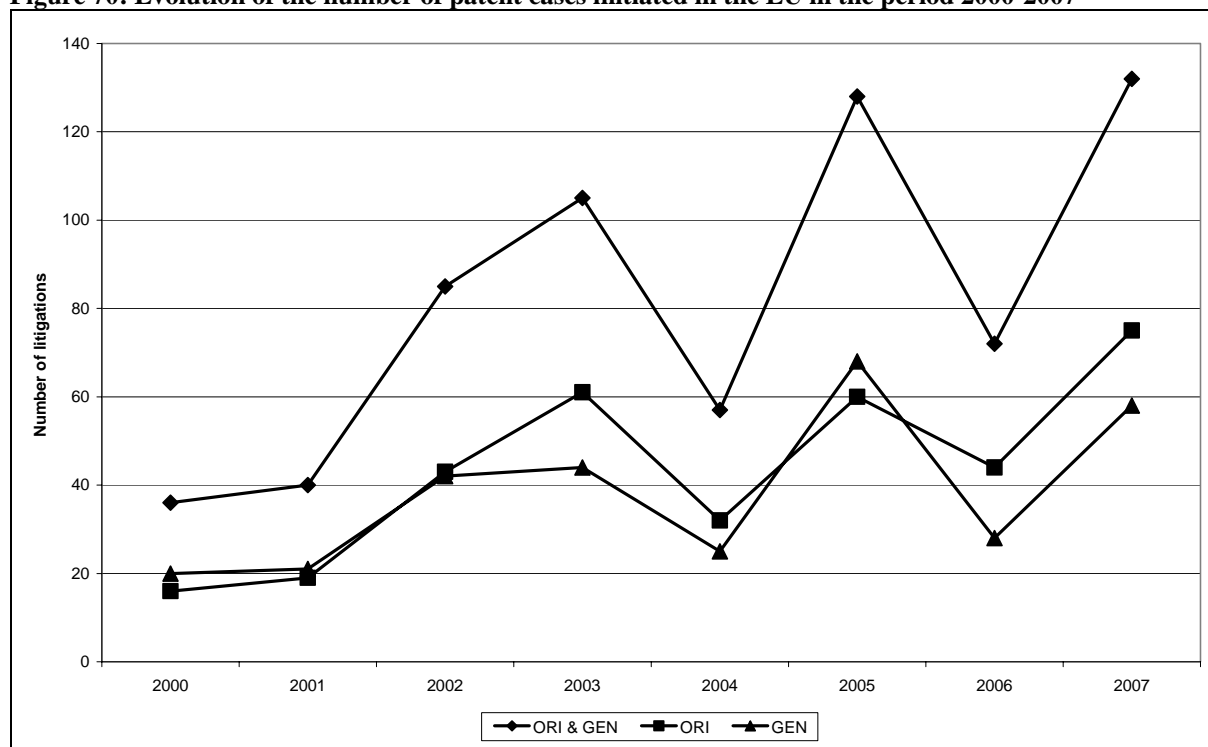
Source: Pharmaceutical Sector Inquiry

- (587) As shown in Figure 69, generic companies initiated a substantial number of litigations (although fewer than those started by originator companies). This can be explained by the fact that generic companies' have been proactive in initiating litigation to obtain a declaration of non-infringement of the relevant patent or its annulment in order to clear generic entry.
- (588) Figure 70 illustrates the trend in the number of patent litigations initiated in the EU by originator and generic companies in the period 2000 to 2007. As it was argued in the context of the public consultation that new EU Member States may contribute significantly to an overall increase in the number of cases, Figure 70 distinguishes between the EU-27 Member States, including those which joined the European Union in 2004 and 2007, and the EU-15 Member States.

⁴⁰³ For the purpose of the sector inquiry, each separate litigation reported is accounted for since, due to the current European patent and judicial system, once validated in a Member State, each patent has an autonomous life of its own entailing a procedural and resource burden required to enforce it or challenge it in each relevant national court. If a generic company strikes down a patent in front of one national court, this does not change the patent situation in any of the other 26 Member States. Accordingly, the challenger needs to confront the sum of all national patents in all those Member States where a product launch is foreseen.

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Figure 70: Evolution of the number of patent cases initiated in the EU in the period 2000-2007

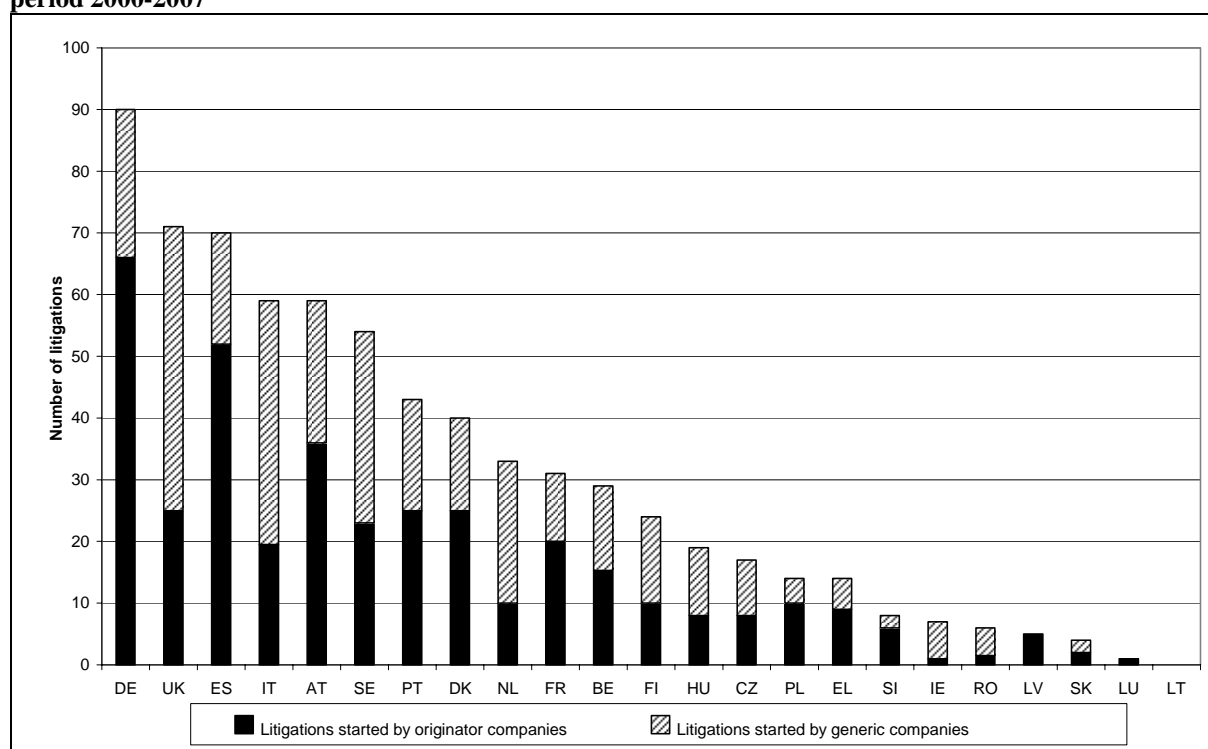


Source: Pharmaceutical Sector Inquiry

- (589) Figure 70 shows that there was a substantial overall increase in the number of cases, which rose nearly fourfold from 36 in 2000 to 132 in 2007. The increase in the number of patent litigations was particularly marked in the initial period from 2000 to 2003 with the number of patent litigations increasing nearly three times. The year 2004 saw a sharp temporary decline in the number of patent cases by nearly half (by 48 cases) compared to 2003. However, in 2005, the number of patent cases sharply increased again more than twice (by 71 cases) only to fall by 56 cases in 2006. Nevertheless, this drop was reversed once again in 2007 when an increase of more than 60 cases was observed. At this point, the number of patent cases reached its highest in the period examined (132).
- (590) The trend in the number of patent litigations initiated either by originator or generic companies (as shown on the graph) followed an essentially similar pattern.
- (591) Figure 70 also shows that the 2004 and 2007 enlargement rounds of the European Union did not have a significant effect on the number of patent cases initiated in the EU by pharmaceutical companies.
- (592) Figure 71 illustrates the distribution in the number of patent litigations initiated by originator and generic companies in the period 2000 – 2007 for all EU Member States.

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Figure 71: Patent litigations initiated by originator and generic companies per EU Member State in the period 2000-2007



Source: Pharmaceutical Sector Inquiry

- (593) We can see that Germany had by far the highest number of cases in the EU (90 cases), followed by the United Kingdom (71 cases) and Spain (70 cases). Between 40 and 60 patent litigations were initiated in Italy and Austria (59 cases), Sweden (54 cases), Portugal (43 cases) and Denmark (40).⁴⁰⁴
- (594) Figure 71 shows that, in most Member States, the majority of cases were initiated by originator companies. Hence, originator companies were by far the most active litigators in Slovenia, Spain, Germany and Poland (with 71 to 75% of initiated cases). Likewise, originator companies launched a substantially higher number of cases in France, Greece, Denmark and Austria (61 to 65% of all cases). All reported cases in Latvia were initiated by originator companies.
- (595) However, there are several Member States where the opposite situation was observed. Whilst the United Kingdom had the second highest number of patent litigations launched in the EU from 2000 to 2007, the vast majority of cases were initiated by generic companies (65 %). This contrasts sharply with the situation in Germany and Spain, as previously discussed. Like the United Kingdom, Italy had the fourth highest overall number of reported patent litigations in the EU, but litigations initiated by originator companies accounted for only 33% of cases as compared to 67% originating

⁴⁰⁴ Figure 71 also shows that the 2004 and 2007 enlargement rounds of the European Union did not have a significant effect on the overall number of patent litigation cases. Only 10% of all reported patent cases were initiated in new Member States.

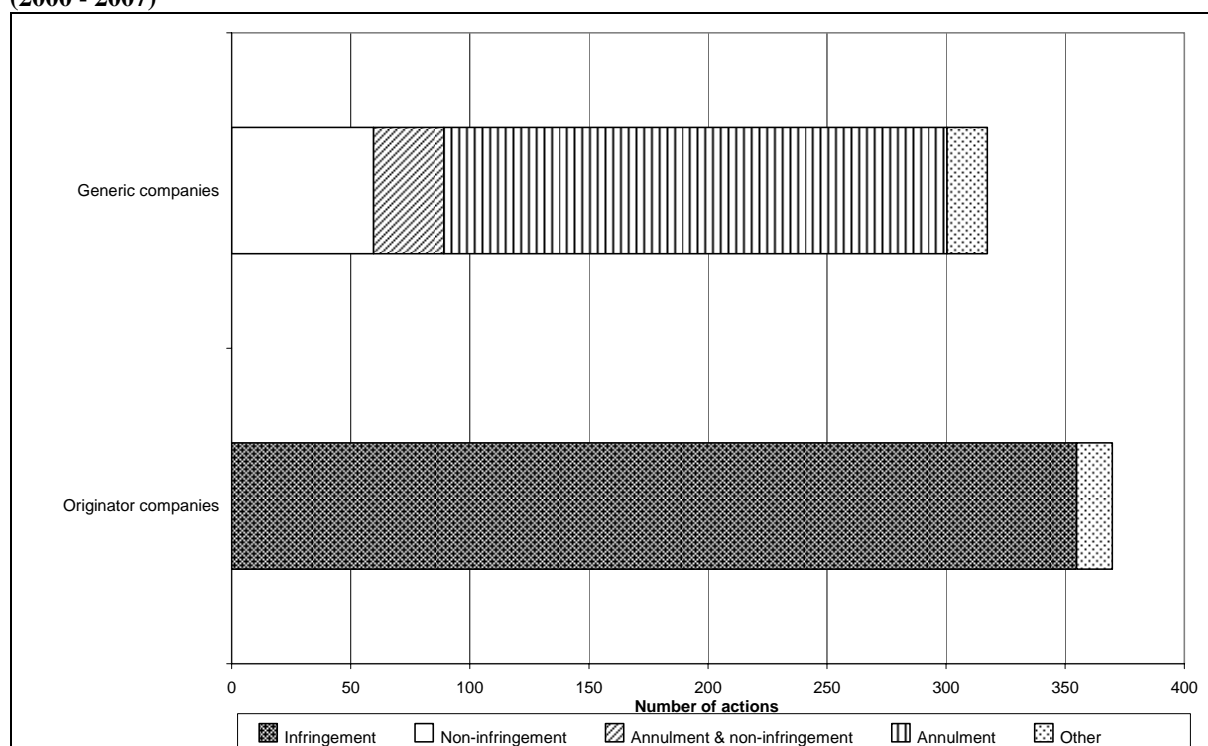
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from generic companies. In the same vein, in Ireland, Romania, the Netherlands, Finland, Hungary, the Czech Republic and Sweden, only 14 to 47% of cases were initiated by originator companies.

2.2.2.2. Number of Patent Litigations Initiated in the EU by Type of Action and Initiating Party

(596) Figure 72 provides an overview of the types of legal actions that were initiated by originator and generic companies.

Figure 72: Number of litigations initiated by originator and generic companies in the EU by type of action (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(597) As might reasonably be expected, infringement actions represented by far the majority of legal actions initiated by originator companies (96%) with other actions accounting for the remaining 4%.⁴⁰⁵ The picture is more varied when it comes to generic companies, where actions for annulment accounted for 67%, followed by declaratory actions for non-infringement (19%) and by joint actions for annulment and a declaration of non-infringement (9%). Other actions initiated by generic companies accounted for the remaining 5%.⁴⁰⁶

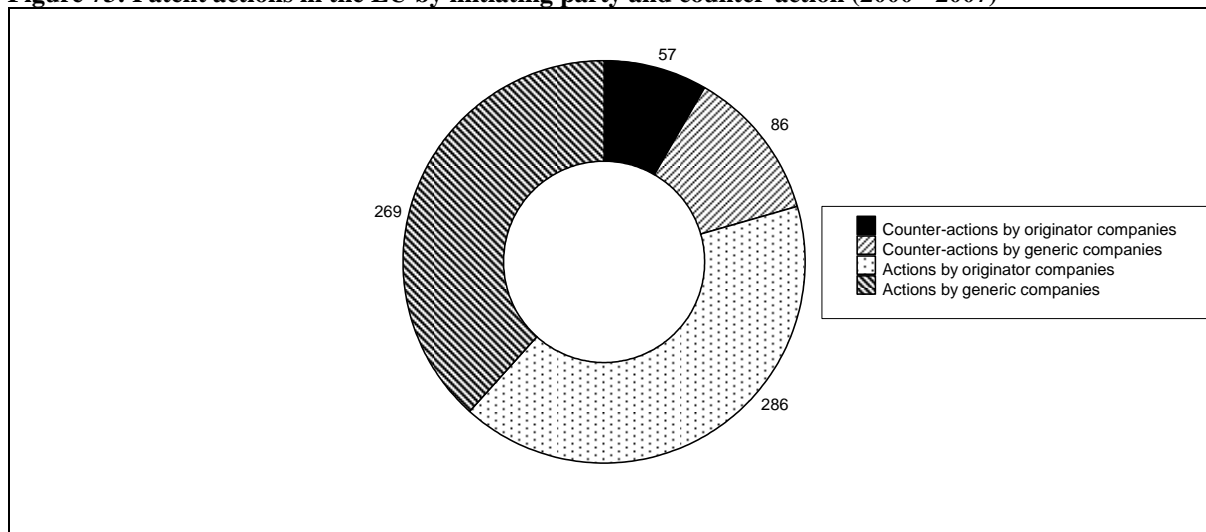
⁴⁰⁵ Respondent companies have indicated such other actions initiated by originator companies to cover, *inter alia*, actions for damages, etc.

⁴⁰⁶ Such other actions initiated by generic companies may be, amongst others, action for damages.

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(598) Figure 73 illustrates the number of legal actions appearing under separate litigation reference numbers, which were reported as having been filed only by an originator company (without any subsequent counter-action by the defendant to appear under the same litigation reference number), only by a generic company or by both (initial action followed by a counter-action, both reported under the same litigation reference number).

Figure 73: Patent actions in the EU by initiating party and counter-action (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(599) Responses show that in 41% of all cases, a patent action was brought by an originator company without there being a counter-action filed by the generic company. In comparison, in nearly 39% of all reported litigations, the action initiated by a generic company was not followed by the launch of a counter-action by an originator company. In 12% of all cases, the patent action brought by an originator company was followed by the launch of a counter-action by a generic company. The cases where the action brought by a generic company was followed by a subsequent counter-action filed by an originator company represented 8% of the total.⁴⁰⁷

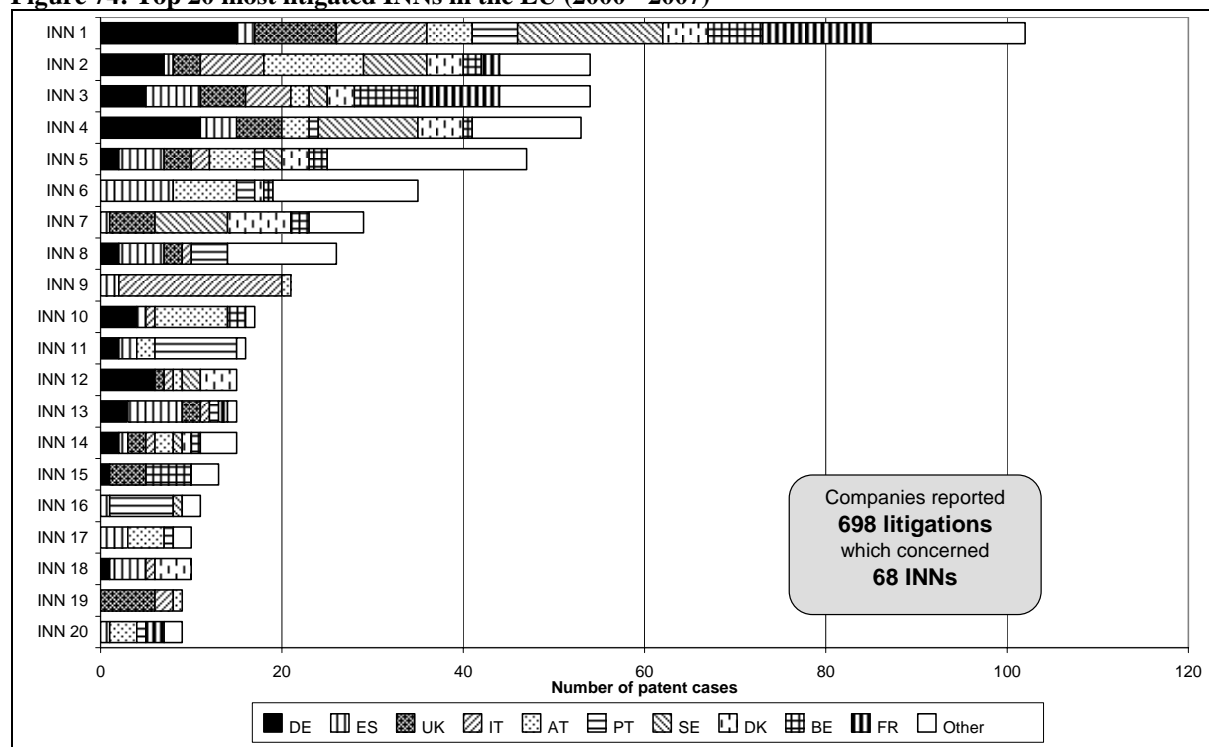
2.2.2.3. INNs Concerned by Patent Litigation

(600) Figure 74 provides an overview of the 20 INNs which were most often the object of litigation in the EU, as presented by EU Member State.

⁴⁰⁷ The actions and the related counter-actions have been coupled on the basis of the litigation reference numbers provided by respondent companies, therefore, it cannot be excluded that the figures on counter-actions are underestimated due to the use of different litigation reference numbers.

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Figure 74: Top 20 most litigated INNs in the EU (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

- (601) Litigation concerning the 20 most litigated INNs accounted for the vast majority of all patent litigation in the EU (80%). In addition, the top 20 INNs accounted for 29 % of all 68 INNs on which litigation was reported.
- (602) The top six INNs were the object of nearly half (49%) of all reported litigations. By far the most litigated INN in the EU was INN 1 with 15% of all cases. The second to fifth most litigated INNs (INNs 2, 3, 4 and 5) were the focus of litigation in 7 to 8% of cases. The sixth most litigated INN (INN 6) was the object of litigation in 5% of cases. The remaining 14 INNs accounted for about 31% of all cases.
- (603) The top three INNs in terms of intensiveness of litigation belong to INNs which were, on the major national markets during the period examined, both among the best-selling medicines (T50 list) and among the best-selling medicines which faced loss of exclusivity (E75 list).⁴⁰⁸ Overall, all of the top 20 INNs belonged to at least one of the two aforementioned groups.
- (604) All of the 20 most litigated INNs were the object of litigation in at least three Member States, whereas the top six INNs were litigated in at least five (and most often eight to

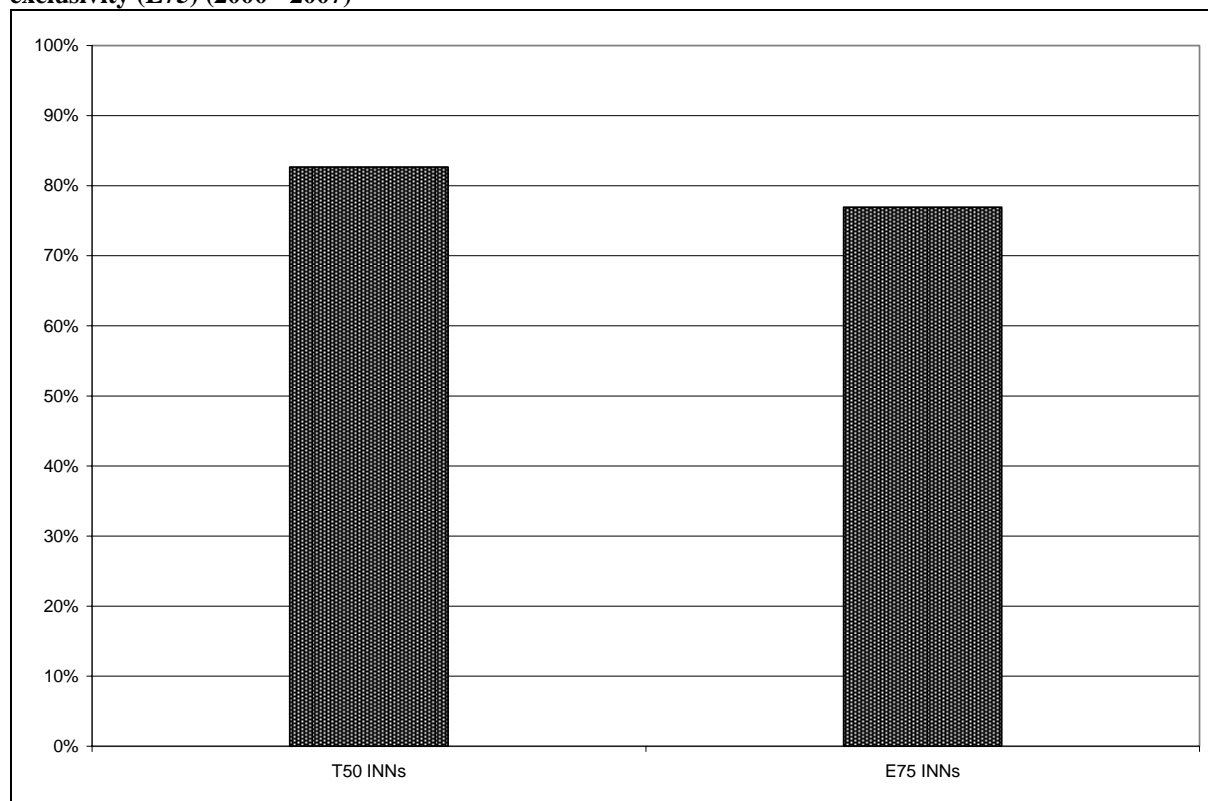
⁴⁰⁸ For more information on the T50 and the E75 lists, please refer to the Annex: Methodology (Annexes to Chapter A).

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nine) Member States.⁴⁰⁹ The reasons for which litigation on any given INN is initiated in a specific Member State appear to be case-specific.

(605) Figure 75 illustrates the percentage of all patent litigation cases, reported by respondent companies, which concerned the best-selling INNs (T50 list) and/or the INNs which faced loss of exclusivity in the period 2000 to 2007 (E75 list).⁴¹⁰

Figure 75: Litigation concerning the best-selling INNs (T50) and the best-selling INNs which faced loss of exclusivity (E75) (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(606) Figure 75 shows that the vast majority (83%) of all reported cases concerned best-selling INNs (T50). Furthermore, more than three quarters of all cases (77%) concerned best-selling INNs which faced loss of exclusivity in the period examined (E75). These findings confirm the relevance of the sample of 219 INNs.

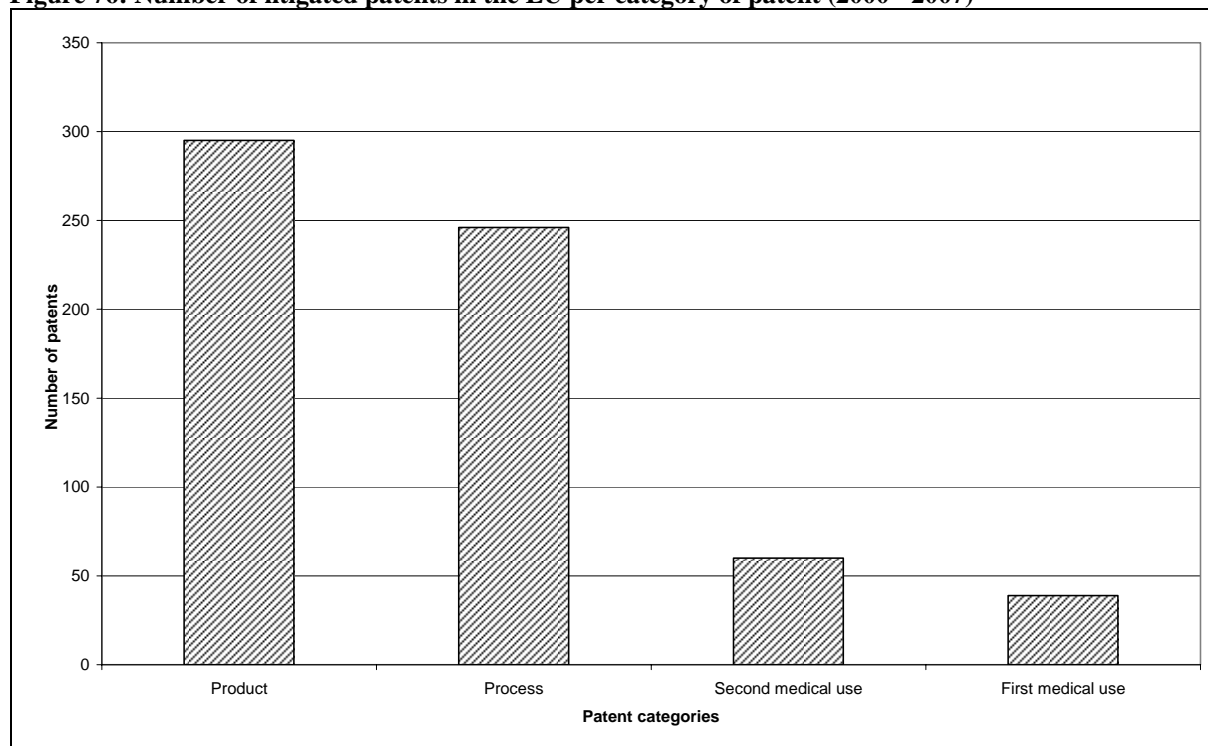
⁴⁰⁹ INN 1 was the subject of a substantial number of cases in Germany, Sweden, France, the United Kingdom and Italy (between 9% and 16% of all cases reported over INN 1 for each). An important number of cases concerning INN 2 were launched in Austria (20%), Germany, Italy and Sweden (13%). The highest number of litigations concerning INN 3 were examined by French and Belgian courts (17% and 13% respectively), followed by courts in Germany, Spain, Italy and the United Kingdom (9 to 11%).

⁴¹⁰ For further details see footnote 408.

2.2.2.4. Categories and Types of Patents Concerned by Patent Litigation

(607) Figure 76 illustrates the number of patents per category of patent as litigated in courts across the EU in the period 2000 to 2007. Companies reported a total of 478 patents litigated across the EU for which patent categories were clearly specified.⁴¹¹

Figure 76: Number of litigated patents in the EU per category of patent (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

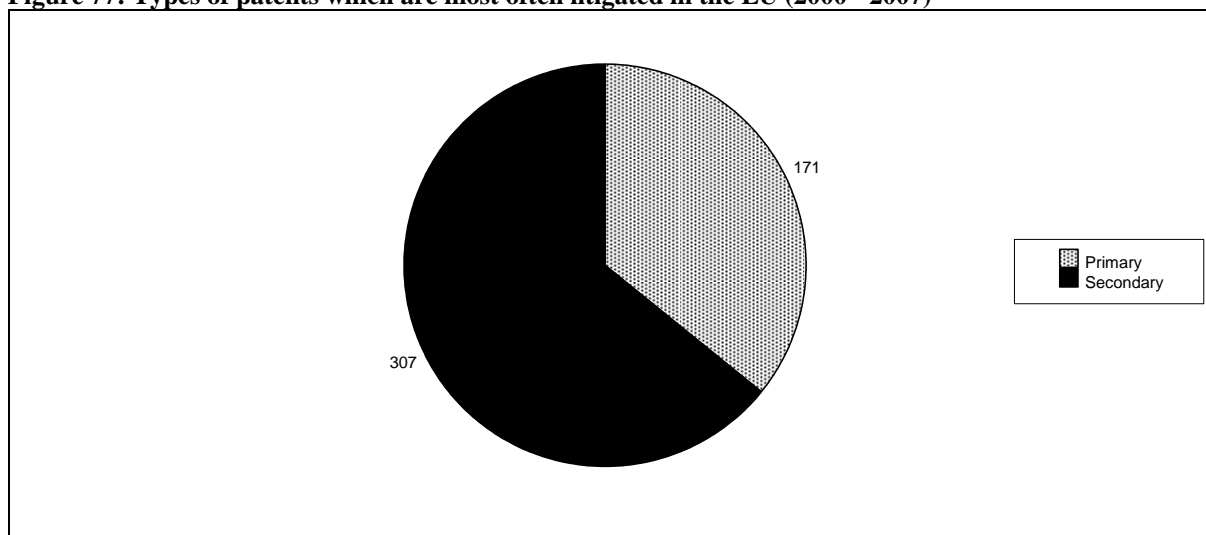
(608) Responses show that a substantial number of litigated patents (62% or 295 out of 478 patents) fell into the category of product patents. Process patents were the second most litigated category of patents with 51% or 246 patents. In contrast, the percentage of litigated first and second medical use patents was substantially lower (8% (39) and 13% (60) of all patents, respectively).

(609) Figure 77 provides an overview of the types of patents (primary or secondary) which were most often the object of patent litigation.

⁴¹¹ It should be noted that any given litigation may concern several patents. In addition, any given patent may fall under one or more different categories. Hence, due to multiple counting, the aggregate number of litigated patents across the four patent categories as listed in Figure 76 exceeds the total number of litigated patents reported by respondent companies (478). The number of patents falling in each of the four patent categories was calculated based on the national publication numbers, i.e. the instances of multiple occurrences of the same national patent were corrected to avoid double-counting. However, one patent may fall under more than one patent category, e.g. a patent that covers product and process claims will belong to both the product and the process category. In such cases, patents were allocated in their entirety to each of the relevant categories, i.e. the patent evoked in the above example would be added as one unit to the product bar and as one unit to the process bar.

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Figure 77: Types of patents which are most often litigated in the EU (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

- (610) Figure 77 shows that secondary patents accounted for nearly two thirds of all litigated patents (64%). Primary patents made up the remaining 36%.⁴¹²
- (611) Results of the sector inquiry also show that originator companies initiated a higher number of cases concerning primary and secondary patents than generic companies (54% versus 46%).
- (612) In contrast to the data reported on disputes, which show that primary patents were the most frequent object of disputes in the EU (see Figure 66), responses indicate that it was secondary patents which were most often the object of litigation across the EU.

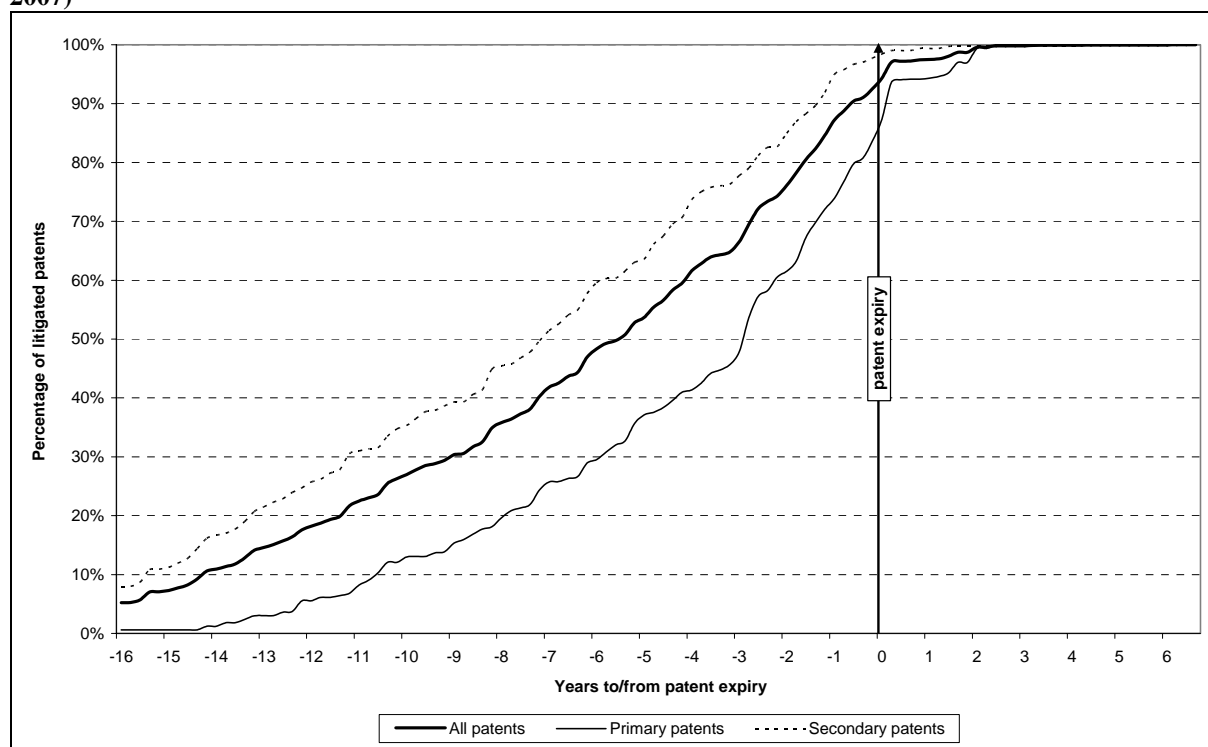
2.2.2.5. Patent Expiry Dates and the Start of Patent Litigation

- (613) Figure 78 illustrates the relationship between the length of time until patent expiry and the date of initiation of litigation, distinguishing between primary, secondary and all patents in general. The vertical axis indicates the (cumulative) percentage of patents being the object of litigation as reported by respondent companies. The horizontal axis lists a given number of years before (16 years) and after (6 years) patent expiry. Each point in the curve relates to a single patent that was the object of litigation proceedings in the period 2000 to 2007. By way of illustration: 10% of primary patents concerned by litigation in that period had still 10.5 years or more to go until expiry. For secondary patents, the corresponding figure is 15.5 years.

⁴¹² The parties raised in litigation cases both primary and secondary patents at the same time in merely 52 cases or 7% of all patent cases reported by respondent companies.

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Figure 78: Relationship between patent expiry dates and the start of patent litigation in the EU (2000 – 2007)



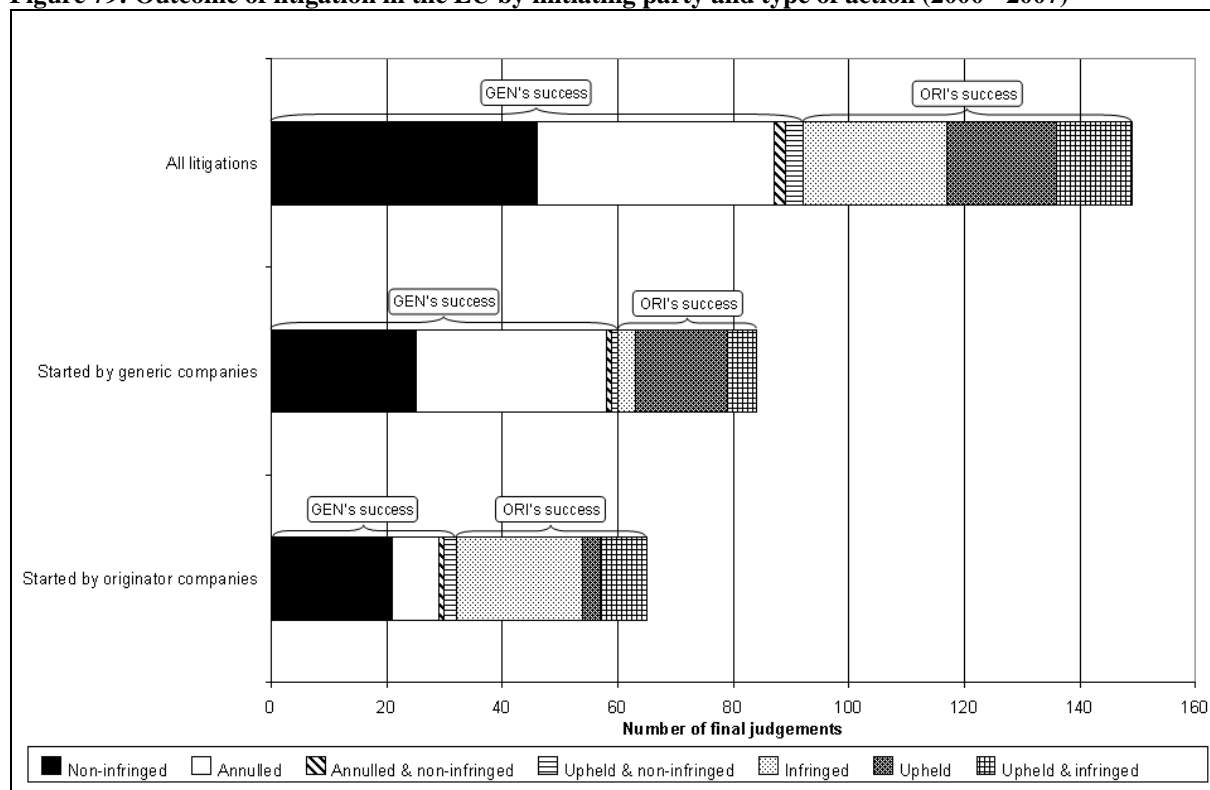
Source: Pharmaceutical Sector Inquiry

- (614) The data provided show that patent litigation may begin shortly after grant. The cumulative number of litigated patents gradually increases as patent expiry approaches. This is true for all patents and the increasing dynamic of this process can be illustrated by the increasingly steep gradient of the curve as the patent expiry date approaches.
- (615) However, the distribution of patent litigations over time reveals substantial differences between primary and secondary patents. The secondary patents curve is less convex than that of primary patents, which means that secondary patents are (a) more equally distributed over the relative period displayed in Figure 78 and (b) more likely to be litigated earlier in the process. As a consequence, the time before patent expiry is relatively longer. For primary patents the opposite is true.
- (616) For example, when the patents covered are those having ten years or more before expiry, the analysis shows that 13% of primary patents were the object of court proceedings versus 36% of secondary patents. Likewise, five years or more prior to patent expiry, 37% of primary patents and as much as 66% of secondary patents had already been litigated in court. Once the patents covered by the analysis include those having one or more years before expiry, the relative difference between primary and secondary patents narrows down with 77% of primary patents being the object of litigation versus 96% of secondary patents.
- (617) At the date of patent expiry (year 0 in Figure 78), the difference between the two types of patents decreased considerably and was down to less than 6 percentage points. A limited number of cases relate to the situation where the date, on which litigation was initiated, falls after the patent expiry date. Those cases were specifically introduced by one of the litigating parties in order to seek damages (for example).

2.2.2.6. Outcome of the Main Action on the Merits

(618) Companies were asked to report on the outcome of patent litigation in all final judgements (*res iudicata*) in the period examined by indicating one of the following outcomes with regard to the litigated patent: (i) non-infringed; (ii) annulled; (iii) infringed; (iv) upheld and (v) other.⁴¹³ Figure 79 illustrates the final outcomes of all litigation reported and the final outcomes of litigation per initiating party (with the exception of final outcomes indicated as "other", where results could not be classified).⁴¹⁴

Figure 79: Outcome of litigation in the EU by initiating party and type of action (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(619) As explained above, respondent companies reported 698 separate litigations. A final judgment was reported in 149 of the litigations, of which 84 were initiated by a generic company and 65 by an originator company. The remaining 549 cases were reported as being either settled (223 cases) or no final outcome was indicated, e.g. they were reported as pending (326 cases).

⁴¹³ The outcome involving the annulment of the patent and a declaration of non-infringement (which may be the result of litigation concerning two different patents or one patent covering several claims, some being annulled and the other declared non-infringed by the court) was subsequently added as some data reported by companies indicated such final outcome of litigation.

⁴¹⁴ Such "other" final outcomes of litigation reported by respondent companies referred to, *inter alia*, settlement agreements.

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- (620) For the purposes of Figure 79, litigation outcomes were divided into two groups labelled "GEN's success" and "ORI's success" according to their likely market consequences allowing or forbidding market entry by a generic company. An outcome is considered a success, from the perspective of an originator company, if the final judgement does not allow generic entry prior to patent expiry. On the other hand, an outcome is considered successful for the generic competitor if the final judgement allows risk-free generic entry.
- (621) Overall results show that generic companies won 62% of all patent litigations reported in which a final judgment was delivered (62%) whereas originator companies were successful in the remaining 38% of cases.⁴¹⁵
- (622) Furthermore, out of all litigation cases in which a final judgment was given on the issue of the validity of a given patent (78 cases), the court revoked the patent in 55% of cases (43) and upheld it in the remaining 45% (35).
- (623) More specifically, generic companies won nearly three quarters of all patent cases they initiated (71%) and were unsuccessful in over one quarter of the cases they initiated (29%).⁴¹⁶
- (624) In comparison, originator companies were successful in slightly over half of the cases they initiated (51%) whilst they lost nearly half (49%).⁴¹⁷
- (625) As Figure 79 shows, generic companies won overall more than 60% of all patent litigations initiated in the EU from 2000 – 2007 in which a final judgment was given.⁴¹⁸ However, this outcome was achieved at the expense of the multiplication of

⁴¹⁵ More precisely, the patent was annulled and declared non-infringed in 27.5% and 30.9% of all cases, respectively. The patent was upheld and declared not to be infringed in 2% of cases, and annulled and declared non-infringed in another 1.3%. In comparison, the patent was upheld and was declared infringed in 13% and 17% of all litigations, respectively. The court upheld the patent and found it infringed in another 8%.

⁴¹⁶ Courts annulled the patent and declared it not to be infringed in 39% and 30% of all litigations initiated by generic companies, respectively. The patent was upheld but found not to be infringed in nearly 1% of litigations, and annulled and declared non-infringed in another 1%. In comparison, the patent was upheld and declared infringed in 19% and nearly 4% of all cases, respectively. Court upheld the patent and declared it infringed in another 6% of cases.

⁴¹⁷ Courts found a patent infringement and upheld the patent in over one third (34%) and 5% of all litigations initiated by originator companies, respectively. The patent was upheld and declared infringed in 12% of litigations. In comparison, in nearly one third of litigations (32%) initiated by the originator party the courts found the patent not to be infringed, and annulled in 12% of cases. The patent was upheld but found not to be infringed in 3% of cases, and was annulled and declared not to be infringed in another 1.5%.

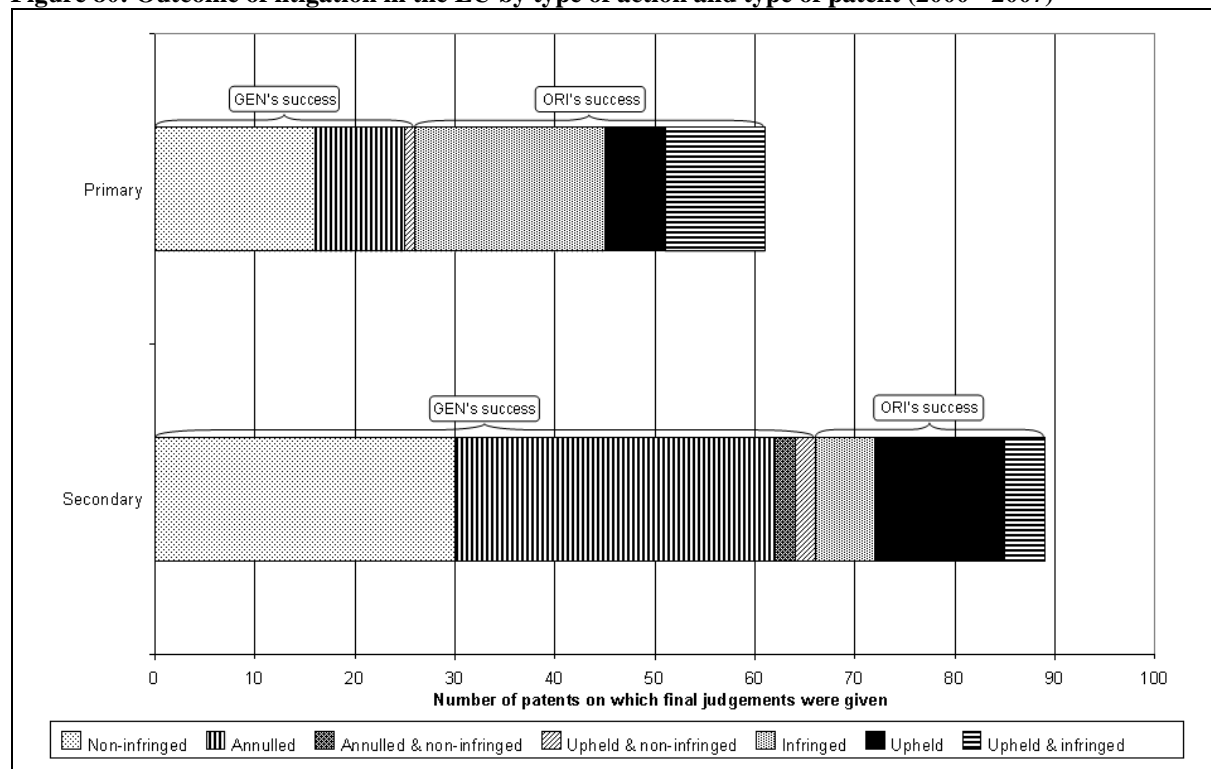
⁴¹⁸ In the course of the public consultation, it has been argued that the sample of final judgements was biased due to the self-selection effect and that it was too small in order to be conclusive. However, it must be noted that even if only a limited number of cases reach final judgement, it is interesting to record their outcome as they can provide insights into the current situation. Furthermore, it must also be noted that the fact that certain patents have not been challenged in court does not necessarily provide certitude as to their ultimate solidity.

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costly and often lengthy litigation before different national jurisdictions, thus entailing a significant burden and legal uncertainty for generic companies. In light of the above, the introduction of a Community patent, which could be challenged and enforced before a unified Community patent court, would significantly increase the legal certainty and efficiency of the European patent system.

(626) Figure 80 illustrates companies' responses as to the outcome of litigation in all final judgements by type of action and type of patent (primary or secondary) given from 2000 to 2007.⁴¹⁹

Figure 80: Outcome of litigation in the EU by type of action and type of patent (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(627) As shown in Figure 80, originator companies won 57% of all cases concerning primary patents in which a final judgement was given, versus 43% for generic companies.⁴²⁰

⁴¹⁹ Figure 80 and Figure 81, contrary to Figure 79, are not based on a number of final judgements, but on a number of patents on which final judgements were given. The difference between the two methods relates to the situation in which a final judgement concerns more than one patent.

For more information on the patent and litigation strategies employed by originator companies see Chapter C.2.1

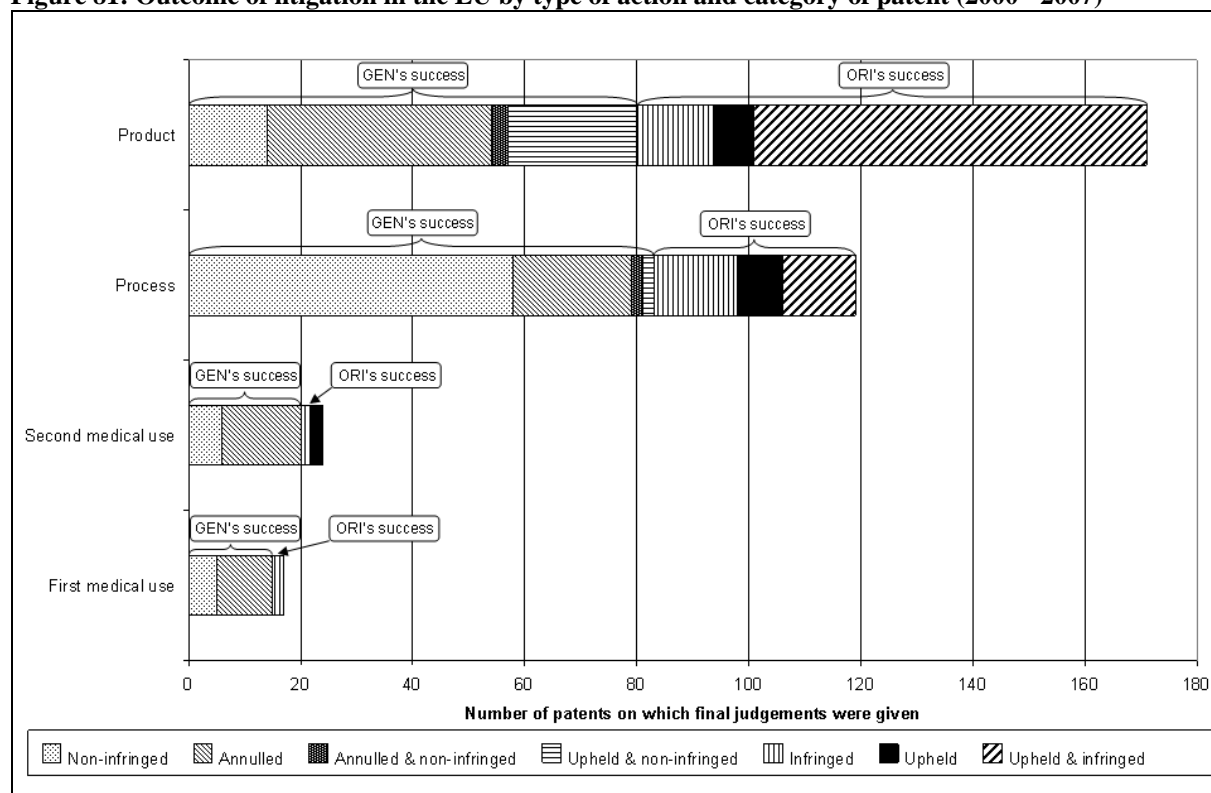
⁴²⁰ In particular, courts upheld the primary patent in 10% of all cases concerning primary patents, and upheld and declared the patent infringed in another 16%. The primary patent was declared infringed in 31% of cases. In comparison, the primary patent was found not to be infringed in 26% of cases concerning primary patents. It was annulled in 15% of cases and upheld but found not to be infringed in another 1.5%.

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(628) The picture is different for secondary patents.⁴²¹ Generic companies won nearly three quarters (74%) of all cases concerning secondary patents in which a final judgement was given.⁴²² In contrast, originator companies were successful in over one quarter of litigations over secondary patents (26%). It should be recalled that secondary patents accounted for nearly two thirds (64%) of all litigated patents in the EU in the period 2000 – 2007 (see Figure 77).

(629) Figure 81 provides an overview of the outcome of litigation in all final judgements rendered in the period 2000 to 2007 shown by patent category.⁴²³

Figure 81: Outcome of litigation in the EU by type of action and category of patent (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(630) Responses show that, by and large, product patents were most often the object of litigation. Originator companies won a slight majority of cases with over 53% of final

⁴²¹ Any comparison between primary and secondary patents can only be drawn insofar as it only concerns the primary and secondary patents that were brought up in litigation ending with a final judgment.

⁴²² Secondary patents were annulled in over one third of all cases concerning secondary patents (36%) and were found not to be infringed in nearly 34% of cases. They were upheld but declared non-infringed, and annulled and found not to be infringed in 2% and 2% of cases. In contrast, secondary patents were upheld and declared infringed in 15 and 7% of cases, respectively.

⁴²³ It should be noted that a given litigation may concern one or several patents falling under one or more patent categories and, therefore, overlaps may occur in the number of cases ending with a final judgement presented on the figure above. For example, one final judgement may annul a patent which is classified as both process and product patent.

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- rulings, concerning product patents, being decided in their favour as against 47% for generic companies.⁴²⁴
- (631) Process patents formed the second most litigated category of patents. More than two-thirds (nearly 70%) of all final judgments handed down on process patents were favourable to the generic litigant, with only 30% of final judgments being favourable to originator companies.⁴²⁵
- (632) Generic companies were particularly successful in winning the vast majority of cases concerning second medical use patents (83%) with originator companies winning a merely 17% of cases.⁴²⁶
- (633) Finally, generic companies were equally successful in challenging first medical use patents, with final judgments in their favour being given in the overwhelming majority of litigations (88% of all cases) compared to only 12% in favour of the originator party.⁴²⁷
- (634) Hence, with the exception of product patents where originator companies were about as successful in litigation, generic companies won the overwhelming majority of cases concerning the other three categories of patents. Hence, it would appear that among litigated patents the strength of process patents, first medical use and second medical use patents is relatively more limited and their challenge before court more often yields favourable results for generic companies.⁴²⁸
- (635) Figure 82 provides an overview of the average duration of litigation, in which a final judgement was given in the period 2000 to 2007, in a sample of 16 Member States, and lists the number of litigations per Member State.⁴²⁹

⁴²⁴ More precisely, courts upheld the product patent and declared it infringed in 41% of all cases over product patents, found the patent infringed in 8% of cases and upheld it in 4%. In comparison, the product patent was annulled and/or declared non-infringed in 33% of all cases.

⁴²⁵ The process patent was found not to be infringed in 49% of cases, and was upheld but declared non-infringed in another 2%. It was annulled in nearly 18% of cases. In contrast, the process patent was upheld, found infringed and upheld and found infringed in nearly 7%, 13% and 11% of all cases concerning process patents, respectively.

⁴²⁶ Second medical use patents were annulled in 58% of all cases concerning second medical use patents and declared non-infringed in another 25%. In comparison, they were upheld and found infringed each in 8.3% of cases.

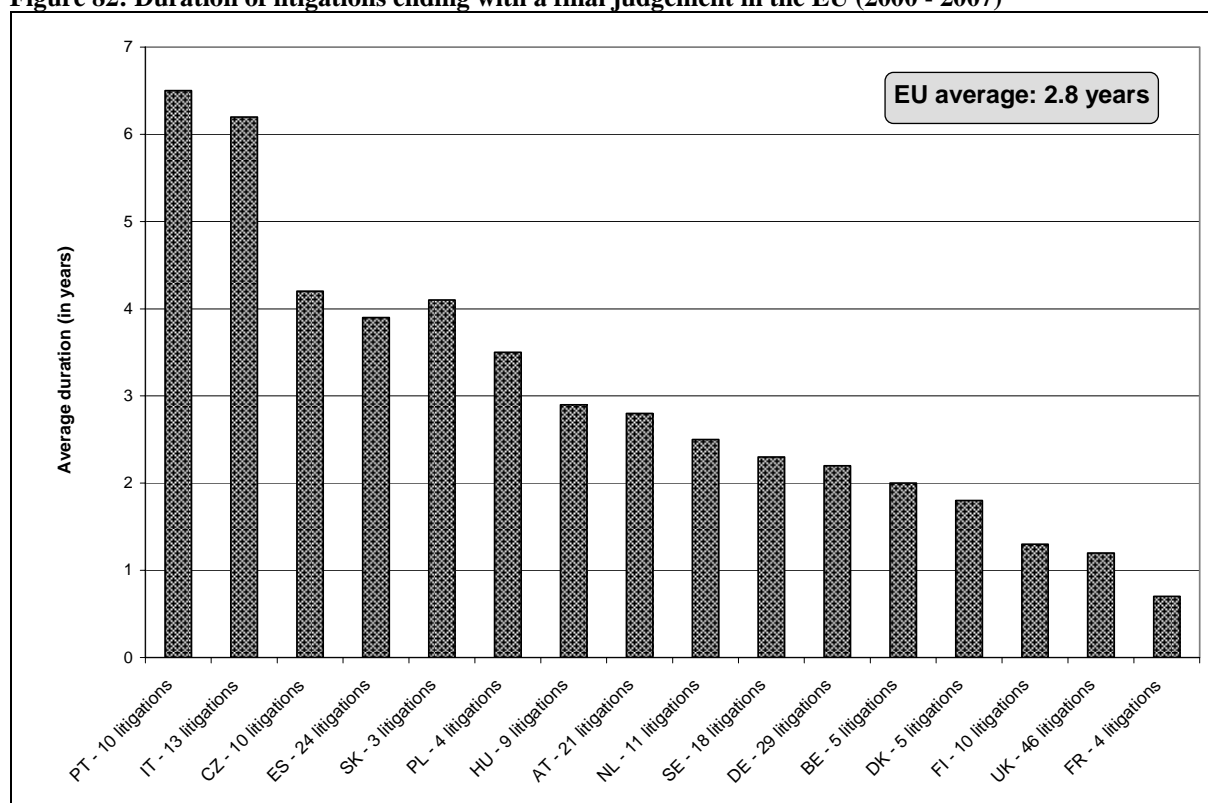
⁴²⁷ First medical use patents were annulled and declared non-infringed in 59% and 29% of all cases, respectively. In comparison, first medical use patents were declared infringed in only 12% of cases.

⁴²⁸ For further information on originator companies' patent and litigation strategies see Chapter C.2.1.

⁴²⁹ It should be noted that litigation scenarios may vary with some cases involving one, and other two or three court instances and a varying degree of complexity of the subject matter.

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Figure 82: Duration of litigations ending with a final judgement in the EU (2000 - 2007)



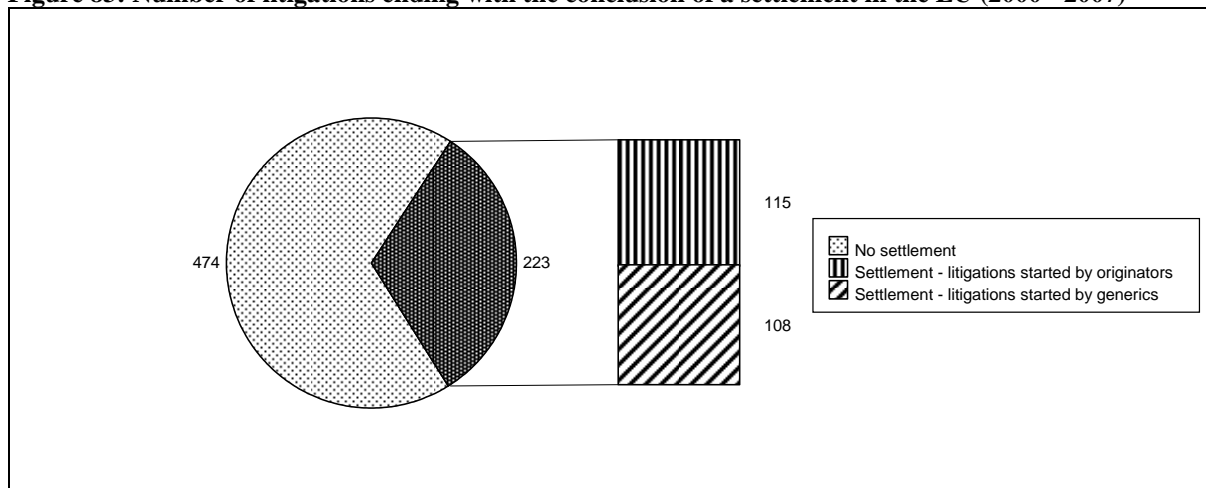
Source: Pharmaceutical Sector Inquiry

- (636) Patent litigation in the EU took on average 2.8 years in the period examined. Figure 82 shows litigation before Portuguese and Italian courts was the lengthiest with an average duration of over six years. In the Czech Republic, the Slovak Republic, Spain, and Poland, litigation took on average between three and four years whilst in Hungary, Austria, the Netherlands, Sweden, Germany and Belgium, litigation had an average duration of two to three years.
- (637) Patent litigation in Denmark, Finland and the United Kingdom took a significantly shorter time with an average duration of one to two years. Lastly, French courts were the most expeditious in examining patent litigation taking on average of less than a year (seven months) to pronounce a final judgement in the cases examined.
- (638) Patent litigation in various Member States, following different procedural rules and with varying length of proceedings, enhances legal uncertainty for generic companies and the risk of divergent outcomes regarding the issue of the validity or the infringement of a given patent. In particular, litigation in some large EU Member States (such as Italy, Spain and Poland) significantly exceeded the EU average length of litigation of 2.8 years. The introduction of a single Community patent and a unified patent judiciary would significantly increase the efficiency of the European patent system by reducing legal uncertainty, litigation costs and resources used as well as shortening the delays incurred.

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(639) Companies were asked to provide information on whether the patent litigation they initiated resulted in the conclusion of a settlement (see Figure 83 below).⁴³⁰ Responses show that a settlement was the outcome of patent litigation in nearly a third of all reported litigations (32%).⁴³¹ Furthermore, out of all litigations which resulted in a settlement, 52% were initiated by an originator company and 48% by a generic company.

Figure 83: Number of litigations ending with the conclusion of a settlement in the EU (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

2.2.2.7. Interim Injunctions

(640) An important remedy for originator companies is the possibility of provisionally restraining the generic company from selling its products until the court decides on the merits of the case. Interim injunctions can be granted in order either to prevent an impending generic entry to the market or to provisionally forbid the marketing of a generic product which is already on the market. For interim relief to be granted, generally the originator company has to establish urgency, the risk of (irreparable) harm and minimum grounds for its main claim.⁴³² The grant of interim injunctions also

⁴³⁰ For further information on settlement agreements between originator and generic companies see Chapter C.2.4.

⁴³¹ The aggregate number of settlements reported in the present section on patent-related exchanges and litigation between originator and generic companies (223 settlements resulting from litigation and 35 resulting from disputes) exceeds the total number of settlements as reported in the section on patent settlements (see Chapter C.2.4). This is explained by the different way in which settlement agreements were counted in the two sections. For the purpose of the present section, one settlement was counted in the case of each litigation ending with a settlement whilst in the context of the section on settlements (see Chapter C 2.4), many settlement agreements covered several litigations in several Member States. Hence, the figures provided in the two sections as such are not comparable.

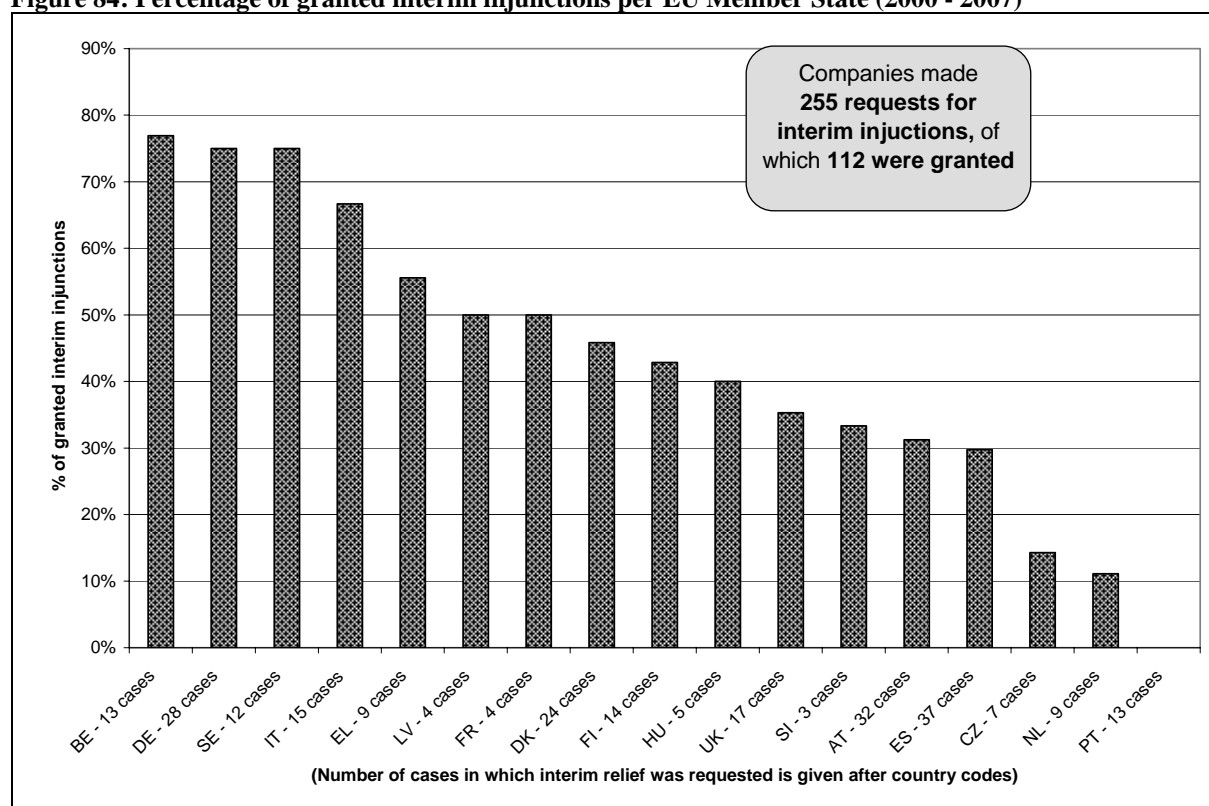
⁴³² Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, pp.45-86, the "Enforcement Directive") harmonised Member States' legislation regarding the means of enforcing intellectual property rights. For more information see Chapter B.2.1.

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entails risks for originator companies which may have to pay compensation to the generic company, whose product has been enjoined, in case the court ultimately invalidates the patent or finds the absence of infringement and revokes the interim injunctions. In the course of the public consultation, it has also been submitted that generic entry prior to patent expiry can have serious consequences for originator companies which may suffer irreversible commercial losses, in particular due to the decrease in price.

- (641) Figure 84 provides an overview of the percentage of patent litigations in which interim injunctions were granted out of all litigations in which a request for interim relief was made, shown per EU Member State. Companies reported 255 requests for interim injunctions made by originator companies from 2000 - 2007, of which 112 (44%) were granted.

Figure 84: Percentage of granted interim injunctions per EU Member State (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

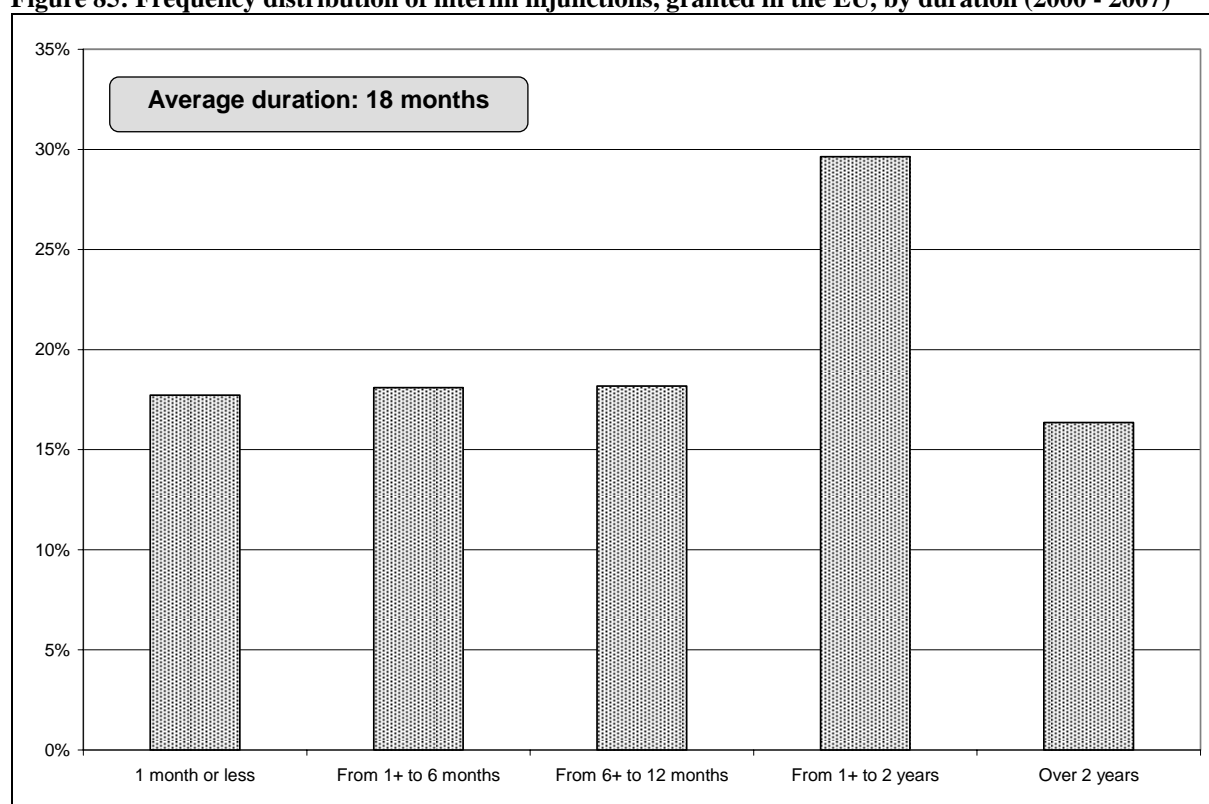
- (642) Courts granted interim injunctions most frequently in Belgium, Germany and Sweden where injunctions were granted in three quarters of all cases in which interim relief was requested (75 – 77% of cases) and in two thirds in Italy (67%). Interim injunctions were granted in (over) half of all cases in Greece, Latvia and France. Courts in Denmark, Finland and Hungary granted interim relief in less than half of all cases (40 to 46%) whereas in the United Kingdom, Slovenia, Austria and Spain interim relief was granted in only one third of all cases (30 to 35%). Courts in the Netherlands, the Czech Republic and Portugal were the least inclined to grant interim injunctions with interim relief agreed in 14%, 11% and none, respectively, of all cases in which it was requested.

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(643) The lack of a single Community patent and a unified patent judiciary result in a substantial burden for originator companies which need to file requests for interim injunctions in all the Member States where their patent rights are (about to be) infringed, without having any certainty as to the outcome of the request. Thus, it can happen that in a request for interim relief in the context of an (impending) infringement of the same INN, one national court may grant injunctions and another may not.

(644) Figure 85 provides an overview of the frequency distribution of interim injunctions granted by Member State courts from 2000 to 2007 in light of their duration.⁴³³ The data have been used as reported by companies on interim injunctions granted in the framework of an initiated main action. Respondent companies were asked to provide the total period during which interim injunctions were granted by accumulating the duration of all interim injunctions granted in the course of a given patent case.

Figure 85: Frequency distribution of interim injunctions, granted in the EU, by duration (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

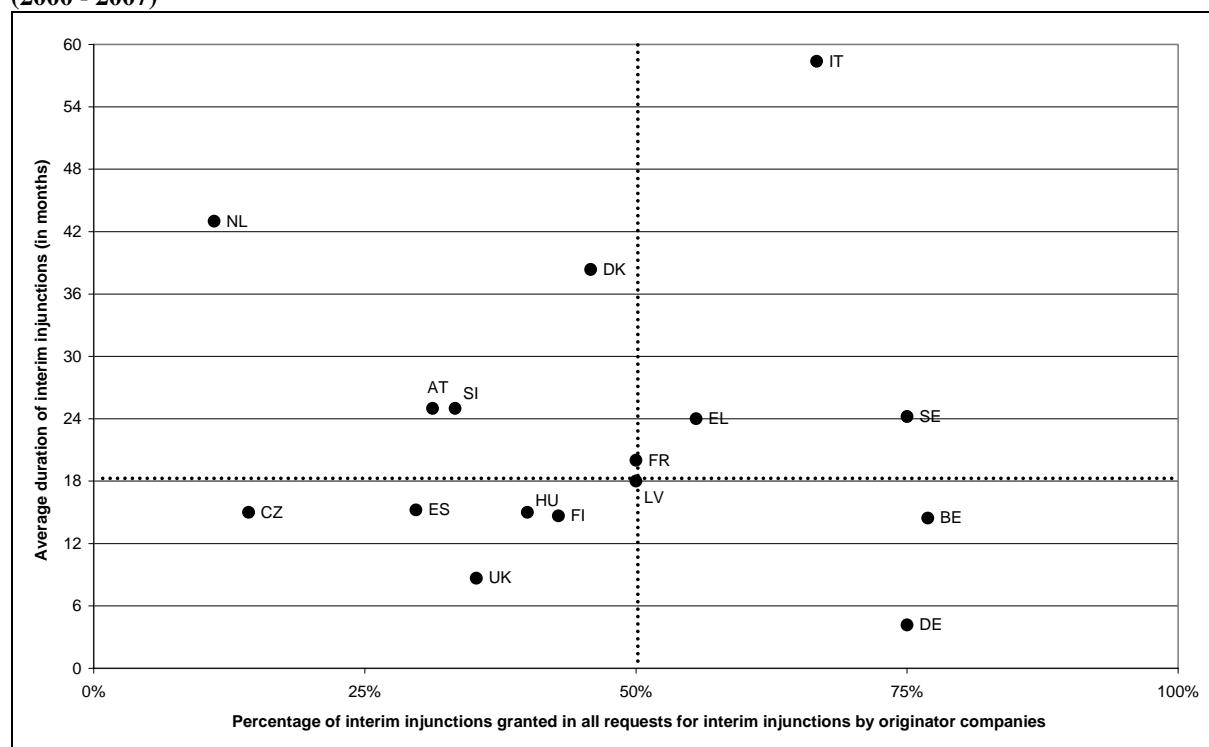
(645) Data reported by companies show that interim injunctions were granted, on average, for a period of 18 months. A significant proportion of interim injunctions (46%) were granted for a period exceeding one year. More precisely, 30% of interim injunctions were granted for a period lasting between one and two years, and 16% were granted for a period exceeding two years.

⁴³³ For the purpose of the present chapter, only requests for interim injunctions made in the framework of a main patent-related legal action have been taken into account.

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- (646) However, more than half of all interim injunctions granted in patent litigation in the EU (54%) did not exceed one year. Thus, 18% of interim injunctions were granted for a period of six to 12 months, another 18% for a period of one to six months, and nearly 18% were granted for a period not exceeding one month.
- (647) Figure 86 shows the proportion of patent litigations in which interim injunctions were granted by EU Member State and the average duration in months of the interim injunctions reported.

Figure 86: Percentage of interim injunctions granted and their average duration per EU Member State (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

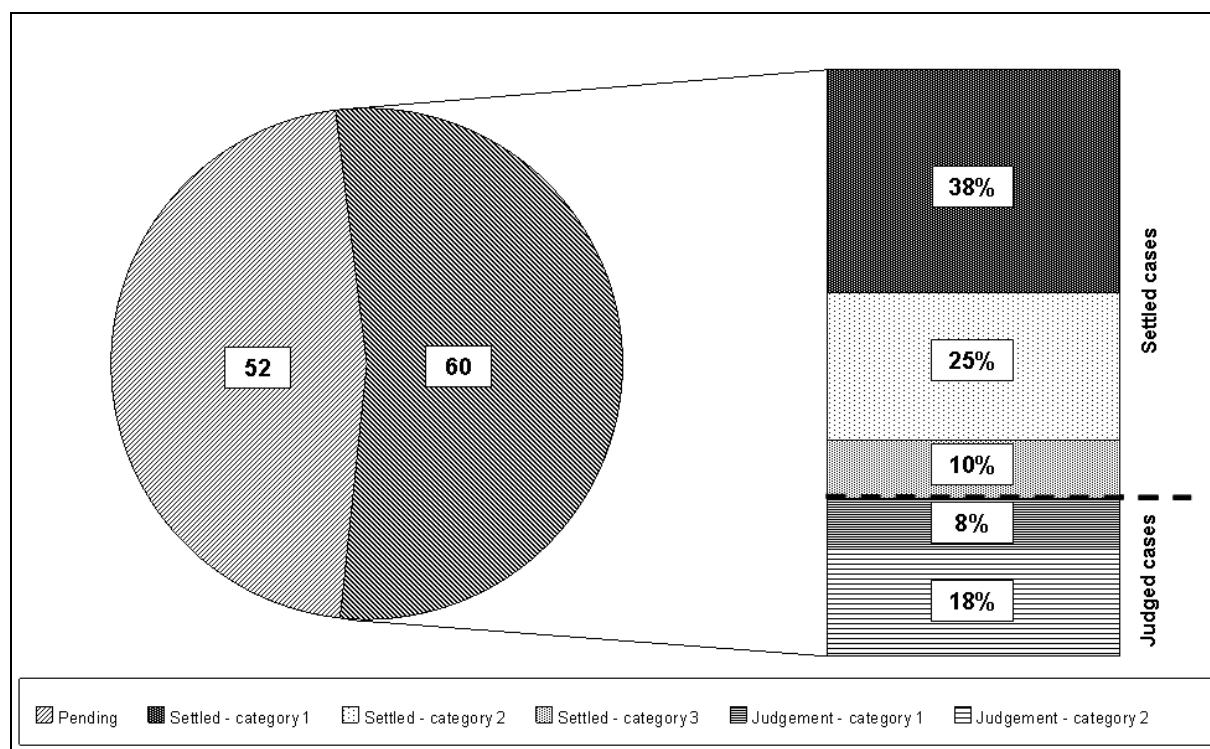
- (648) Figure 86 divides Member States into four different groups according to (a) the average duration of interim injunctions, where a division was made between the Member States in which the interim injunctions were granted, on average, for less and for more than 18 months (which is the EU average), and (b) the proportion of litigations in which interim injunctions were granted, where a division was made between Member States having more or less than 50% of litigations in which interim injunctions were granted out of all litigations in which interim relief was requested.
- (649) These divisions create four rectangular boxes (see the dotted lines in Figure 86) of which the lower left and the upper left rectangles are the most populated. The countries situated in the lower left rectangle are characterised by the relatively shorter duration of the interim injunctions granted (less than 18 months) and the lower percentage of litigations in which interim injunctions were granted (less than 50% of litigations: the rectangle includes the Czech Republic, the United Kingdom, Hungary, Finland and Spain). In the countries situated in the upper left rectangle, interim injunctions had a relatively longer average duration (more than 18 months) and were likewise granted in less than half of litigations (the Netherlands, Austria, Slovenia, and Denmark).

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(650) In the lower right rectangle, which includes Belgium and Germany, interim injunctions were equally granted for an average duration of less than 18 months but the proportion of cases involving interim injunctions was relatively higher (more than 50% of cases). In the upper right rectangle, which includes Greece, Sweden and Italy, interim injunctions were granted for a higher average duration (more than 18 months) and in a higher proportion of cases (more than 50%). In Latvia and France,⁴³⁴ interim injunctions were granted in 50% of all cases for an average duration of 18 and 20 months respectively.

(651) Figure 87 shows the outcome of patent litigation cases in which interim injunctions were granted as reported by respondent companies.

Figure 87: Outcome of cases in which interim injunctions were granted as reported by respondent companies



Source: Pharmaceutical Sector Inquiry

(652) Out of 112 cases in which interim injunctions were granted, in 60 cases respondent companies reported a formal closure by means of either settlement agreement (44) or final judgment (16). The remaining cases were reported to be pending. It concerned 52 cases.

⁴³⁴ The discrepancy between the data on the length of patent litigation in France and the duration of interim injunctions can be explained as follows. The data reported on interim injunctions granted in France concerned mostly ongoing patent cases for which no duration could be provided yet, whilst the data on the length of litigation in France relied on the limited number of cases ending with a final judgment which had been reported by respondent companies.

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- (653) With regard to the closed cases, their outcomes were further categorised according to the respective settlement provisions or judgements. Among the closed cases, the single largest category consists of 23 settlement agreements that provided for a value transfer from the originator to the generic company and/or allowed for generic entry before the end of the protection period as claimed in the litigation proceedings by originators. In Figure 87, these 23 settlements fall into the first category of settlements and represent 38% of all closed cases. Based on the terms of the settlement providing a value transfer to the generic companies involved in the litigation and/or their early entry, the outcome of these cases appear to be particularly favourable to the generic companies.
- (654) The opposite cases, in which a value transfer took the direction from the generic to the originator company and/or generic entry was delayed until the end of the protection period as claimed in the litigation proceedings by originators, were allocated to the third category of settlements. They represent 10% of all final cases and should be counted as success for the originator companies. The second, middle category contains all other settlement agreements for which it was not possible to establish unequivocally whether a given settlement should belong to category 1 or 3. They represented 25% of all final cases.
- (655) Figure 87 also provides a breakdown of 16 cases with interim injunctions that ended with final judgements. These cases were divided into two categories: (a) category 1, in which the generic company was successful and (b) category 2, in which the originator company obtained a favourable judgement in the main proceedings on substance. The former category contains five cases, while the latter eleven cases.⁴³⁵
- (656) To sum up, the subsample of cases with interim injunctions shows two particular features, namely: a high ratio of settled cases (73%, i.e. 44 out of 60 cases, which are final) and a low ratio of judged final cases (27%, i.e. 16 out of 60 cases). Furthermore, it is interesting to note that in the subgroup of settled cases, there is a tendency to end litigation with the conditions that are favourable to generic companies (i.e. either allowing generic entry or a value transfer from the originator to the generic company). Even if this cannot be regarded to be a conclusive indication as to likely outcome of the respective court cases, this element needs to be borne in mind when interpreting a higher proportion of the cases with interim injunction won by originator companies (11 out of 16 cases).
- (657) The overall picture is thus more nuanced than one would have expected from the cases in which interim injunctions, the most restrictive legal tool, were granted, taking into account that, when requesting interim injunctions, the applicant is usually required to show that he is likely to succeed in the main proceedings and to demonstrate urgency. Adding up the actual generic successes (8%) and the settled cases appearing to be particularly favourable to the generic companies (38%), it would seem that in almost a

⁴³⁵ The analysis of the outcome of the main proceeding on the merits in the sample under investigation is not intended to suggest that national legal systems should provide for a preliminary assessment of the likely outcome of the case before interim injunctions may be granted, which however is the case in a number of Member States.

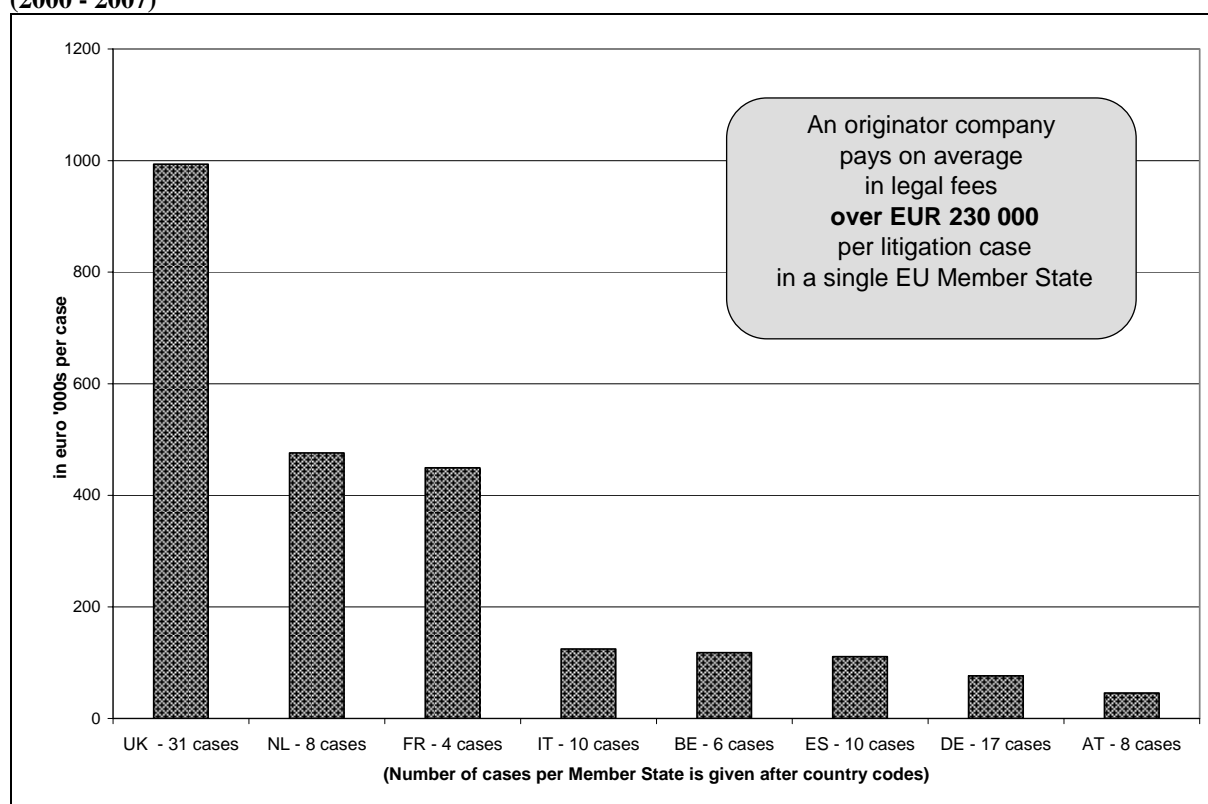
PHARMA SECTOR INQUIRY – MAIN ISSUES INVESTIGATED

half of the closed cases the grant of interim injunctions might not have been justified, whilst in another 25% of the cases that were settled the situation is unclear.

2.2.2.8. Cost of Fees for Legal Advice Incurred in Patent Litigation

(658) Companies were asked to report the total costs incurred for each litigation to which they were a party, including a break-down of lawyers' fees, man-hours used and other costs. The average legal fees⁴³⁶ incurred by originator companies per litigation and per EU Member State are examined below (see Figure 88) by reason of their importance for the total cost of patent litigation. For the purpose of graphic presentation, the sample covers some of the largest Member States of the EU, on which more substantial amount of data was provided.

Figure 88: Average legal fees per litigation and per Member State as reported by originator companies (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

(659) Responses show that originator companies paid, on average, € 230,000 in legal fees per case in a single Member State. Responses also show that legal fees incurred in patent litigation before UK courts were particularly high, with an average of € 993,000 per litigation. The second highest average legal fees (which were roughly half of those in the United Kingdom) were incurred in patent litigation in the Netherlands and

⁴³⁶ For the purpose of the report, legal fees can be defined as the fees charged for advice by external lawyers in patent proceedings.

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France (an average of € 476,000 and € 449,000 per litigation). In Italy, Belgium and Spain, legal fees in patent cases ranged between € 111,000 and € 124,000 on average. Finally, it was apparent that, on average, legal fees were lowest in Germany and Austria (€ 76,000 and € 46,000).⁴³⁷

- (660) As to the total cost of pursuing patent litigation in the EU in the period 2000 to 2007, data reported by respondent companies show that, on a rough estimate, the total cost exceeded € 420 million.⁴³⁸
- (661) As evidenced by companies' replies, legal fees incurred in multiple patent litigations in various EU Member States are very substantial. In addition to the high legal fees, litigation costs generally also include court fees, cost of experts, costs related to technical investigations and possibly appeal procedures, and translation costs required by litigation before different jurisdictions. Therefore, the cost of patent litigation in the EU could be substantially lower if the European patent system relied on a Community-wide patent, which could be challenged and enforced before a unified patent judiciary.
- (662) According to a conservative estimate, around 30% of the litigation cases reported by respondents were duplicates of already pending proceedings in other national jurisdictions between the same parties.⁴³⁹ This figure does not include those duplicates where an originator company was in litigation over the same medicine with different generic counterparties, which are considered independent from each other. The figure provides a rough indication as to potential savings in the pharmaceutical sector if only a unified patent judiciary was established.

2.2.2.9. Contradicting Decisions

- (663) The data collected during the sector inquiry also allowed to analyse whether national courts reached contradicting decisions on the same underlying issues in patent litigations.⁴⁴⁰ Such contradicting decisions are possible if a court in one Member State decides that the contested patent is valid, whilst a court in another Member State declares it invalid, or if a court in one Member State declares that the product launch of a generic version would infringe the patent rights of the originator company, whilst a

⁴³⁷ It should be noted that litigation scenarios may differ with some cases involving several instances and a varying degree of complexity of the subject matter.

⁴³⁸ The total cost of litigation consists of legal fees, costs of own labour (i.e. man-hours spent by the company's employees on a given case) and other costs. The estimation is based on the figures made available in the framework of the sector inquiry and extrapolated for those litigation cases for which the requested information was not provided by respondent companies. Furthermore, the estimation takes into account the likely costs incurred by the counter-party to litigation.

⁴³⁹ For the importance of each litigation case for the present analysis, see footnote 403.

⁴⁴⁰ It should be noted that – legally speaking – the court cases pending in different Member States do not deal with the same subject matter as the geographic scope of the underlying patents is not identical.

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court in another Member State finds that the patent would not be infringed by such action.

- (664) Such contradicting rulings were found in a total of 16 cases out of the 149 final judgements reported in Figure 82, i.e. 11% of all cases. This is a significant finding since the existence of conflicting final judgements inevitably harms the legal certainty for the companies that are active in a given product on other EU markets.

Summary

Enforcing patent rights in court is legitimate and a fundamental right guaranteed by the European Convention on Human Rights: it is an effective means of ensuring that patents are respected. Like in any other industry the inquiry's findings show, however, that litigation can also be an efficient means of creating obstacles for generic companies, in particular for smaller ones. In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants.

Taking into account the 219 molecules in the sample, originator and generic companies identified at least 1,300 patent-related out of court contacts and disputes concerning the launch of generic products in the period 2000 to 2007. The vast majority of disputes were initiated by the originator companies, which most often invoked their primary patents, e.g. by sending warning letters.

The number of patent litigation cases between originator and generic companies increased by a factor of four between 2000 and 2007. In total, 698 cases of patent litigation between originator companies and generic companies were reported in relation to the medicines investigated.

Of these, 223 cases were settled, and the courts rendered final judgements in 149 cases. The remaining 326 litigation cases were either pending or withdrawn. Whilst the originator companies initiated the majority of the cases, generic companies won 62% of the 149 cases. The average duration of the court proceedings was 2.8 years, but varied considerably between Member States, from just over six months to sometimes more than six years.

In contrast to the primary patents invoked in the pre-litigation phase, originator companies mainly invoked secondary patents during litigation.

In 30% of the cases litigation was initiated between the same parties in more than one Member State with respect to the same medicine. In 11% of the final judgments reported, two or more different courts in different EU Member States gave conflicting final judgments on the same issue of patent validity or infringement.

Originator companies asked for interim injunctions in 255 cases, and were granted such injunctions in 112 cases. The average duration of the interim injunctions granted was 18 months. In 46% of the cases in which injunctions were granted the subsequent court proceedings in the main case ended either with final judgments favourable to the generic company, or settlements which appear to be favourable to the generic company as they allowed early entry for the generic company and/or foresaw a value transfer to it. In addition there were a number of further patent settlements, for which a final classification (i.e. favourable to the generic or the originator company) was not possible.

The total cost of patent litigation in the EU relating to the 68 medicines on which litigation was reported for the period 2000 – 2007, is estimated to exceed € 420 million, of which a significant proportion could have been saved, if the cross-border duplication of cases linked to the absence of a Community patent and a specialised patent litigation system could have been avoided.

2.3. Oppositions and Appeals

- (665) This section analyses oppositions and appeals filed by generic companies in respect of patents held by originator companies.
- (666) The possibility of opposing an originator company's patent allows a generic company to seek legal clarification or remedy. At the end of the opposition procedure the patent-in-suit is either maintained (rejection of the opposition), revoked or amended.⁴⁴¹ Oppositions constitute a legal mechanism which enhances patent quality.
- (667) In the previous chapter, the report analysed the litigation faced by generic companies, e.g. because originator companies invoke their patents against them. The opposition procedure is a way for generic companies to obtain verification of the validity and scope of an originator company's patent, which may be invoked in litigation.⁴⁴² If, in the opposition, this patent is proved to be invalid, it will be either revoked or its scope will be reduced. This may then allow the generic company to enter the market without facing the risk of infringing that patent. However, oppositions can only be launched within a certain period after the grant of a patent.⁴⁴³
- (668) This section focuses on the opposition procedures before the European Patent Office (EPO). Appeals of EPO decisions on oppositions to the Boards of Appeal are also taken into account. National opposition procedures concerning national patents before the offices and bodies of the Member States are briefly considered.
- (669) Opposition and appeal proceedings before the EPO are two separate and distinct procedures, the former being examined by the Opposition Divisions, the latter being examined by the Boards of Appeal. A similar separation of the two procedures is also seen in many national procedures. In other words, from a procedural point of view, both procedures are separate, as highlighted by the EPO in the context of the public consultation.
- (670) While this procedural separation is acknowledged, one should bear in mind that one aspect of this inquiry, and the subject of the present section, is how to assess companies' use of patents in their commercial strategies, which can in principle delay the entry of other actors on the market. The time taken before a final decision has been issued in a case, whether this be after opposition only or after opposition with a subsequent appeal, was therefore considered to be of greater importance than a detailed description of the individual stage, since it is only after a final decision has been issued

⁴⁴¹ For further details see Chapter B.2.1.

⁴⁴² In case a patent is challenged in front of a national court, parties in opposition may ask under certain circumstances to accelerate the opposition procedure. For further details see Chapter B.2.1. and D.1.

⁴⁴³ During the public consultation, it was underlined that third parties can already submit observations during the examination of a patent application (art. 115 EPC). This could in principle enhance the quality of granted patent as well as reduce the number of filed oppositions before the EPO. However, only few observations seem to be submitted at this early stage. For further details, see Chapter B.2.1. and D.1.

that competing companies have a clear idea of where patent protection lies. This means that, from the point of view of the competitive process, reaching a final decision as such, be it already in the opposition procedure or in the subsequent appeal, is of particular interest for the analysis undertaken in the present report. Hence, this section focuses on final outcomes in opposition and appeal procedures have been taken as a whole.⁴⁴⁴

- (671) Regarding opposition and appeal procedures, it should be noted that decisions of the EPO (including the Boards of Appeal) are valid in all European Member States where a national patent has been validated. As long as the EPO (including the Boards of Appeal) does not reach a final revocation, national courts may still decide on the validity of a national patent which resulted from an EPO patent.⁴⁴⁵ Nevertheless, some national courts regularly stay proceedings when an opposition procedure before EPO is pending, until the EPO has issued its decision. For further details on EPO and the appeal procedures, please refer to Chapter B.
- (672) Before focussing on oppositions by generic companies against originator companies' patents, this section will first present data on oppositions in general, including oppositions by various types of opponents, e.g. other originator companies. More specifically, this general section provides information on the total number of oppositions by various types of opponents; a comparison between oppositions in pharmaceuticals and in all sectors; the INNs most opposed and the duration of opposition procedures. A brief overview of oppositions before the national offices and bodies of the Member States is also provided. Subsequently, a more detailed analysis is presented of all oppositions (including appeals), where generic companies opposed the patents of originator companies during the period 2000 – 2007.⁴⁴⁶ The report presents the number of opposition procedures and opponents, and then goes on to examine the types of patents opposed. The section outlines the outcomes of the final opposition and appeal decisions. Finally, it looks into the cases where an originator company entered into a settlement with an opposing generic company.

2.3.1. General Information

2.3.1.1. Number of Opposition Procedures and Opponents

- (673) In total, 170 opposition procedures against originator companies' patents were reported for the period 2000 - 2007. These opposition procedures concerned 73 distinct INNs

⁴⁴⁴ The approach proposed here was also suggested by EFPIA in the context of the public consultation.

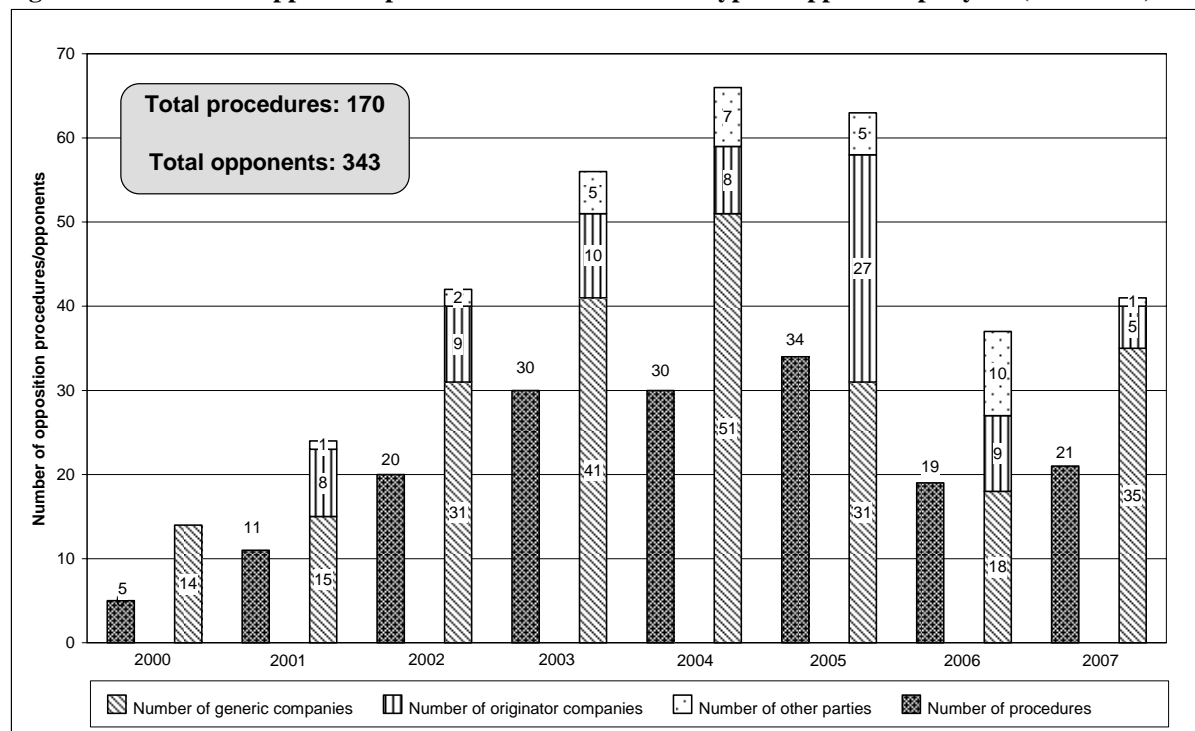
⁴⁴⁵ Even if the validity and scope of an EPO patent was confirmed by the Opposition Divisions and the Boards of Appeal, its national validation can still be challenged before national courts.

⁴⁴⁶ For the analysis of opposition procedures, in which originator companies oppose the patent of other companies, see Chapter C.3.3

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out of the 219 INNs for which information was gathered as part of the sector inquiry.⁴⁴⁷ In these 170 opposition procedures, a total of 343 opponents were active.⁴⁴⁸

Figure 89: Number of opposition procedures before EPO and type of opponents per year (2000-2007)



Source: Pharmaceutical Sector Inquiry

- (674) Figure 89 above presents the total number of opposition procedures and opponents broken down by year⁴⁴⁹ for the period 2000 - 2007. There are two bars for each year. The first bar indicates the number of opposition procedures and, separately, the second bar shows the number of opponents (relating to these procedures).
- (675) Opposition procedures increased from five procedures in 2000 to 21 in 2007. They reached a peak in the years 2003, 2004 and 2005 when 30, 30 and 34 procedures were reported, respectively. The number of opponents follows a similar pattern, reaching a peak of 56, 66 and 63 opponents in 2003, 2004 and 2005, respectively.
- (676) In Figure 89, the annual total number of opponents is further divided up into generic companies, originator companies and other opponents. The category of other opponents also includes the so-called "straw men". A straw man is a party filing oppositions and/or appeals on behalf of other parties, whose identity must not be revealed. Straw men are often employed if the actual opposing party does not wish to be known by the party opposed. As one generic company explained in this context:

⁴⁴⁷ For further information on the INNs most concerned, please see below Section C. 2.3.1.2.

⁴⁴⁸ The same companies may be involved in a number of opposition procedures.

⁴⁴⁹ The year refers to the start of the opposition procedure.

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"[To disclose] the identity of the opponent in an EPO opposition procedure increases the risk that the applicant starts litigation actions against the generic companies."

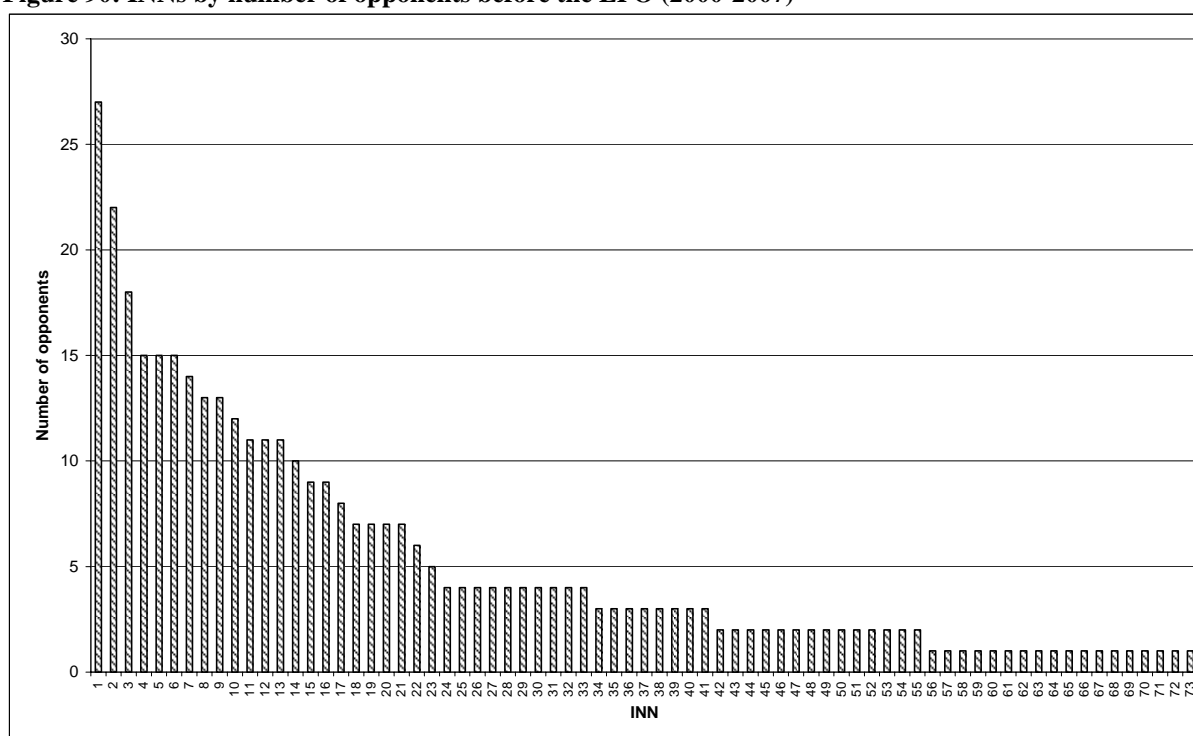
(677) Another generic company added:

"Straw man is a feature clearly to be maintained given the particularities of the patent system and the aggressivity of the originator companies."

2.3.1.2. INNs most Concerned

(678) As mentioned earlier, information was gathered on oppositions concerning 219 INNs. Patents regarding 73 INNs were concerned by opposition, with certain patents relating to these INNs attracting far more oppositions than others.

Figure 90: INNs by number of opponents before the EPO (2000-2007)



Source: Pharmaceutical Sector Inquiry

(679) Figure 90 above lists the number of opponents for any of the 73 INNs concerned by oppositions.⁴⁵⁰ This figure indicates that in the period 2000 - 2007 the bulk of opponents concerned only a part of INNs. Further analysis showed that around one third of the INNs most concerned by oppositions belonged to the top 20 best selling INNs within the E75 list and around a quarter of them belonged the top twenty best selling INNs within the T50 list.

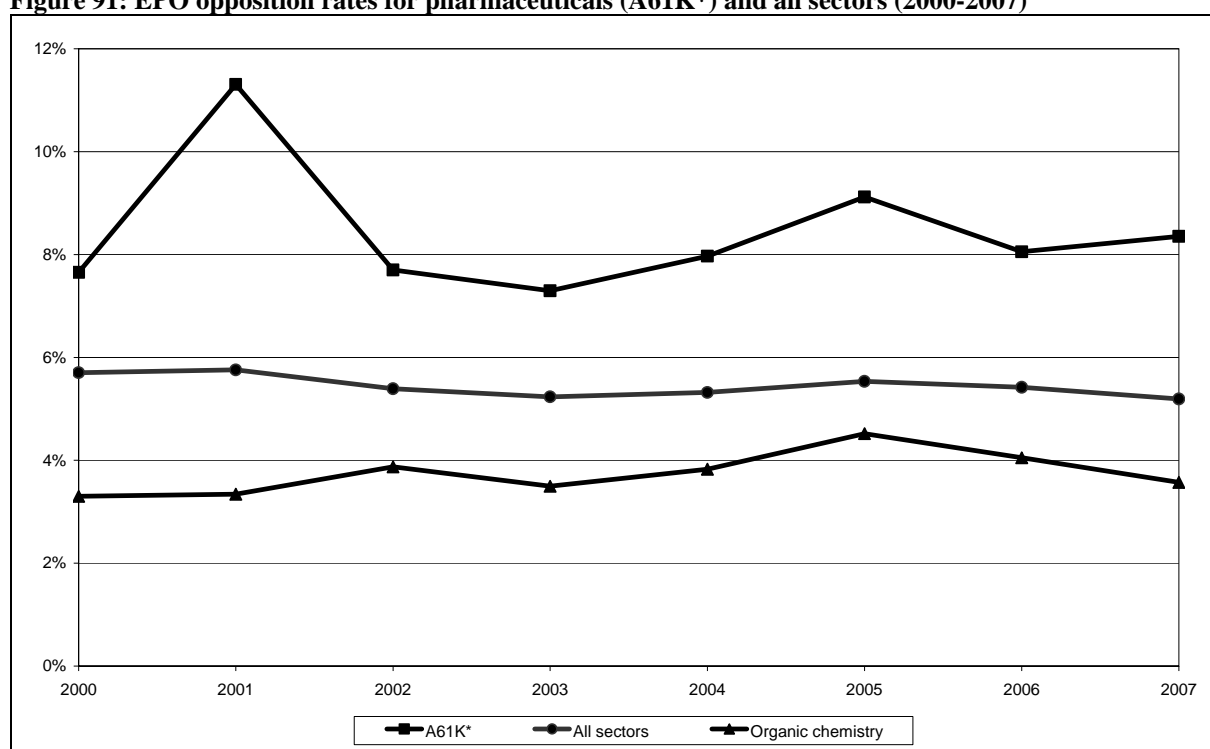
⁴⁵⁰ An opponent involved in an opposition procedure concerning several INNs is counted as one opponent for each of the INNs.

2.3.1.3. Comparison between EPO Oppositions in Pharmaceuticals and in all Sectors

(680) For the purpose of the sector inquiry, it is also considered useful to compare the oppositions filed before the EPO in the pharmaceutical sector with the oppositions in organic chemistry as well as the ones filed in all sectors during the period 2000 – 2007, as provided by the EPO.

(681) Figure 91 illustrates that, in the period 2000 – 2007, the opposition rate (i.e. the number of oppositions filed per 100 granted patents) in the closest available proxy for pharmaceuticals (A61K*)⁴⁵¹ is consistently higher than the opposition rate in organic chemistry and all sectors taken together. In A61K* the opposition rate ranged from 7.3% to 11.3%, compared to organic chemistry where it ranged from 3.3% to 4.5% and all sectors where the opposition rate was between 5.2% and 5.8%.

Figure 91: EPO opposition rates for pharmaceuticals (A61K*) and all sectors (2000-2007)



Source: Pharmaceutical Sector Inquiry (based on data EPO)

2.3.1.4. Duration of Procedures (Oppositions and Appeals)

(682) The following section analyses the duration of procedures, taking into account all procedures which were reported as final, the earliest starting in 1999 and the latest ending in 2008.⁴⁵² The duration indicated contains procedures where Opposition

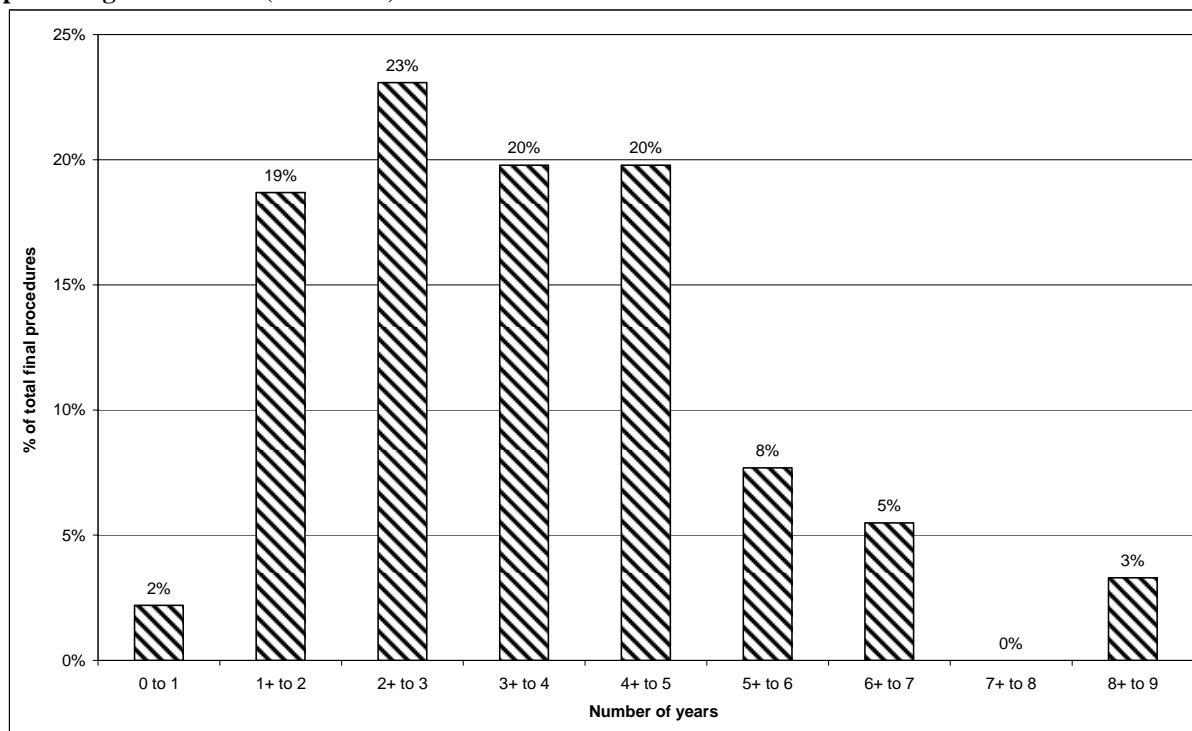
⁴⁵¹ For further explanation on A61K*, see Chapter C.1.1.2.

⁴⁵² In order to provide a better sample, the analysis of Figure 92 considers 91 opposition procedures (including appeals) in the extended period 1999 to 2008. Moreover, the duration is calculated from the

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Divisions or Boards of Appeal have rendered final decisions (*res iudicata*). In other words, in this section the whole duration is measured which is on average necessary to receive a final decision on the validity and/or the scope of an EPO patent of an originator company.

Figure 92: Average duration to achieve final decision on validity and/or scope of EPO patents as percentage of the total (1999-2008)



Source: Pharmaceutical Sector Inquiry

(683) Figure 92 above shows the percentage of total final procedures lasting an average number of years. It can be seen that only approximately 21% of the opposition and appeal proceedings receive a final decision within two years. In most cases (approximately 79%), it takes more than two years to reach a final decision and, for some cases, it can take up to nine years in total before a final decision is reached. At the same time, the average duration of the opposition procedure was approximately 3.6 years from the initiation of the procedure until the final ruling (including in the sample final cases with and without appeal).⁴⁵³ In this context, an originator company stated:

"It will often take many years to determine an opposition, given the pace at which the EPO and its appeal procedures operate."

starting date of the opposition procedure, it does not consider the nine months filing period for opposing a patent that reasonably prolongs the legal uncertainty of the patent validity.

⁴⁵³ It must be noted that the EPO strives to further improve its performance concerning the duration of opposition and appeal procedures.

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- (684) Some generic companies believe that originator companies whose EPO patents are opposed may, in some instances, prolong the opposition procedure.⁴⁵⁴ Examples of statements from different generic companies include the following:

"In our experience the opposed originator company practically always tries to prolong both the EPO opposition and the appeal procedure."

"The originator companies usually try to extend these procedures as long as they possibly can."

"In cases where we filed an opposition to a European Patent granted to an originator company, we have experienced that the originator company prolonged the opposition procedure by requesting and obtaining a six-month extension of the time to reply to the opposition. This is however in accordance with the provisions of the EPC, that allow this extension request. We don't have a similar experience in appeal procedures."

"[The effect of prolongation of procedures on our company is] the lack of commercial certainty, since the originator company may sue the opponent company for patent infringement before the national courts on the basis of patents that, in our view, have been improperly granted and, therefore, opposed."

- (685) A number of opposing originator companies indicated that in view of the duration of these procedures, they are obliged to have recourse to national courts in order to gain some legal certainty.⁴⁵⁵ One company explained:

"[...] Therefore it can take up to 7 years or something more to get a final decision from the EPO. Some National Courts are particularly good at providing decisions quickly. [...] National revocation action or actions may be filed in parallel to a European Opposition in key territories or territories where prompt decision may be expected. Some National Courts may stay any such actions until the final outcome of the European opposition is known, but many (for example UK and Belgium) will not if it appears that legal certainty is important and the proceedings at the EPO have some time still to run."

Where a company has a particular product to launch in a particular jurisdiction it may prefer to launch national revocation proceedings because they are often determined (e.g. in the UK) inside 1 year."

- (686) Out of the 73 INNs concerned by opposition and the 78 INNs concerned by litigation in the period 2000 - 2007, 40 INNs were concerned by both opposition and litigation in that period.⁴⁵⁶

⁴⁵⁴ During the public consultation, it was claimed that patent holders request additional time in order to better respond to an opposition.

⁴⁵⁵ See also footnote 442.

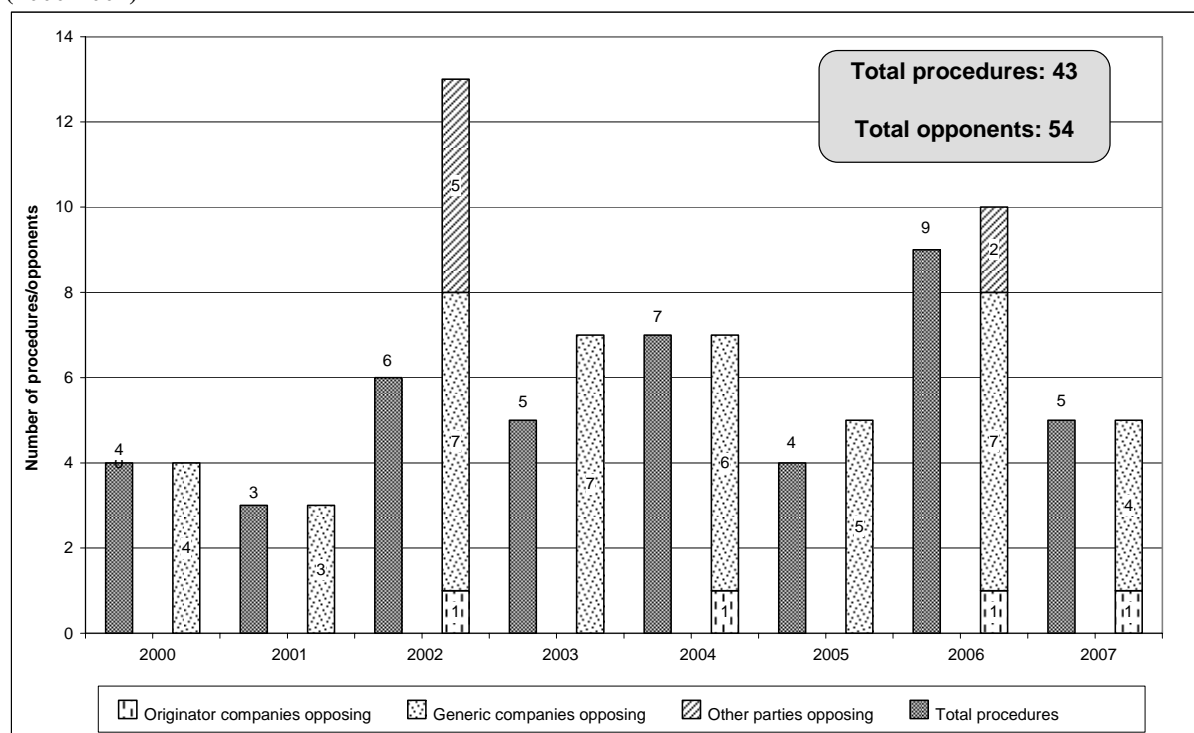
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(687) It must be stressed that, unlike a decision of the EPO or the Board of Appeal which clarifies the patent situation for all designated contracting states, the judgments of national courts are only valid for the Member State in question. As shown above for generics,⁴⁵⁷ this could, in principle, multiply the number of Member States where litigation must be carried out.

2.3.1.5. National Opposition Procedures

(688) For the sake of completeness, the report provides general data on national procedures before the offices and bodies of the Member States concerning the 219 INN for which information was collected. However, it should be emphasised that the amount of information gathered on oppositions before the EPO (including appeal) was substantially greater than that on comparable national procedures. The information provided here on the number of national procedures in the period 2000 - 2007 gives a conservative estimate.

Figure 93: Number of national opposition procedures before offices and bodies of the Member States (2000-2007)



Source: Pharmaceutical Sector Inquiry

(689) Figure 93 above presents the total number of opponents and opposition procedures at national patent offices, broken down by year for the period 2000 - 2007. For each year,

⁴⁵⁶ These findings do not intend to indicate that litigations in front of national courts and opposition procedures have the same nature and objectives.

⁴⁵⁷ For further details see Chapter C.2.2.

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Figure 93 provides two bars. The first bar indicates the number of opposition procedures at national patent offices and, separately, the second bar shows the number of opponents (relating to these national procedures), broken down into generic companies, originator companies and other opponents.

- (690) The number of national opposition procedures ranged from three in 2001 to nine in 2006. Compared to the number of opposition procedures before the EPO (see Figure 94), the number of national opposition procedures is substantially lower throughout the period. The number of opponents during the period was also considerably lower than for the EPO oppositions. It reached a peak of 13 in 2002, but otherwise remained fairly stable with between three and ten opponents per year.

2.3.2. Opposition and Appeal Procedures with Generic Companies as Opponents

- (691) After the presentation of the general information on opposition procedures, the following section analyses opposition and appeal procedures before the EPO (including appeal) where a generic company opposed the patent of an originator company. The section starts by analysing the types of patents opposed and then goes on to examine the outcome of opposition and appeal procedures in further detail.

2.3.2.1. Number of Opposition Procedures, Opponents and Types of Patents Opposed

- (692) A total of 109 opposition procedures in which generic companies opposed the patent of an originator company were reported in the period 2000 - 2007. Overall, generic companies acted as opponents on 236 occasions. These numbers further illustrate that, on average, there are at least two⁴⁵⁸ generic companies opposing the originator patent in any given procedure.⁴⁵⁹
- (693) Regarding the types of patents opposed, the sector inquiry shows that generic companies concentrate their oppositions on secondary patents.⁴⁶⁰ Originator companies may be aware of this, as the following statement by an originator company illustrates:

⁴⁵⁸ $236/109 = 2.16$.

⁴⁵⁹ However, this does not mean that in the 109 opposition procedures the patents of 109 different originator companies were opposed and that the 236 opponents were 236 different generic companies. In fact, one and the same generic company and originator company can be involved in a number of opposition procedures.

⁴⁶⁰ This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying interventions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

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"Oppositions are more often filed against [our company's] secondary patents [...] than patents that protect new compounds. [...] [G]eneric companies do monitor when [our company's] patents are granted and then have the opportunity to (and in fact do) file oppositions."

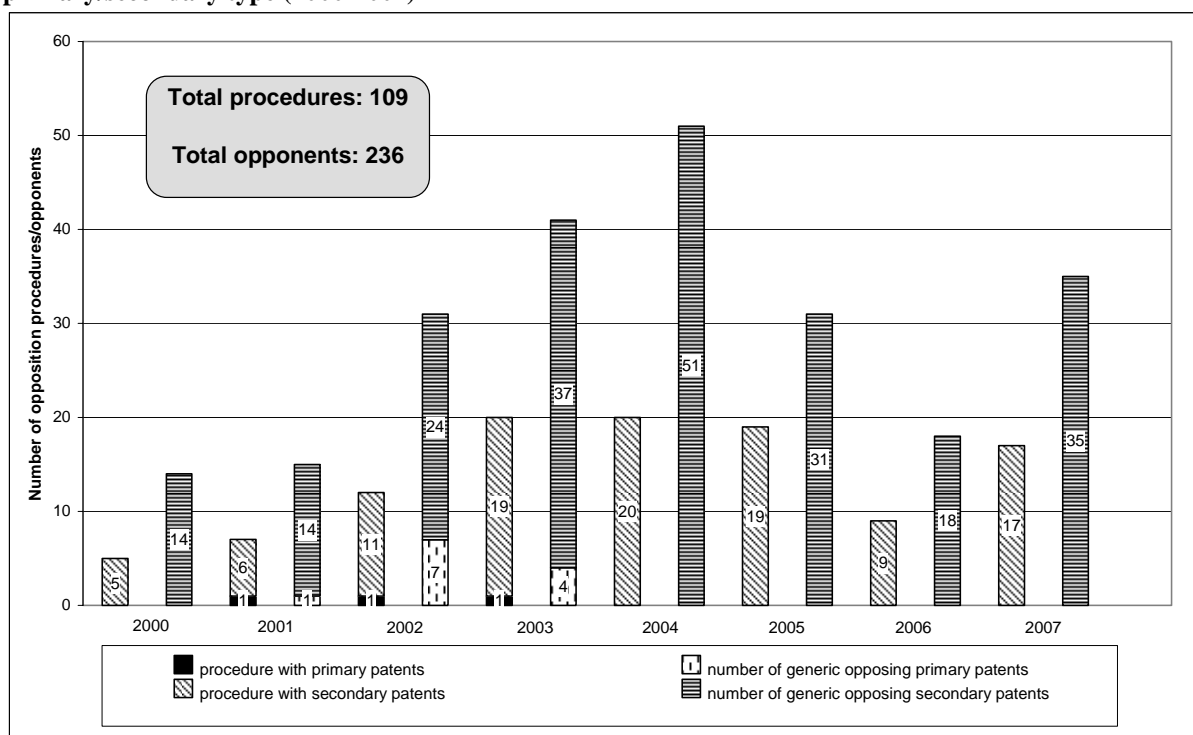
(694) Concerning opposition procedures, a generic company indicated:

"In the future we will use more the opposition procedure because many non-inventive patents are being approved which affect us due to the heavy abuse of the patent system."

(695) Figure 94 below shows the total number of opposition procedures and opponents (generic companies) by year for the period 2000 - 2007. It provides two bars for each year, one relating to the number of procedures and the other relating to the number of opponents (relating to these procedures). Moreover, it distinguishes between opposition procedures related to primary and secondary patents of originator companies. It also distinguishes the opponents according to the same criterion. Figure 94 illustrates the fact that practically all opposition procedures (106 out of 109) concern secondary patents of originator companies. Such procedures peak in particular in the period from 2003 to 2005, where respectively 20, 20 and 19 opposition procedures against secondary patents were begun. Only in the years 2001 - 2003 were few primary patents opposed.

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Figure 94: Number of opposition procedures before the EPO initiated by generic companies per primary/secondary type (2000-2007)



Source: Pharmaceutical Sector Inquiry

2.3.2.2. As indicated Analysis of the Outcomes of Final Opposition and Appeal Decisions

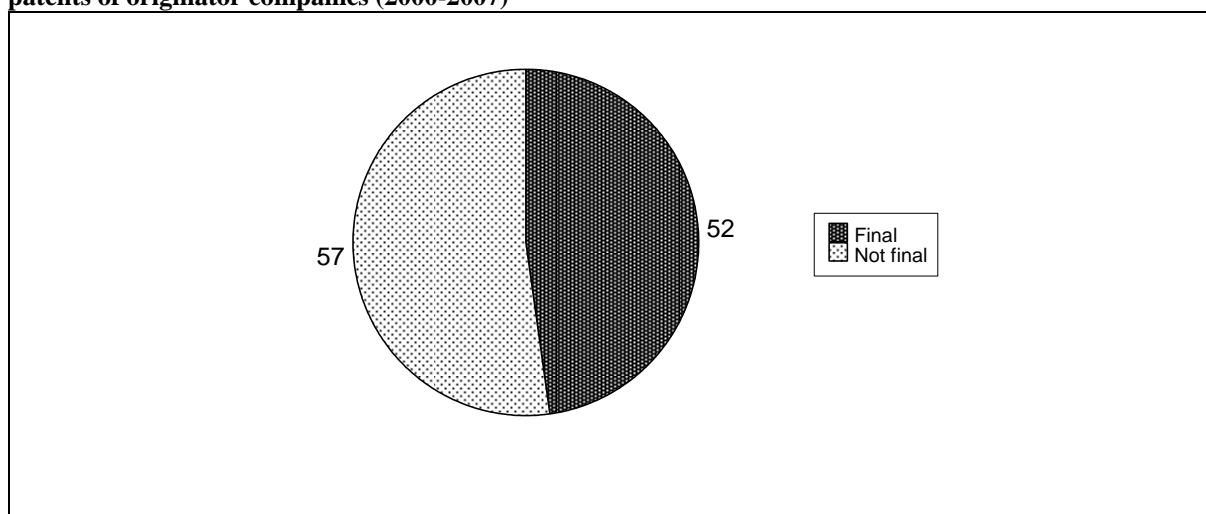
(696) This section analyses the final outcomes of opposition or appeal procedures (*res iudicata*). In principle, no further distinction between the two is made, as what is of interest here is the eventual fate of the originator company's patent.

(697) By Figure 95, a final decision was reached in 47.7% (52 out of 109) of the procedures initiated in the period 2000 - 2007. In the remaining 52.3% (57 out of 109) a decision is still outstanding. This can be partly explained by the very lengthy procedures, as mentioned previously.⁴⁶¹

⁴⁶¹ For further details see Subsection C.2.3.1.4.

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Figure 95: Final and pending opposition and appeal procedures involving generic companies against the patents of originator companies (2000-2007)

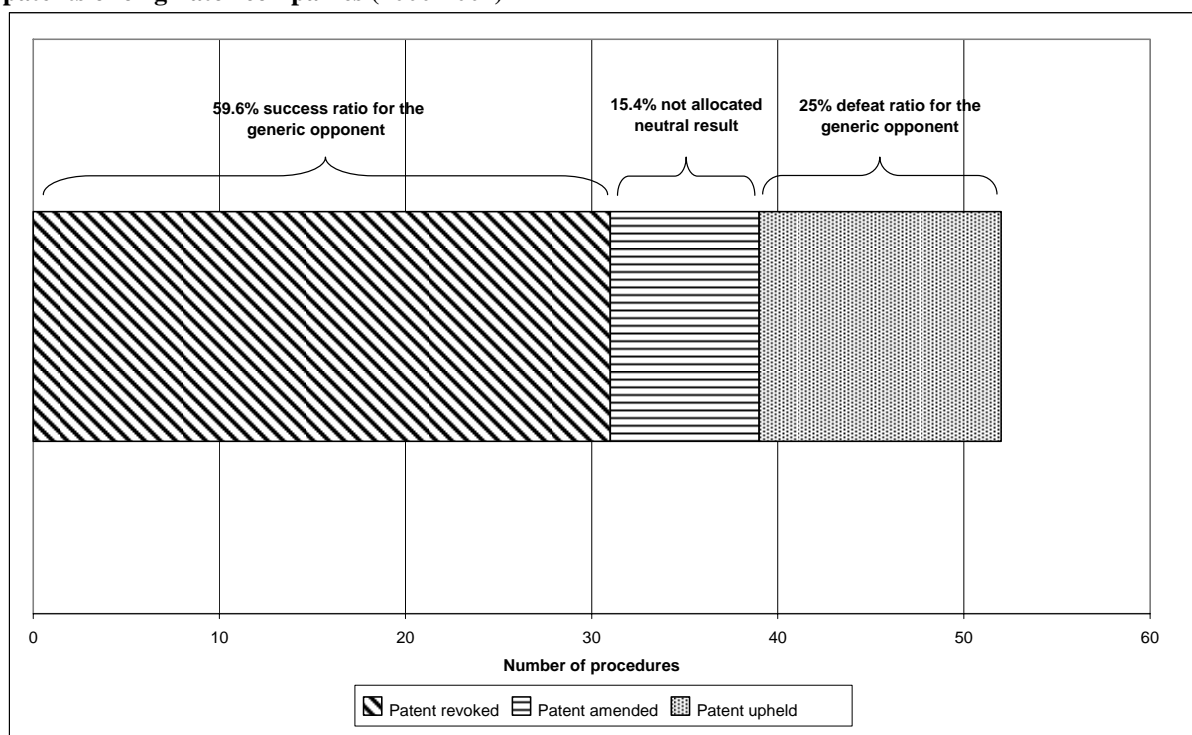


Source: Pharmaceutical Sector Inquiry

(698) Figure 96 reports the number of cases in which the originator companies' patents were revoked, amended or upheld by final decision. The following picture emerges: in 59.6% (31) of all final cases, the originator company's patent was revoked and in 15.4% (8) the patent was reduced in scope (reported as amended). Only in 25% (13) of the final cases, was the originator company's patent upheld. In the context of the public consultation, the EPO and other stakeholders pointed out that final outcomes resulting in amendments cannot clearly be identified as a success or defeat for either side involved in opposition and appeal procedures, therefore amendments are not allocated to either side.

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Figure 96: Final outcomes of opposition and appeal procedures involving generic companies against the patents of originator companies (2000-2007)⁴⁶²



Source: Pharmaceutical Sector Inquiry

(699) From the above it is fair to conclude that, measured by final outcomes, generic companies won the vast majority of opposition and appeal procedures. Even if the final outcome resulting in amendments would hypothetically be counted as defeat for the generic companies, the picture that generic companies won the majority of cases would remain unaltered. Three of the final decisions related to (and revoked) a primary patent, whilst the remaining ones related to secondary patents.

2.3.2.3. Settlements

(700) The sector inquiry's documents show that settlements between originator and generic companies may also take place in the context of opposition procedures. As one originator company stated:

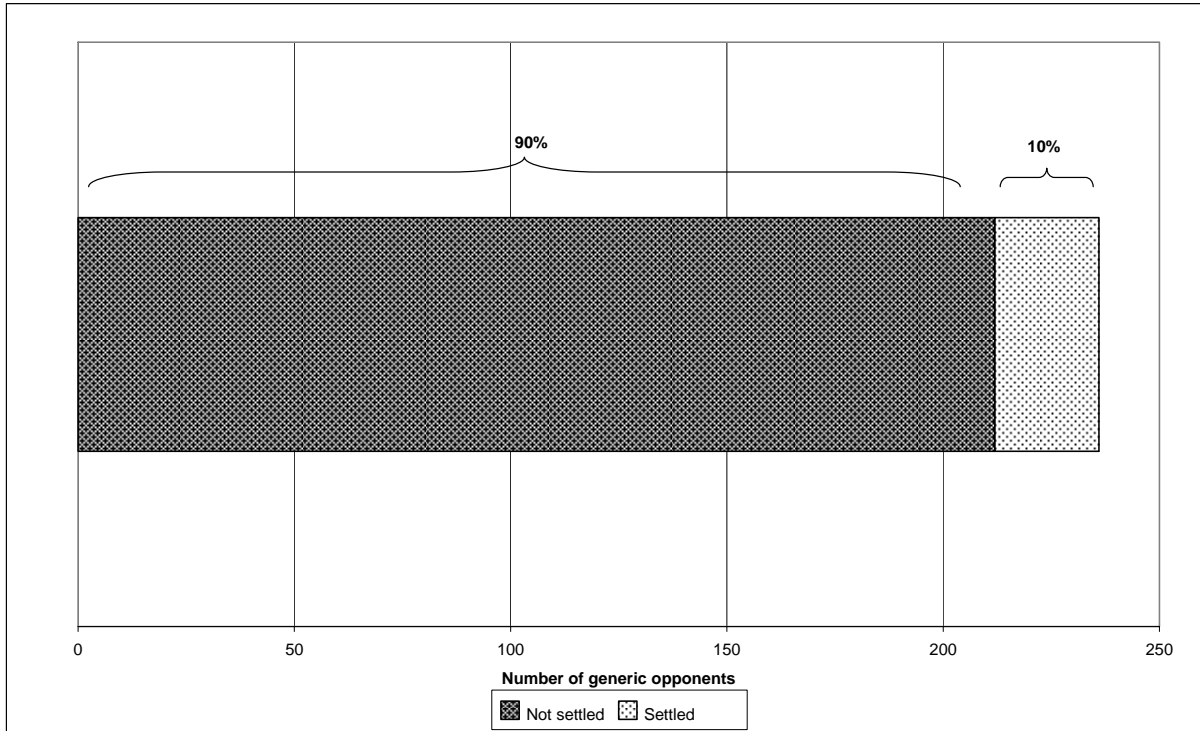
"In subsequent negotiations, [a generic company] consented to withdraw the opposition [against our patent] in consideration for the amendment and a narrowing down of the process claims of the patent."

(701) Figure 97 shows that respondent originator companies settled with 24 of the 236 opposing parties (10%). These settlements concerned 13 different opposition procedures. The settlements are described in more detail in Section C.2.4.1.

⁴⁶² Figure revised following update received from stakeholders.

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Figure 97: Number of settlements with generic companies as opponents (2000-2007)



Source: Pharmaceutical Sector Inquiry

Summary

The sector inquiry confirms that the opposition rate (i.e. the number of oppositions filed per 100 granted patents) before the EPO is consistently higher for the pharmaceutical sector (about 8%) than it is in organic chemistry (about 4%) and across all sectors (overall EPO average: about 5%). Based on the information gathered, generic companies almost exclusively opposed secondary patents. In the cases where they opposed, generic companies prevailed in approximately 60% of final decisions rendered by the EPO (including the Boards of Appeal) in the period 2000 to 2007 and the scope of the originator patent was restricted in another 15% of the cases.

However, on average, it took more than two years to obtain approximately 80% of final decisions (including appeal procedures). Whilst it is acknowledged that opposition and appeal procedures – from a procedural point of view – are separate procedures, from a commercial perspective, the time until the final decision is taken – be it in opposition or appeal – is relevant. The duration of the procedures considerably limits the generic companies' ability to clarify the patent situation of potential generic products in a timely manner.

2.4. Settlements and other Agreements

2.4.1. Patent Settlement Agreements between Originator and Generic Companies

- (702) The aim of this chapter is to describe the patent settlement practice between originator and generic companies in the EU during the period from January 2000 to June 2008. More specifically, this chapter will describe the general considerations of companies and the key factors they take into account when deciding whether or not to enter into a patent settlement agreement. Secondly, this chapter will contain a more detailed description of patent settlement agreements concluded in the EU between January 2000 and June 2008. Finally, the chapter contains a brief overview of the established patent settlement practice in the USA, as well as a comparison of settlement trends in the EU and USA.
- (703) It should be noted first of all that the aim of this chapter is not to provide guidance on whether certain types of settlement agreements could be deemed compatible or incompatible with EC competition law.⁴⁶³ Such an assessment would require an in-depth analysis of the individual agreement, taking into account the factual, economic and legal background.⁴⁶⁴ In this respect, the Commission will further investigate whether individual company behaviour may have fallen foul of the competition rules.

2.4.1.1. Patent Settlements in the EU: an Overview of the Main Characteristics

- (704) Patent settlement agreements are commercial agreements to settle actual or potential patent-related disputes. Patent settlement agreements are concluded in order to resolve claims in patent disputes, opposition procedures or litigation where no final adjudication has been handed down or there has not yet been a court proceeding. The primary aim of a settlement agreement is to end the dispute, opposition procedure or litigation.
- (705) Patent settlements are fact-specific, depending on the dispute at issue. As they are commercial agreements, they also reflect the negotiated positions of the parties. Consequently, the specific contents and terms of settlement agreements vary.
- (706) However, certain basic elements and features are found in all EU settlement agreements between originator and generic companies. First, the object of a settlement agreement is to resolve the actual or potential dispute, opposition procedure or litigation concerning the manufacturing and/or marketing of a generic version of a

⁴⁶³ See Annex to Chapter EC Competition Law (Annexes to Chapter A).

⁴⁶⁴ During the public consultation, it has been submitted that settlement agreements between originator and generic companies should undergo some sort of scrutiny. In this respect, it is interesting to note that in other jurisdictions, such as in the USA, certain settlement agreements have to be filed with the Antitrust Agencies.

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product which is claimed to be protected by a patent. Secondly, the geographic scope of an EU settlement agreement typically covers those Member States in which the dispute, opposition or litigation has occurred and possibly territories in which there is a high probability of it occurring. Finally, patent settlement agreements in the EU are usually intended to be the full and final settlement of the specific claims of the parties.

- (707) As will be explained in more detail in subsequent sections, the starting point for companies to conclude a settlement is that they disagree at the outset of the litigation/dispute/opposition about whether the patent of the originator company is valid and/or whether the manufacturing or sales activities of the generic company infringe the originator company's patent. As in any other area of commercial disagreement, the parties concerned may have an interest in ending a dispute, opposition or litigation and instead reaching a settlement as a compromise. The parties may prefer to discontinue the dispute or litigation because it proves to be costly and time-consuming, and might also be unpredictable in its outcome. Settlements are thus a generally accepted way of ending disputes, opposition procedures and litigation.⁴⁶⁵
- (708) However, as shown by the enforcement action of the USA competition authorities, in particular the Federal Trade Commission, it might also be argued that settlements contain arrangements that could fall within the scope of competition rules. A patent settlement agreement might, for example, lead to a delay in a generic product's entry in a specific market in return for a payment by the originator company to the generic company. Ultimately, it is the consumer who pays the price for such a delay in market entry.
- (709) For the purposes of the sector inquiry, detailed questionnaires were sent both to companies that are producers of originator medicines and to companies that are producers of generic medicines. In particular, the Commission's services requested them to submit copies of all patent settlements concluded between originator companies and generic companies for the period from January 2000 to June 2008. Companies were asked to submit the complete settlement agreements, including annexes, as well as subsidiary and related agreements (e.g. licence, distribution, supply agreements). In total, 43 originator companies and 27 generic companies submitted comprehensive replies to the questionnaires.⁴⁶⁶
- (710) In total, 207 patent settlement agreements were submitted. Figure 98 breaks down their number on a yearly basis. In the period 2000 – 2002, the number was lower than for the last six years in which, on average, some 25-30 patent settlement agreements were concluded every year in the EU; the exception was the year 2005, when 53 settlements were concluded.

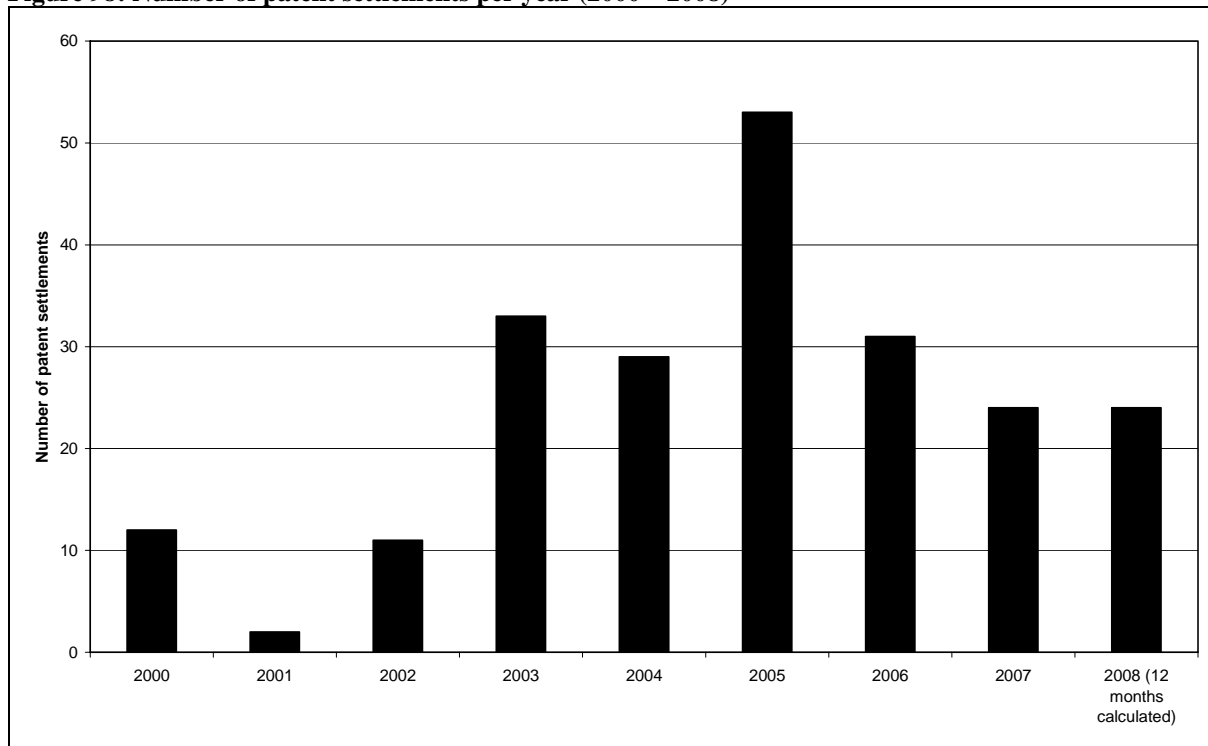
⁴⁶⁵ In the context of the public consultation, some stakeholders expressly supported this view stating that a settlement in many instances is an efficient way for parties to end a dispute.

⁴⁶⁶ Initially, the Commission sent the questionnaires to 46 originator companies and 39 generic companies. Some companies were, however, omitted from the scope of the sector inquiry, since it became clear that they were not producers of medicinal products and were therefore unable to contribute to the sector inquiry.

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(711) Figure 99 shows the number of INNs covered by settlements per year. As is clear from the figure, the number has increased over the last eight years. In the first three years, from 2000 to 2002, four INNs were, on average, covered by settlements per year. In the period from 2003 to 2005, the average was eleven and in the last three years, an average of 14 INNs were covered per year.

Figure 98: Number of patent settlements per year (2000 – 2008)

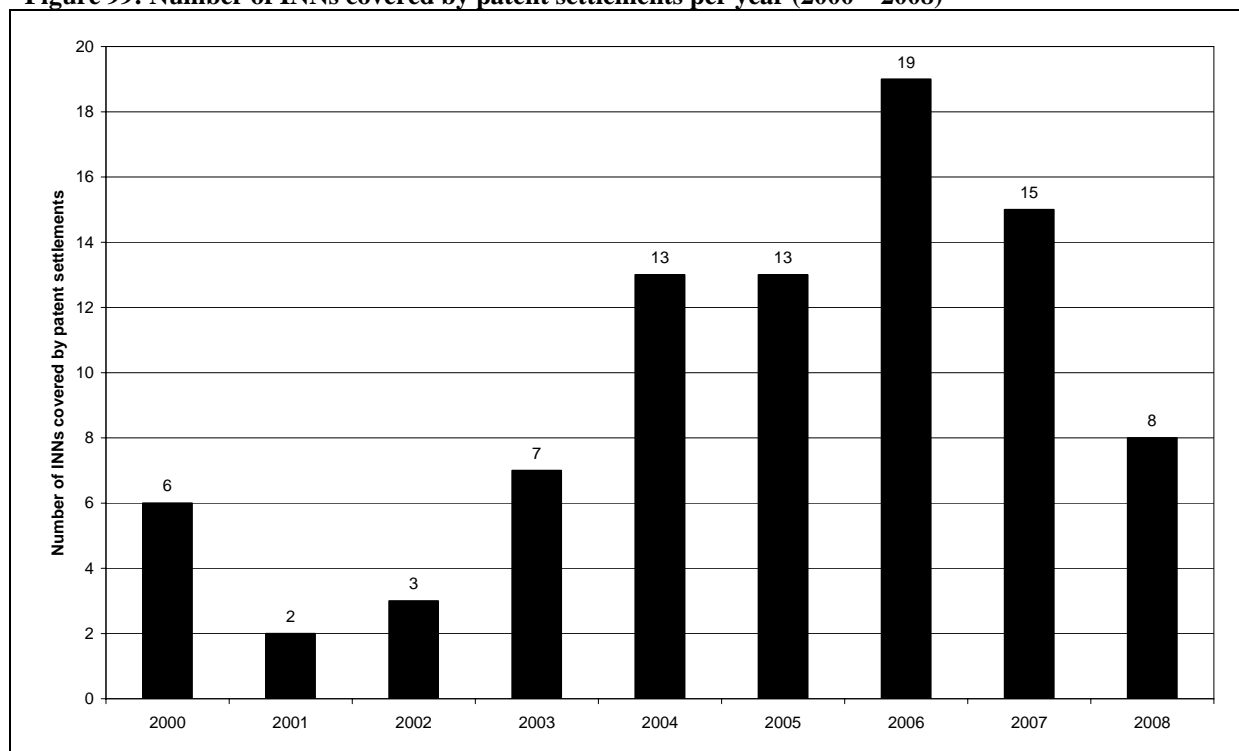


Source: Pharmaceutical Sector Inquiry

Note: The figure for 2008 (24) is calculated on the basis of 12 settlement agreements received by the Commission which had been concluded in the first 6 months of 2008.

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Figure 99: Number of INNs covered by patent settlements per year (2000 – 2008)

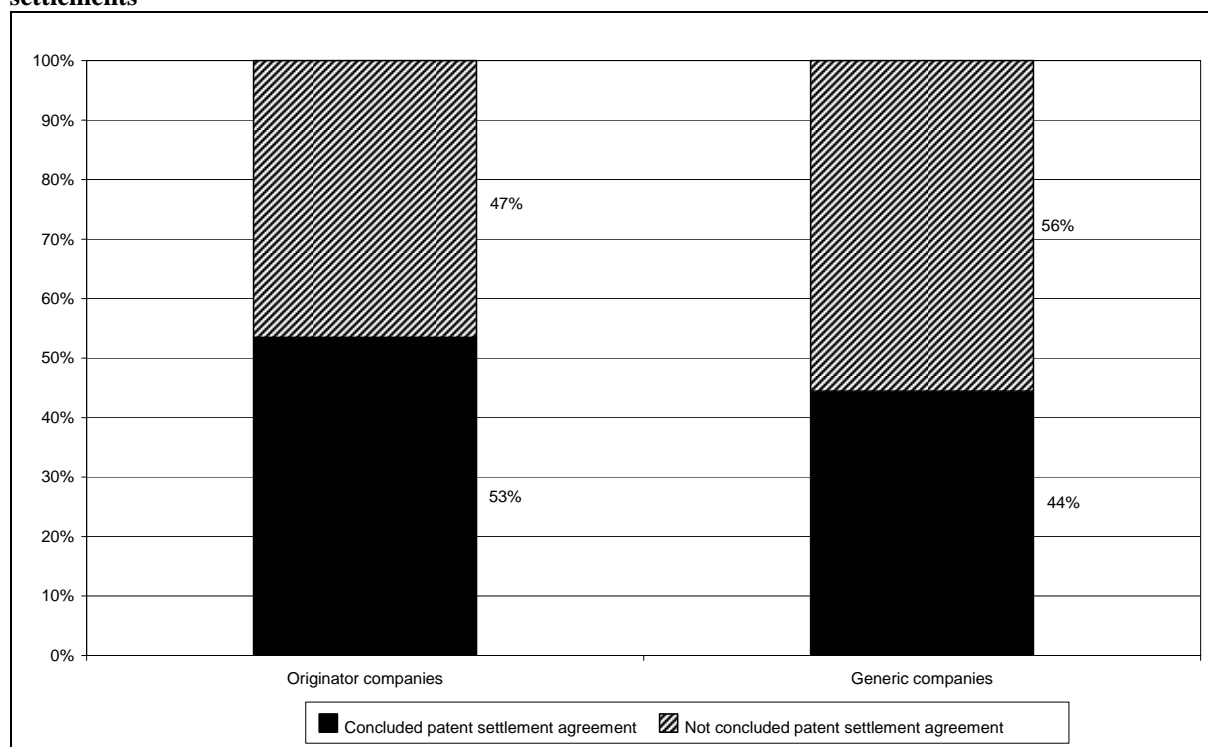


Source: Pharmaceutical Sector Inquiry

- (712) Out of the 43 originator companies that responded to the questionnaires during the sector inquiry, more than a half (23 companies or 53%) had concluded settlement agreements with generic companies. As far as generic companies are concerned, 44% of the 27 generic companies that responded to the Commission's questionnaires had concluded settlement agreements with originator companies.

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Figure 100: Percentage of originator companies and generic companies that had entered into patent settlements



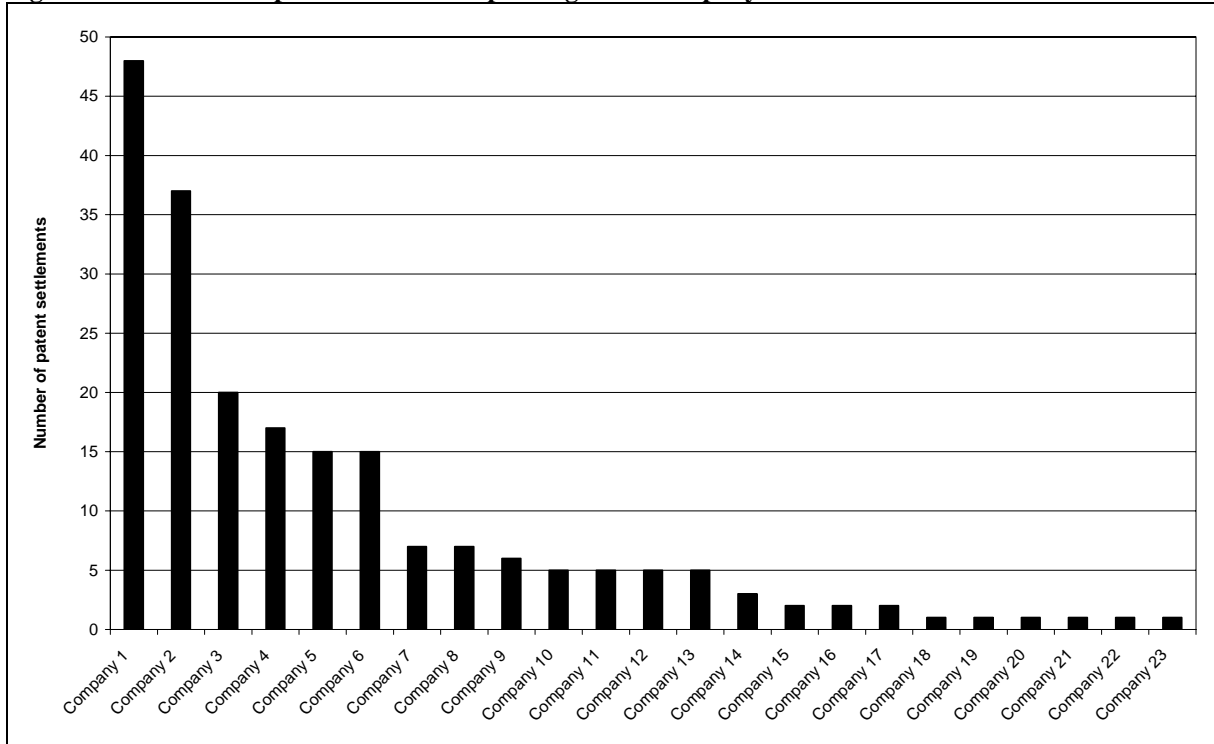
Source: Pharmaceutical Sector Inquiry

- (713) Figure 101 gives the number of settlement agreements concluded by each originator company. As mentioned above, a total of 23 originator companies concluded settlements. There was a large variation in the number of settlements concluded by originator companies with two companies accounting for 85 of the 207 settlements (41%). In total, more than two thirds of all patent settlement agreements were concluded by the five originator companies with the highest number of patent settlements.
- (714) Whereas the majority of the findings in this report are based on a selection of some 219 INNs⁴⁶⁷, the findings in this chapter are not limited to that particular selection. Companies were asked to submit all settlements, irrespective of the INN concerned. Nonetheless, of the 49 INNs for which a patent settlement had been concluded, 42 INNs - or 86% - were included in the Commission's initial selection of INNs. In total, patent settlements had therefore been concluded for 19% of the INNs in the selection (see Figure 102).

⁴⁶⁷ See Annex Methodology (Annexes to Chapter A).

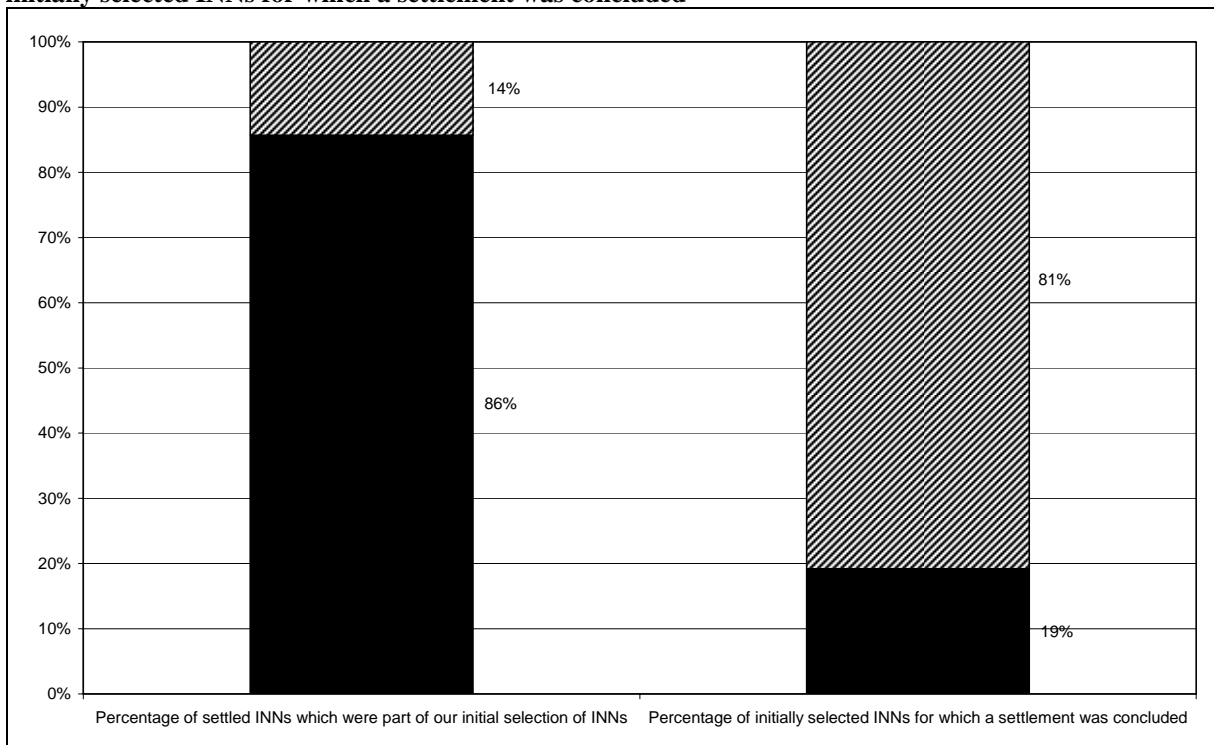
PHARMA SECTOR INQUIRY – MAIN ISSUES INVESTIGATED

Figure 101: Number of patent settlements per originator company



Source: Pharmaceutical Sector Inquiry

Figure 102: Percentage of settled INNs which were part of the initial selection of INNs & number of initially selected INNs for which a settlement was concluded



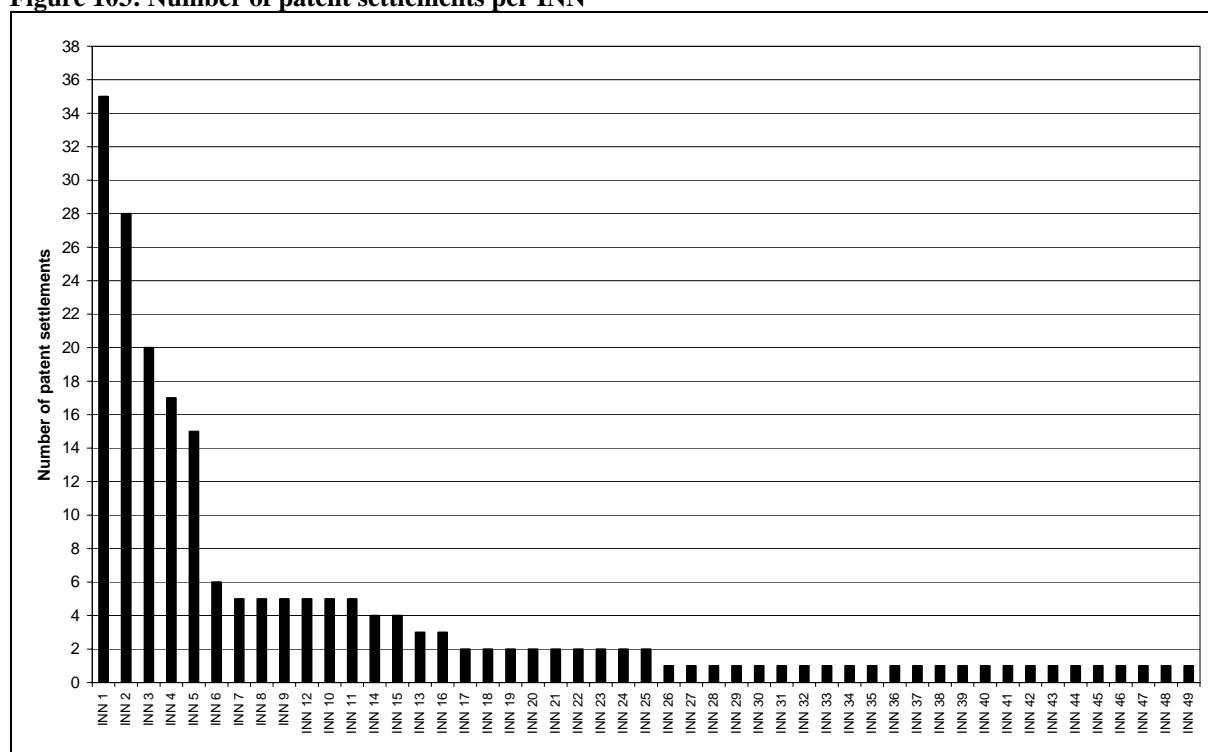
Source: Pharmaceutical Sector Inquiry

(715) Figure 103 shows the number of settlement agreements concluded for each of the 49 INNs. It is clear that for certain INNs companies have concluded a significant number of patent settlement agreements. In particular, it is interesting to note that for the first

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two INNs, 63 settlements were concluded, which represents 30% of the total settlement agreements. Of the 49 INNs, 31 (63%) were among the best-selling medicines. Of the 15 INNs with the highest number of settlements, 11 (73%) were among the best-selling medicines which lost exclusivity (E75).⁴⁶⁸

Figure 103: Number of patent settlements per INN



Source: Pharmaceutical Sector Inquiry

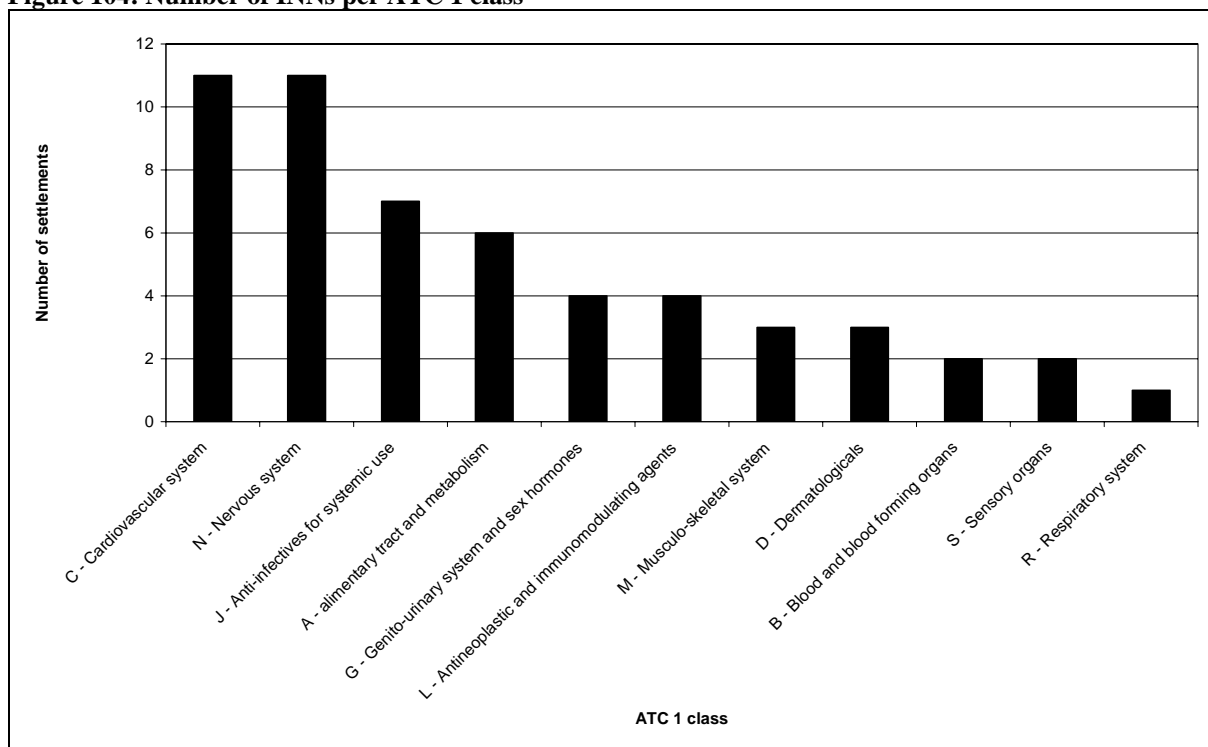
- (716) As Figure 104 shows, the 49 INNs covered 11 of the 14 ATC 1 therapeutic classes in the ATC classification system⁴⁶⁹. Certain ATC 1 therapeutic classes had a higher number of INNs for which a patent settlement had been concluded. The two ATC 1 therapeutic classes with the most INNs were the cardiovascular system (ATC C) and the nervous system (ATC N), each with eleven INNs, followed by the therapeutic classes: J (Anti-infectives for systemic use) and A (alimentary tract and metabolism) with eight and six INNs respectively. The only ATC classes not represented were: H (Systemic hormonal preparations, excluding sex hormones and insulins), P (Antiparasitic products, insecticides and repellents) and V (Various).

⁴⁶⁸ For more information on the E75 list see Annex Methodology (Annexes to Chapter A).

⁴⁶⁹ For an explanation of the ATC system see the glossary.

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Figure 104: Number of INNs per ATC 1 class



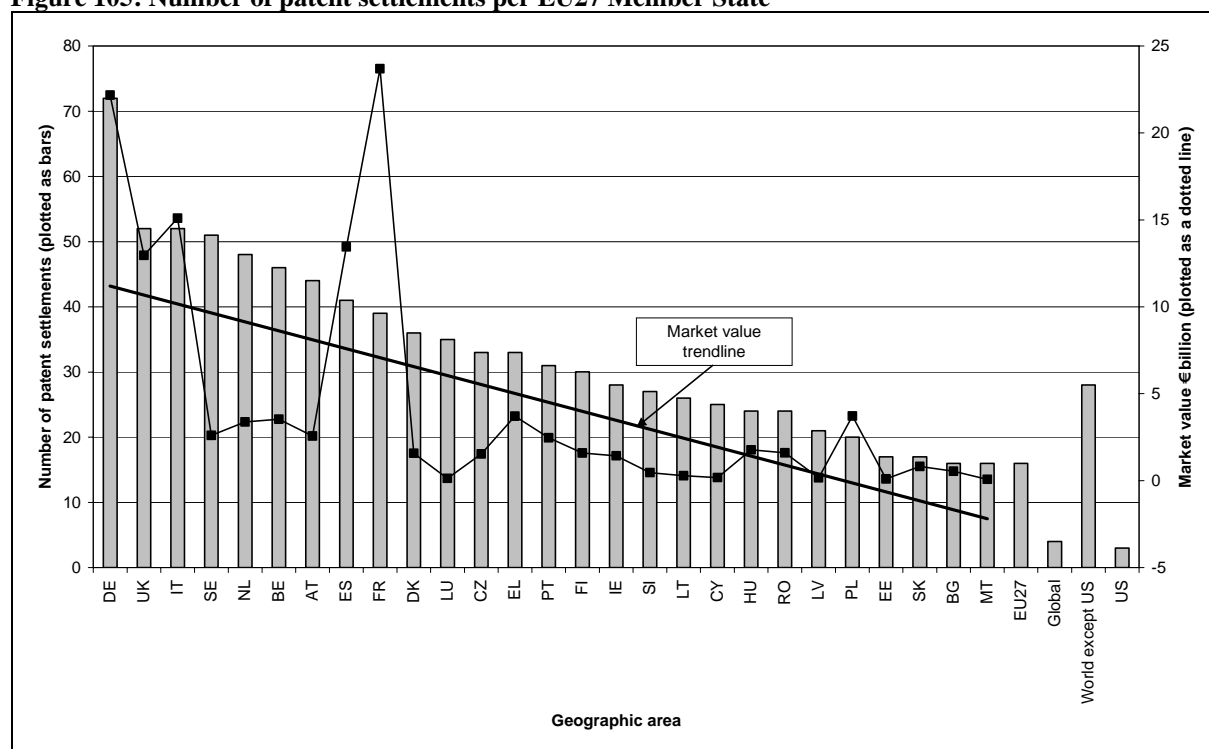
Source: Pharmaceutical Sector Inquiry

Note: Some INNs are registered in more than one ATC 1 class. The total number of INNs in the figure therefore does not match the total number of INNs for which a settlement was concluded.

(717) Figure 105 breaks down the number of settlements concluded in the geographic area covered by the agreement. Every agreement covered at least one EU Member State. Some settlement agreements covered more than one EU Member State or covered the EU as a whole. These agreements are reported in Figure 83 as "separate settlement agreements" by Member State. In addition, some agreements covered countries in the rest of the world excluding the USA; some covered the USA and some were global. The figure also compares the number of patent settlements covering the EU Member States and gives the value of the pharmaceutical market (sales of pharmaceutical products at ex factory prices) for each of the EU Member States. The figure shows that more settlement agreements were concluded for countries with a high pharmaceutical market value than in countries with a lower market value.

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Figure 105: Number of patent settlements per EU27 Member State



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

Note: Agreements covering more than one geographic area are counted for each area. The market value figures are for sales of prescription medicines for human use, at ex-factory prices. The black line shows a linear market value trend line for the dotted line indicating the total market value. Figures for Greece, Romania, Bulgaria, Slovenia, Cyprus and Malta include sales of non-prescription medicines. Sales information for Cyprus and Malta are from EPFIA.

2.4.1.2. Companies' General Considerations and Decision Making Processes with Regard to Patent Settlements in the EU

Considerations of Companies when Entering into Patent Settlement Agreements

- (718) Pharmaceutical companies in the EU see patent litigation cases as fact-intensive, legally complex, lengthy and costly. The conclusion of a settlement agreement is seen as an alternative way forward to continuing litigation until final judgment.
- (719) Even though both originator companies and generic companies submitted that they apply no general policy guidelines when entering into settlement agreements, and thus decide on a case-by-case basis, it is possible to identify some key factors which are taken into consideration in the assessment of patent settlement agreements.
- (720) The fundamental factor considered by originator companies when deciding whether to enter into a settlement agreement with generic companies is the strength of their position in the patent litigation (the expected likelihood of winning). When companies assess their position as strong, they do not consider entering into a settlement agreement. However, if their chances of winning are assessed less strong and there is a great deal at risk, they give careful consideration to the possibility of settling with the other party.

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- (721) Generic companies, on the other hand, are more concerned with the cost of litigation. Generic companies maintain that they cannot financially afford lengthy and extremely costly litigation. Patent litigation cases are considered to be resource intensive, including personnel-related costs. In addition to procedural legal costs, the likelihood of fully recovering the costs incurred plays an important role. Generic companies also try to avoid large damages claims by the patent holder (in particular if they entered "at risk"), should the court of last instance decide that the patent is valid and has been infringed. Generic companies thus consider settlement as an opportunity to reduce costs (IP and legal costs, senior management time). One generic company observed:

"If the costs and time of litigation in respect of the products being subject of litigation would be destructive to our current business and would not allow us to focus on other business objectives, we would rather enter into an agreement on fair terms instead of carrying out dispute or litigation."

- (722) As part of the process of determining the probability of winning or losing a patent litigation, an internal and external evaluation of a patent portfolio is often carried out. The local legal environment, parallel litigation on the same INNs, the duration of the patent protection, the scope of that protection and the position of the competitors are also taken into account. In particular, for generic companies the risk/success evaluation can often be very complex owing to a high number of patents (allegedly) protecting a product and/or the process and the confusion created as to the exact scope of the patent protection. A generic company made the following observation in this regard:

"Patent litigation can be so complex and technical that settlement can be of interest. We can never know the ultimate outcome when patent litigation begins, even though we may have undertaken prior IP review and evaluation. This is because the evaluation of the risk may evolve from one month to another, according to internal assessments, as well as external circumstances (developments in the case, new case law, regulations etc.)."

- (723) Originator companies also assess the chances of obtaining an interim injunction. Some originator companies – according to their submissions – settle cases in which it has been impossible to obtain an interim injunction against the generic company, whereas some generic companies stated that they had no interest in concluding a settlement if a court refused to grant an interim injunction to the originator company, since they can continue to be present on the market. An originator company commented as follows:

"We often settle not because we think that we had a weak case, but because it would have been impossible to obtain an interim injunction against a generic company. Thus, there is no longer any significant commercial benefit in continuing litigation, in particular after the entry of other generic companies."

- (724) The above quote also demonstrates that originator companies consider the likelihood of a second or third generic company entering the market. If they consider the likelihood as high, they prefer to settle. The issue is also of great interest to the generic company. If it is the first company on the market and there is no Court decision to the effect that a patent is invalid, the settlement might mean that, for a given period of time, it is the only generic company on the market. In any event, generic companies aim to secure the earliest possible entry date with a reasonable degree of certainty. A

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settlement is thus seen as an arrangement to fix the launch dates for the products at issue. In this respect, a generic company observed:

"When deciding what type of settlement agreement to conclude, we aim at obtaining the earliest possible entry date with a reasonable degree of certainty, weighing the considerable risk that continuing the litigation would result in us being excluded from the market for the entire patent term."

- (725) Another factor that originator companies find especially relevant when deciding to enter into a patent settlement agreement is the importance of the product at issue in the litigation and its market size. Originator companies aim to safeguard the marketing and sales of the product under patent litigation, in particular when the product is a "blockbuster" or a product that accounts for a significant percentage of the turnover of the company concerned.
- (726) The expected duration of the litigation, in combination with the expected date of loss of market exclusivity, are also important aspects that influence a company's decision to enter into a settlement. The likelihood that the litigation will continue over a very long time clearly has an impact on the parties. In general, both originator and generic companies decide to settle the pending litigation if the patent expires in the meantime.
- (727) The likelihood of winning the patent litigation at issue also depends upon the evidence available (proof of validity and infringement) and on the potentially competent jurisdiction, since patent law and rights are national in nature and their application varies from one country to another. This creates opportunities for companies to choose, in the first place, in which country they will start the litigation and, at a later stage, in which country they will settle, depending on the local legal procedures, the local legislation and case-law, the quality of the court and the efficiency of the national judicial system. One originator company observed:

"Even with the strongest case, there is always a risk in putting a case before a court. Extraneous factors (over and above the actual strength of the case) can affect the outcome: e.g. judicial error, poor court strategy, error on the part of the company or its advisors. [...] These concerns are magnified where similar issues may be raised in a number of jurisdictions, thus multiplying the uncertainty. This is currently the case in Europe, where the national nature of patent rights and of patent litigation enables a degree of "forum shopping" by a potential entrant who can (and will) choose jurisdictions which can give the best opportunity of a valuable precedent settling success."

- (728) In certain circumstances, the originator companies see settlements as structured agreements with patents remaining in force. Whenever a settlement agreement is concluded, there may be no court ruling on the patent's validity or on any alleged infringement. Accordingly, the patents remain potential obstacles to further generic competition. Whilst the originator company has not yet achieved its ultimate objective of preventing generic entry until the patent(s) expire(s), it has at least been able to delay it and possibly even gain concessions from the generic company, e.g. by keeping it out of selected markets. In exchange, the originator company may pay a lump sum to the generic company or grant a licence to market its product. Such a deal is also beneficial for the generic company, if the latter is allowed to stay in a specific market,

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despite the patent remaining in force (see Subsection C.2.4.1.4. on category B.II. settlements).

- (729) Another important consideration seems to be whether there is existing cooperation between the parties and whether the parties have previously settled disputes and/or litigation. Settlement discussions can provide an opportunity for companies to identify areas where they can work together. For example, a generic company might have a particular expertise in formulation processes, or have a developed distribution network in territories which are of interest to the originator company, or have access to manufacturing expertise which the originator company would wish to use. If the parties are able to reach an agreement that benefits them both, then such an arrangement will be concluded. One originator company described this as follows:

"Despite the potentially acrimonious and adversarial nature of litigation, settlement discussion can provide an opportunity for companies to identify areas where they can work together in a commercially sensible way, taking advantage of opportunities which might not previously have been apparent."

Decision Making Processes

- (730) Depending on the size of the company, various internal decision-making processes are followed when concluding settlement agreements. For large companies these processes are more formal than for smaller and medium-sized companies. In the latter, companies' decisions related to settlements do not require formal written consent from the Board. In large international companies, settlements of patent litigation are managed centrally through the patent departments of the parent company and evaluated through their corporate offices.
- (731) Some originator companies review all IPR litigation through a specific committee which also reviews patent settlement proposals and whose agreement is required before entering into any settlement. In some companies, a steering committee is created to follow up litigation and these steering committees are also in charge of engaging in settlement discussions and preparatory work on settlement agreements.
- (732) In other companies, the decision-making process typically involves the local and regional management and the approval of the appropriate local board of the company under the relevant jurisdiction, not least because the subsidiaries are run as profit centres that have to decide locally on the costs of litigation. In addition, the legal, intellectual property, R&D and commercial departments are all consulted. Some companies have submitted that settlement agreements are sometimes evaluated by oral discussions and are not necessarily recorded in writing.
- (733) In many cases, external advisors are consulted, including specialists advising in particular on intellectual property questions, as well as contract law and competition law (both national and EC). In local jurisdictions, patent litigation is often carried out by relying on outside legal counsel who might participate in settlement discussions.

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Conclusions on Key Factors

- (734) Originator and generic companies were asked to provide a prioritised list of the five most important considerations when deciding whether to enter into a patent settlement, and on what terms, with another company.⁴⁷⁰
- (735) Based on the replies, Table 21 shows the factors which the originator companies consider as most important when deciding to enter into patent settlements and on what conditions (more than one possible answer allowed).

Table 21: Originator companies' five most important considerations for entering into patent settlement agreements

	Consideration	Mentioned by % of originator companies who responded
1	Strength of own company's position in the case (probability of winning or losing)	95%
2	Market size and revenue of the originator product to be protected	82%
3	Expected costs/avoided costs of litigation and impact on personnel cost	68%
4	Inherent uncertainty involved in patent litigation	68%
5	The expected duration of litigation	55%

Source: Pharmaceutical Sector Inquiry

- (736) Of the respondent originator companies questioned, 95% indicated that the most important factor that they take into account when considering a patent settlement is the probability of winning or losing the patent litigation, i.e. the strength of their position in the case. The second most important factor is the size of the market in question and the revenue of their product that needs to be protected. Originator companies attach equal importance to balancing the expected costs and the litigation costs avoided (including impact on personnel resources), as well as to the inherent and substantial uncertainty involved in patent litigation. Finally, more than half of the respondent originator companies mentioned the expected duration of the litigation in question as one of the five most important factors to be considered.
- (737) Originator companies did not mention any considerations as to the damages suffered by public health schemes. This is also evidenced by the following witness statement made by an originator company in an important patent case when explaining why the company decided to settle and enter into a supply agreement with the generic company:

⁴⁷⁰ Some originator and generic companies indicated that they were unable to provide such a prioritised list, in abstract terms because patent litigation and patent settlements are highly subjective and the importance of factors that are taken into consideration are case-specific.

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"[We] recognised that there would be a financial loss from any generic entry into the [INN] market. By entering into a supply agreement with [generic company], [we] could obtain a profit on [our] supply price and maintain some certainty of profits (although at a reduced level) on [the distributed INN]. The alternative was to risk losing sales to [generic company] and to make no return on them at all."

(738) Generic companies that responded to the question consider the following factors as the most important when deciding whether to enter into patent settlements with an originator company and on what conditions.

Table 22: Generic companies' five most important considerations for entering into patent settlement agreements

	Consideration	Mentioned by % of generic companies who responded
1	Expected costs/avoided costs of litigation and impact on personnel cost	75%
2	Inherent uncertainty involved in patent litigation	67%
3	Strength of the company's position in the case (probability of winning or losing)	67%
4	The country where litigation takes place	42%
5	The expected duration of litigation	42%

Source: Pharmaceutical Sector Inquiry

(739) For the vast majority of generic companies (75%), avoiding the costs related to litigation and also the impact on personnel costs (including monetary and personnel resources) are their major concerns. This is particularly the case when they receive either very limited or no revenues from the product during the court proceedings.⁴⁷¹ Generic companies attach equal importance to the uncertainty in patent litigation and to the likelihood of success in the patent litigation. The Member State in which the litigation takes place and also the expected duration of the litigation at issue are taken into consideration too.

⁴⁷¹ This might be less true in cases where a generic company decides to launch its product "at risk" and/or to challenge in Court the patent validity, since the generic company should have calculated and internalised the risk and the associated litigation costs.

2.4.1.3. Patent Settlement Agreements in the EU

- (740) This section analyses the patent settlement agreements between originator companies and generic companies with relevance to any of the EU27 Member States that were concluded between January 2000 and June 2008. A patent settlement is considered relevant for the EU27 Member States even if only part of the agreement relates to one of the EU27 Member States (or parts of that Member State) and the other part of the agreement relates to countries in the rest of the world. As indicated above, originator companies and generic companies submitted a total of 207 separate patent settlement agreements in their responses to the sector inquiry's questionnaires. The vast majority of the settlements was reached in the context of litigation cases⁴⁷², the remaining settlements were concluded in out of court disputes and/or in the framework of opposition proceedings.
- (741) The agreements were categorised on the basis of two main criteria. First, they were categorised according to whether they limited the generic company's ability to market its own product in the market concerned by the settlement. Agreements limiting generic entry are categorised as B-type, whereas agreements that do not limit generic entry are categorised as A-type.
- (742) Secondly, for all the agreements in which generic entry was limited – i.e. category B – an analysis was made to ascertain whether they involved any type of value transfer from the originator company to the generic company. The agreements which included a value transfer from the originator company to the generic company are categorised as B.II, whereas agreements which do not include such a value transfer are categorised as B.I.

⁴⁷² See Chapter C.2.2. above, *nota bene*: one settlement agreement can relate to more than one litigation case.

Box: Categorisation criteria – patent settlement agreements

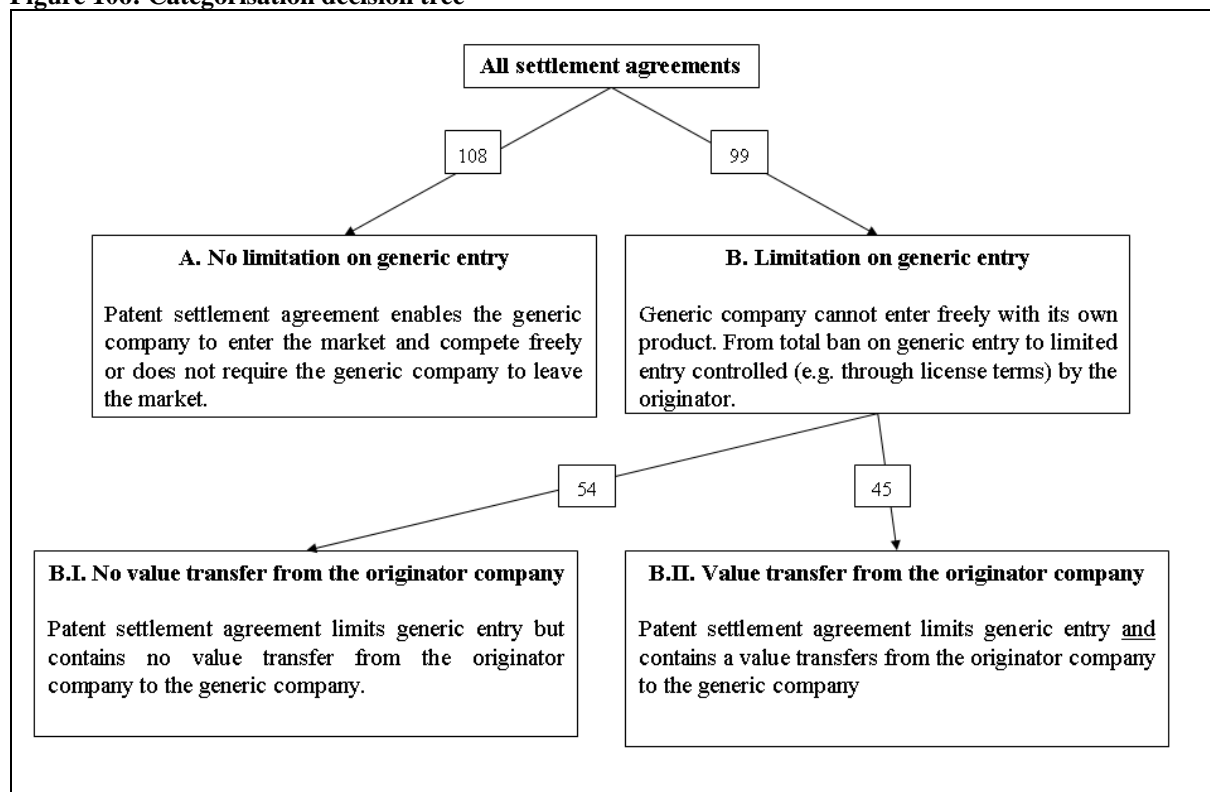
1. Limitation of Generic Entry

The generic company's entry can be limited in several ways. The clearest limitation of generic entry is when the settlement agreement contains a clause explicitly stating that the generic company recognises the validity of the originator company's patent(s) and refrains from entering the market until the patent(s) have expired. If the parties to a patent settlement agreed that the originator company should grant a licence to certain patent rights to the generic company, thereby allowing it to enter the market, the agreement was still categorised as limiting generic entry. The reason for this is that the generic company cannot enter the market with its own product unless it has an agreement with the originator company. Accordingly, the generic company's entry is partly or wholly controlled by the originator company through the terms of the concluded licence agreement. In line with the definition, the generic company is therefore unable to compete on the market – without limitations. The same is true for patent settlement agreements in which the parties agree that the generic company can become a distributor of a product of the originator company or if the generic company will source its supplies of the active ingredient from the originator company.

2. Value Transfer to the Generic Company

Value transfer to the generic company in patent settlement agreements can take different forms. The most clear-cut value transfer is a direct monetary transfer (e.g. payment of a lump sum) from the originator company to the generic company. Monetary transfer can also take the form of compensation for the generic company's legal cost(s) in the patent dispute or can be classified as the purchase of an asset, for example the stock of a product which is in the generic company's possession. Other types of value transfer include distribution agreements in which the generic company becomes a distributor of a product of the originator company or a "side-deal" in which the originator company grants a commercial benefit to the generic company, for example, by allowing it to enter the market before patent expiry in another geographical area or with another product. Furthermore, value transfer could consist in granting a patent licence to the generic company. A patent licence enables the generic company to enter a market with a product but, as explained above, the commercial freedom of the generic company is limited by the terms of the licence agreement which, for instance, can include limitations on the quantity of the types of products that the generic company may sell. A patent licence may be exclusive or non-exclusive, may be limited to the geographic area in which the patent dispute between the parties has taken place and may be granted royalty-free or royalty-bearing. The terms of the licence agreement determine the level of the value transfer to the generic company.

Figure 106: Categorisation decision tree

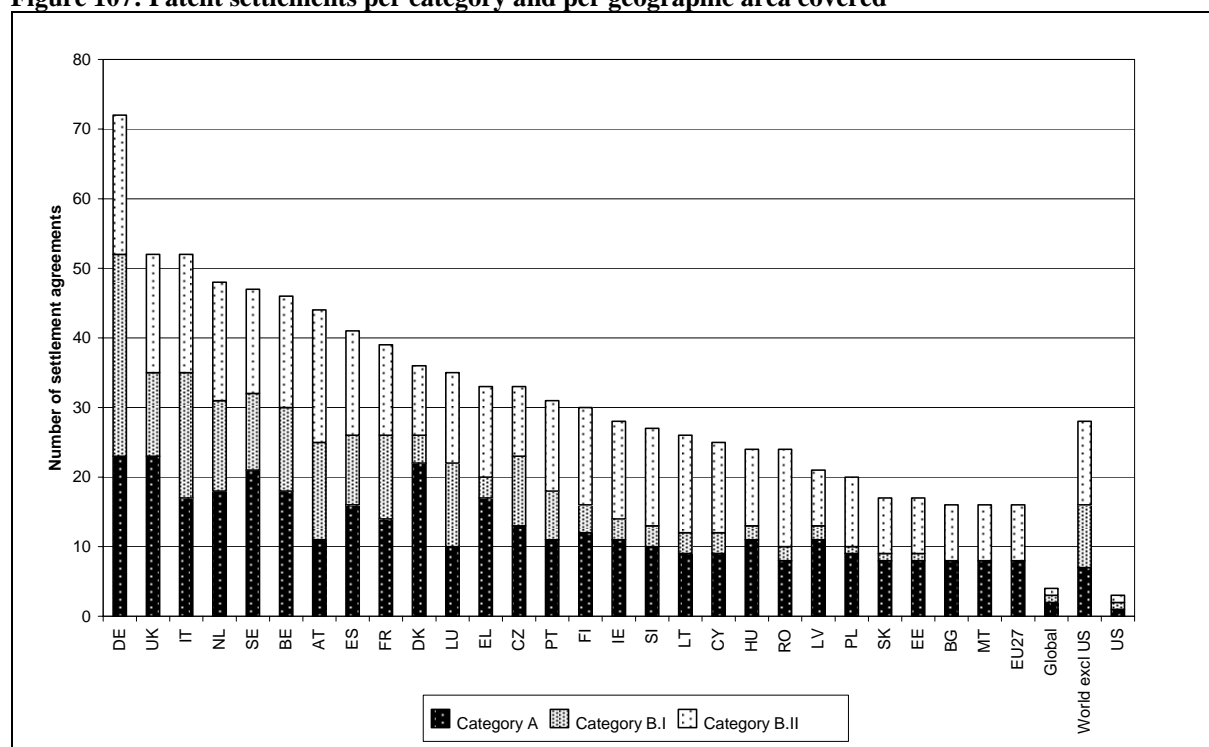


Source: Pharmaceutical Sector Inquiry

- (743) A total of 108 of the 207 settlement agreements (52%) concluded in the period between January 2000 and June 2008 in at least one EU27 Member State imposed no limitation on the generic company's ability to enter and market its product. These were consequently categorised as belonging to category A. The remaining 99 agreements included a limitation on the generic company's ability to market its product. Of the 99 category B agreements, 54 agreements (55%) included no value transfer from the originator company to the generic company. They were subsequently categorised as B.I. The remaining 45 agreements (45%) limited generic entry and included a value transfer from the originator company. These were categorised as B.II.
- (744) Figure 107 breaks down the number of settlements per category concluded per geographic area covered by the agreement. Compared with Figure 105, Figure 107 shows a variation in the breakdown of the three categories between Member States. Some Member States which have a large number of settlement agreements have a higher share of category A settlements – for instance Denmark, which in total is covered by 36 agreements, of which 22 (61%) are category A. At the other end of the scale, Austria was covered by 44 agreements, of which 33 (75%) were category B.

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Figure 107: Patent settlements per category and per geographic area covered



Source: Pharmaceutical Sector Inquiry.

Note: Agreements covering more than one geographic area are counted for each area.

2.4.1.4. Main Categories of the Patent Settlements

(745) This section describes in detail the different types of patent settlement agreements between originator and generic companies that fall into the above three categories.

A. Agreements that did not limit the generic company's ability to market its own product (category A)

(746) As mentioned above, 108 of the total of 207 patent settlement agreements that were analysed (i.e. 52%) did not explicitly limit the generic company's entry into the market. In these agreements, the generic company was free to market its own generic product in the geographic market concerned, on a given date and under the conditions chosen by the generic company itself.

(747) Litigating parties entered into category A settlement agreements for a variety of reasons and the terms of the settlement agreements took various forms, depending on whether or not the generic company had entered the market (at risk) or whether the settlement was concluded close to the time when the originator company lost market exclusivity.

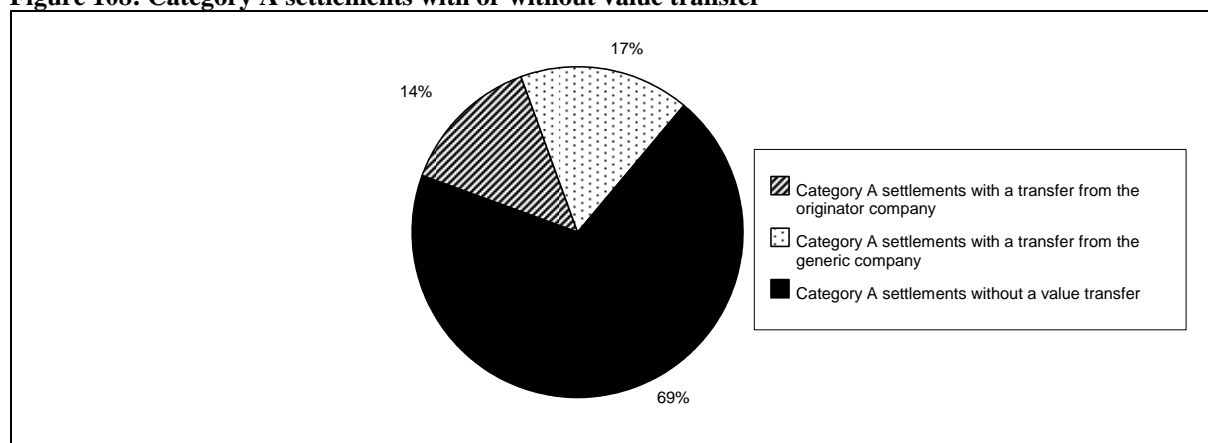
(748) Of the 108 settlement agreements in category A, the generic company that concluded the settlement was already present in the market in 69 cases (64%). In all but one of these cases another generic company was also already present in the market when the settlement was concluded. In another 20 of the 108 agreements (19%), the generic company that concluded the settlement was not present in the market but another

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generic company was. Only in 11 cases (10%) no generic company was present in the market.

- (749) Furthermore, the clear majority of category A settlement agreements were concluded after or just around the time when the originator company's product effectively lost market exclusivity. In such circumstances, the most rational course may be for companies to settle their dispute and avoid further legal costs, as the generic company would, in any event, be free to enter the market with its own product at this point.
- (750) However, some of the agreements were concluded prior to the point at which the originator company's product lost exclusivity. One reason behind such agreements that was mentioned by originator companies was the originator company's inability to prove the generic company's infringement. This may have been the case either because the originator company was not granted an interim injunction or because the originator company had already lost the case in the first instance in the area concerned by the settlement or in another geographic jurisdiction. Another reason given by originator companies was that the originator company agreed to let the generic company enter the market in return for the generic company withdrawing its patent invalidity claims.
- (751) In the former situation, an originator company might decide that the chances of winning an appeal or litigating on the same issue in another geographic area are so low that the costs and risks associated with the litigation outweigh the possible benefits. Therefore, it can be more beneficial for the company to settle the litigation and allow the generic company to enter the market. A settlement in this situation could also be preferable for the generic company as it would remove any further delays to market entry
- (752) A clear majority (69%) of category A settlement agreements did not include a payment, but were concluded on a so-called "walk-away" basis. Such an agreement is the most likely outcome if both parties believe that continuing the litigation would be a waste of time and/or resources.

Figure 108: Category A settlements with or without value transfer



Source: Pharmaceutical Sector Inquiry.

Box: Example: Category A patent settlement agreement with no value transfer

One generic company challenged the validity of an originator company's patent in a Member State and obtained marketing authorisation. In parallel, another generic company filed a non-infringement action claiming that its product was not infringing any of the originator company's patent(s). The originator company filed counteractions against both generic companies and applied for interim injunctions, which were refused by the court.

Following the refusal by the court to issue an interim injunction, the parties decided to settle the litigation. The originator company withdrew its counteractions and undertook not to initiate patent infringement actions in the future against the two generic companies in the geographic area concerned. In return, the generic companies agreed to discontinue their litigation claims. The result of the patent settlement was that the generic companies were free to enter the market with their own product.

- (753) However, some of the category A settlements included a value transfer from the originator company to the generic company. One example was the case in which an originator company was first granted an interim injunction against a generic company's product but later lost the main infringement case. Under such circumstances, the generic company could claim damages for lost sales it incurred whilst it was prevented from marketing its product.
- (754) Another example very similar to the one above is the case of a generic company which was planning to enter a market and faced an infringement claim by an originator company, although the Court later declared the patent invalid or not infringed. The possible outcomes of such situations are identical to those described above, apart from the fact that the generic company, rather than being ordered by an interim injunction to exit the market, was actually stopped from entering the market.

Box: Example: Category A settlement with a payment from the originator company to the generic company and agreed early generic entry in another territory

The parties were involved in patent litigation in a Member State. The originator company's request for an interim injunction was initially upheld by the court, but its formulation patent was later declared invalid. The parties decided to discontinue the litigation and settle. As a result of the settlement, the generic company was able to enter the market and, in addition, received a lump sum as compensation for loss of sales incurred during the period covered by the interim injunction. Furthermore, the originator company agreed that the generic company could launch an authorised generic product in another country (outside the EU), in which the patent had not yet expired. Ultimately, the generic company became the exclusive partner of the originator company in that country.

- (755) Some of the cases where the originator company's patent(s) expired before a final judgment was reached, also included a value transfer from the generic company to the originator company if – in the assessment of the parties – the patent was valid, but the generic company had entered at risk. Such compensation covered legal fees and damages. However, in such a case the settlement agreement could also provide for a payment from the originator company if the generic company had a good chance of proving that it was wrongfully kept out of the market.

Box: Example: Category A settlement, with a payment from the generic company to the originator company

After lengthy litigation (lasting more than ten years) in a Member State without any final result, the parties decided to settle the litigation because the originator company's patent, at issue in the litigation, had expired.

As part of the settlement agreement, the generic company accepted that it had infringed the originator company's patent and agreed to pay damages to the originator company. By concluding the settlement, both parties mutually relinquished their claims/counterclaims for the past and future concerning the patent in-suit and the generic company was free to market its product in the Member State concerned.

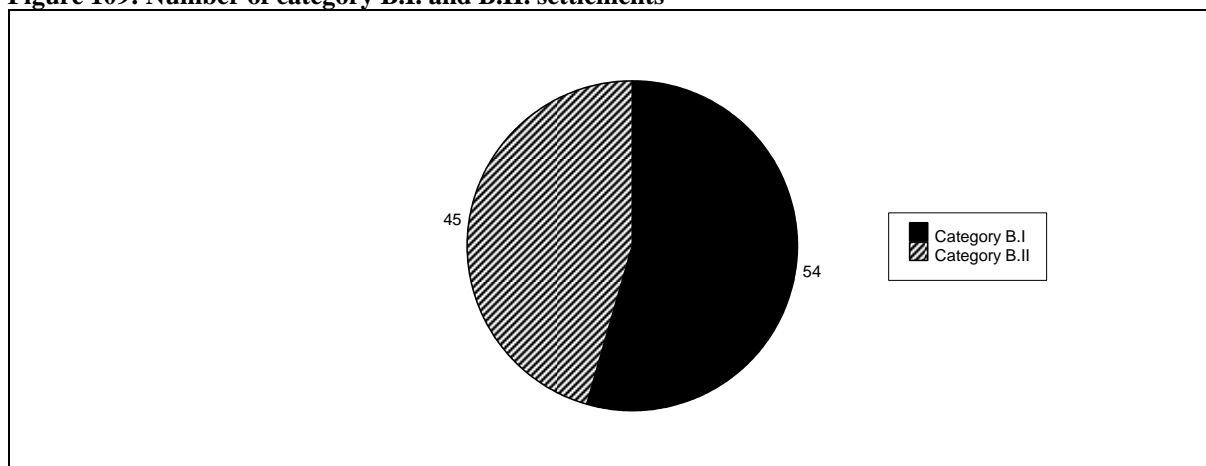
- (756) The sector inquiry confirmed that in 15 category A settlements (14%), the originator company made a value transfer to the generic company. In total, more than € 20 million was transferred from originator to generic companies. In one agreement, the value transfer flowed to the generic company in the form of a "side-deal" involving elements not directly related to the resolution of the patent litigation. In this "side-deal", the generic company obtained a licence to market another product not subject to the patent litigation.
- (757) In 18 category A settlements (17%) the originator company received a value transfer from the generic company as compensation for damages. However, the total value transferred from the generic companies amounted only to € 2.5 million.

B. Agreements that limited the generic company's ability to market its own product (category B)

- (758) A total of 99 of the patent settlement agreements submitted (48%) included an explicit limitation on the generic company's ability to market its own product. As explained above, the generic company's entry can be limited in several ways. Some settlement agreements provided that the generic company would recognise the validity of the originator company's patent(s) and would refrain from entering the market until the relevant patents had expired. In other cases, the generic company agreed either not to enter or to withdraw its generic product and, in exchange, obtained a licence to exploit the patent or became the originator company's distributor and was thus able to market the originator company's product. The latter cases are still categorised as limiting generic entry, since – although the generic company can enter the market – it can do so only under the conditions of the licence agreement concluded with the patent holder.

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Figure 109: Number of category B.I. and B.II. settlements



Source: Pharmaceutical Sector Inquiry

B.I. Agreements that limited the generic company's ability to market its own product but included no value transfer to the generic company (category B.I.)

- (759) Some 54 patent settlement agreements (26%) included an explicit limitation of the entry to market by the generic company, but no value transfer to the generic company. In these agreements, the generic company agreed to enter only after the patent(s) at issue had expired. The background to category B.I. settlements and the terms of the settlement agreements can take various forms. However, the main characteristic of this category of settlement agreements seems to be that the originator company had won the patent infringement case against the generic company, at least before the court of first instance. Further to this, the generic company recognised the full validity of the patent and agreed not to market its product until after expiry of the relevant patent.
- (760) In almost all category B.I. settlement agreements, the validity of the originator company's patent and the patent infringement by the generic company were recognised by a court decision prohibiting the latter from marketing its generic product until after patent expiry. In some cases, the court ordered the generic company to pay damages to the originator company for having infringed the originator company's patent. The generic company had an interest in settling the case, very often before the final court ruling that established the costs/damages to be paid. Further to this, the generic company undertook to accept the court ruling(s) as final, rather than appealing against them. At the same time, it recognised the validity of the originator company's patent(s) and/or agreed not to challenge its/their validity in the future. It also undertook either not to enter the market or to stop marketing its own product until after the expiry of the patent(s) concerned.

Box: Example: Category B.I. settlement with a payment from the generic company

An originator company's request for an interim injunction against a generic company in two Member States was upheld by the courts. The parties decided to settle and accepted the interim injunctions as being the final outcome of the patent litigation. The originator company undertook not to pursue claims for damages against the generic company for marketing its product in the two Member States. The generic company furthermore withdrew its product and agreed to pay the originator company's legal costs.

Box: Example: Category B.I. settlement with delayed entry and a payment from the generic company to the originator company

An originator company obtained several interim injunctions on the basis of an SPC, under which the generic company was prohibited from importing and marketing its generic product in a Member State until after expiry of the patent concerned. In addition, all the generic products were put into temporary custody until the final ruling. The originator company requested penalties and fines, while the generic company filed a nullity action against the patent.

The parties decided to settle. The generic company accepted the interim injunctions as final and withdrew its nullity action against the originator company's patent. Moreover, it agreed to pay to the originator company a lump sum for legal fees and communicated to the originator company the exact quantities of the generic product sold in the Member State before the settlement. The originator company waived its rights against the generic company under the patent proceedings in the Member State concerned and undertook to file no further interim injunctions, no further infringement actions and no claims for damages. The originator company furthermore withdrew claims for criminal prosecution.

- (761) The total value transfer from generic companies to originator companies amounted to a little over € 7 million (disregarding the value attributable to the destruction of the generic products).⁴⁷³

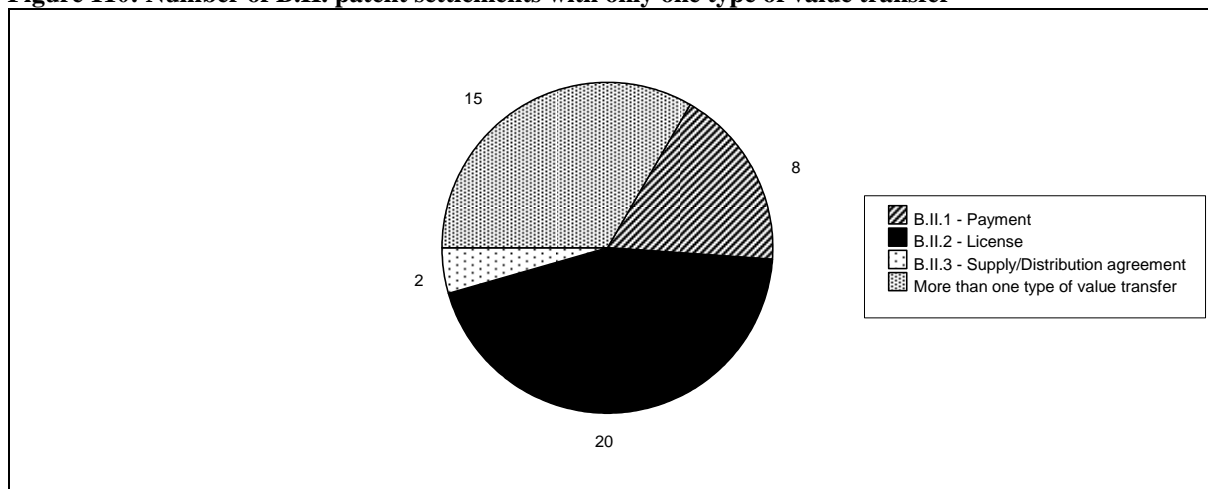
⁴⁷³ The total value is calculated in the basis of the responses received from the originator companies.

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B.II. Agreements that limited the generic company's ability to market its own product and included a value transfer to the generic company (category B.II.)

- (762) Of the total number of 207 agreements, 45 patent settlement agreements limited the generic company's ability to market its own product and included a value transfer from the originator company.
- (763) During the public consultation, some stakeholders expressed concern that all settlement agreements which were characterised as B.II in the report were deemed anticompetitive. In this regard it is important to underline, as stated in the beginning of this chapter, that any assessment of whether a certain settlement could be deemed compatible or incompatible with EC competition law would require an in-depth analysis of the individual agreement, taking into account the factual, economic and legal background.
- (764) The value transfer flowing to generic companies in the settlement agreements took different forms, and 15 agreements included several types of value transfer. As far as the 30 agreements that included only one type of value transfer were concerned, eight of them included a payment from the originator company to the generic company, 20 included the granting of a licence to the generic company, and two agreements included a supply and/or distribution agreement with the generic company (see Figure 110).

Figure 110: Number of B.II. patent settlements with only one type of value transfer

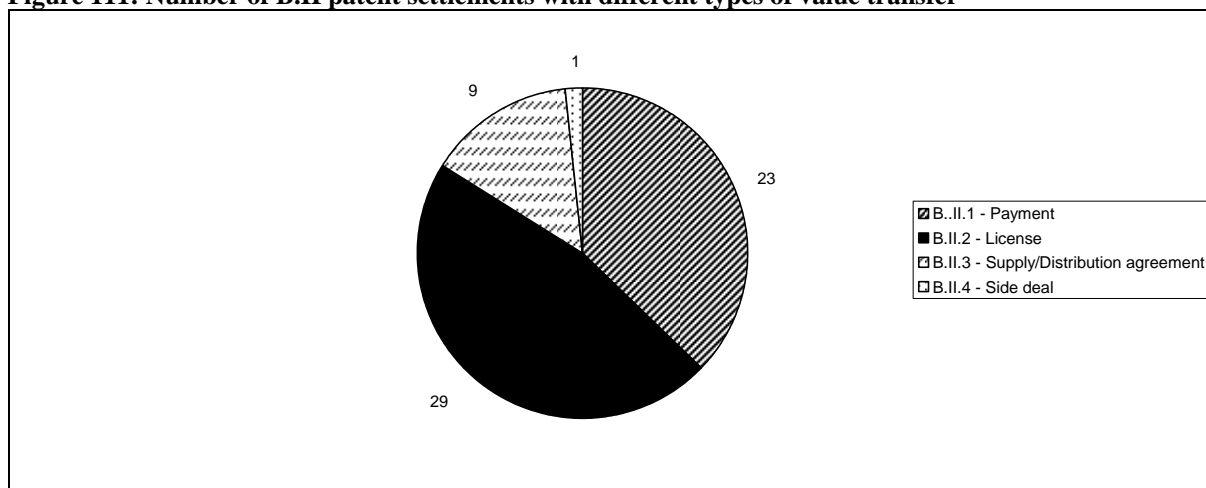


Source: Pharmaceutical Sector Inquiry

- (765) Taking all B.II. agreements into account, 23 agreements (51%) included a payment from the originator company to the generic company, 29 settlements (64%) included a licence, nine cases (20%) included a supply and/or distribution agreement and one settlement agreement (2%) included a 'side deal' with the generic company (see Figure 111).

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Figure 111: Number of B.II patent settlements with different types of value transfer



Source: Pharmaceutical Sector Inquiry

Note: Settlement agreements including more than one type of value transfer are counted in each category.

(766) The settlement agreements which included a direct payment from the originator company to the generic company took various forms. In six agreements, the generic company agreed not to enter the market until the court had given its judgment on the issue of patent infringement. One of these settlement agreements also included a distribution agreement in which the generic company would be able to sell limited quantities of the product at issue in the litigation in one Member State.

Box: Example: Category B.II. settlement with payment from the originator company

A generic company was on the verge of selling a generic product in a Member State without the originator company's consent. The latter filed a request for an interim injunction and began patent infringement litigation. The parties decided to settle. The generic company agreed not to market its generic product in the Member State concerned until the court had passed judgment in the patent infringement case. It also transferred the stock of its product to the originator company. In exchange, the originator company paid a lump sum to the generic company.

(767) In the remaining 17 settlement agreements which included a payment from an originator to a generic company, the generic company agreed either to exit, or not to enter the market until after the originator company's patent(s) had expired. Nine of these agreements were combined with licensing agreements between the parties (royalty-bearing or royalty-free), allowing the generic company to sell or produce certain quantities of its product in a limited territory.⁴⁷⁴ Other four settlement

⁴⁷⁴ In the context of the public consultation, some stakeholders expressed concern that the report put into question the legality of settlement agreements which include a licence to the generic company and agreements concerning the launch of an authorised generic. As previously explained, the report does not assess whether certain types of agreements are compatible or incompatible with European competition rules. Nor does it aim to provide guidance on the legal assessment of certain agreements. Reference is here made to the annex EC competition law which describes the EC competition rules in order to provide an overview of the legal framework for this report. Settlement agreements that include a licence is

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agreements were linked to a supply or a distribution agreement making the generic company a distributor (or sub-distributor) of limited quantities of the originator company's product in certain geographic areas. One of these agreements included a clause guaranteeing the generic company's net profit in connection with the sales. Other agreements included a marketing contribution paid by the originator company and/or a payment to the generic company compensating it for its legal costs, while some agreements mention the originator company buying the generic company's stock of the product it had intended to market.

Box: Example: Category B.II. settlement with purchase of stock of products, payment and distribution agreement

Further to an interim injunction, a generic company was prevented from launching its generic product in the Member State concerned. However, after a judgment that was unfavourable to the originator company in the patent litigation, the originator company was ordered to pay the loss of profits due to the other party for the period when the injunction was in place. The parties decided to settle in order to avoid excessive costs and time-consuming litigation (particularly in view of the number of expert witnesses that were required in order to determine the potential lost profits due to the generic company).

Further to the settlement, and besides ceasing litigation, the originator company agreed to buy the generic company's stock of products at a price fixed in the agreement, to pay a lump sum as a marketing allowance and to pay 50 % of the legal costs incurred by the generic company in the litigation.

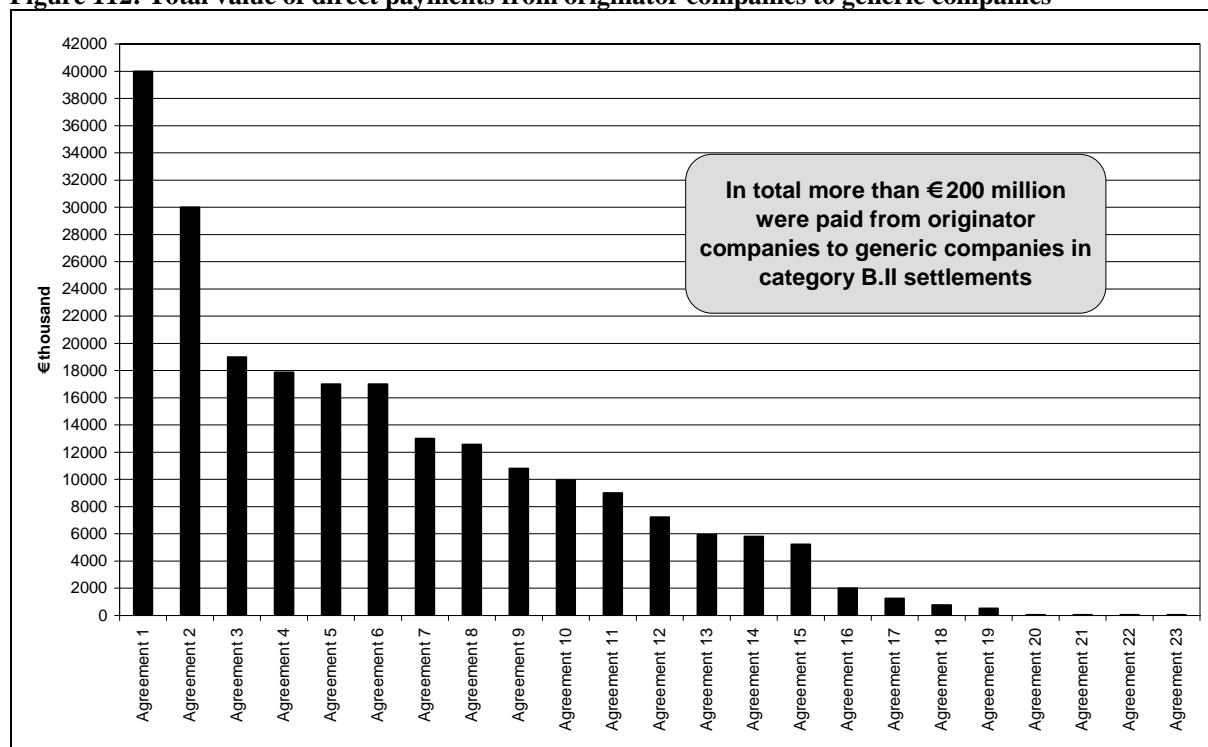
The generic company agreed to enter into a sub-distribution agreement with the originator company's exclusive distributor in the Member State concerned with an exclusive purchase obligation, thereby agreeing not to sell any active substance from another source for the duration of the agreement.

- (768) In total more than € 200 million was transferred from originator companies to generic companies in the 23 settlement agreements which included a direct payment from the originator company. It should be noted, however, that the net transfer does not take into account the value of royalty-free licences to generic companies, or the possible value transfers from generic companies to originator companies.

characterised as B.II because the entry onto the market is partly or wholly controlled by the originator company through the licence terms. In line with our definition of limitation on generic entry, the generic company is therefore unable to compete on the market without limitations on, for instance, the quantities it can sell.

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Figure 112: Total value of direct payments from originator companies to generic companies



Source: Pharmaceutical Sector Inquiry

Note: Value in € was calculated using historic exchange rates from the date on which the settlement agreement was signed. Figure has been updated from the preliminary report due to additional information received.

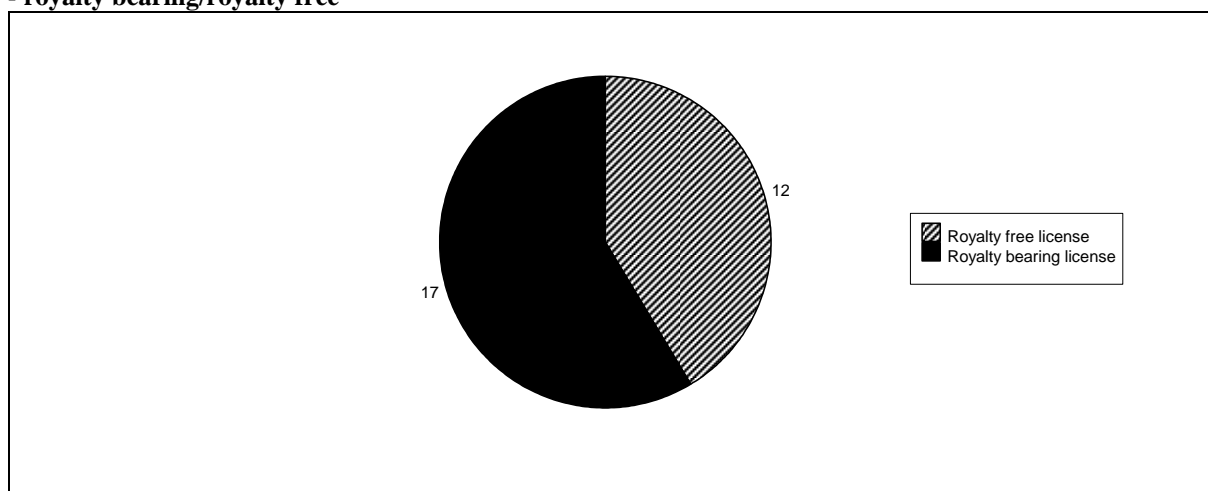
- (769) Patent settlements with a value transfer from the originator company to the generic company can be used to delay the market entry of the latter beyond the point in time when it would have expected to be able to enter the market, for example following a judgment in the litigation. The delay of independent entry can also occur where the generic company agrees to enter the market in a more limited fashion than it would have done in the absence of a settlement, for example as a licensee – see below – or a distributor of the originator company.
- (770) An example of a settlement that delayed generic competition was a case in which an originator and a generic company settled litigation shortly before a judgment was expected by the court in the patent litigation and agreed that the generic company should refrain from entering the market. As part of the settlement agreement, the originator company made a payment to the generic company. In a subsequent similar litigation concerning the same subject matter, the originator company's patent was revoked and the generic challenger was able to enter the market. Through the settlement, the originator company was able to postpone the LoE for its product by several years.
- (771) Apart from the settlement agreements which included both a payment from the originator company and a licence, another 20 agreements included the granting of a

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licence to the generic company.⁴⁷⁵ In the majority of the agreements, the parties agreed to withdraw all litigation, waive all claims, undertake not to initiate new litigation concerning the same subject matter in the future in return for the originator company granting a licence to the generic company.

- (772) In all the agreements in which the originator company granted a licence to the generic company (29 cases), the licence was limited in scope; moreover, in the majority of cases, the licence only covered certain versions or dosages of the originator company's product. In the majority (59%) of the licence agreements, the generic company paid royalties to the originator company (see Figure 113). These agreements therefore included a value transfer to both parties. In the remaining 12 agreements (41%), the licence was granted royalty-free to the generic company and the generic company was the only recipient of a value transfer.

Figure 113: Number of settlements where the originator company licensed an IPR to the generic company - royalty bearing/royalty free



Source: Pharmaceutical Sector Inquiry

Box: Example: Category B.II. settlement with a royalty-free licence

In addition to a settlement agreement between the parties covering non-EU countries, the generic company agreed to withdraw its actions for non-infringement and annulment of the originator company's patents in several Member States. The generic company also agreed not to market the product at issue, directly or indirectly, in any of these countries until an agreed date. After the agreed date, the generic company obtained a non-exclusive, royalty-free licence to manufacture/market its products in the Member States concerned.

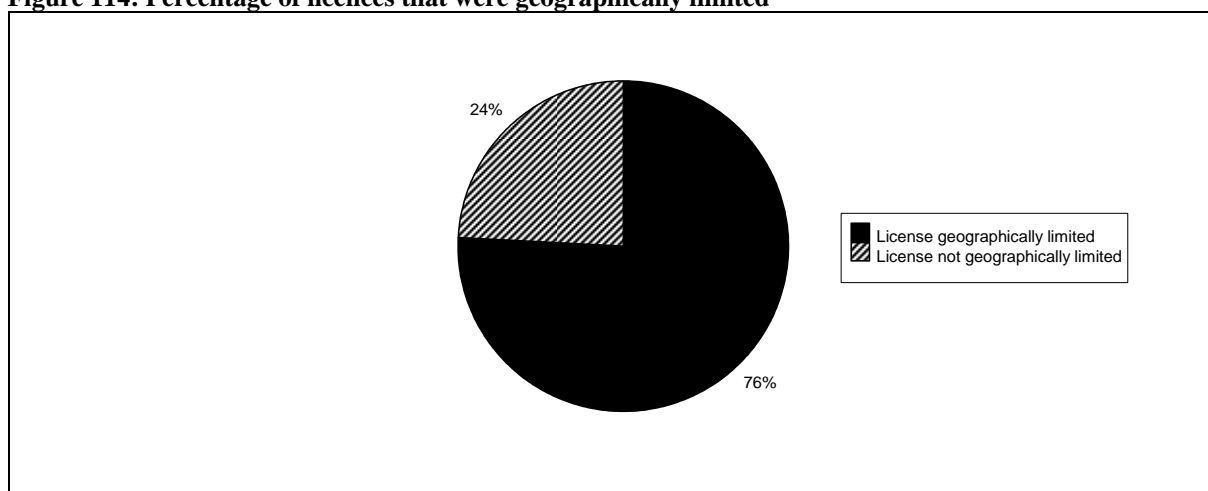
⁴⁷⁵ In total, 29 of the B.II. settlement agreements included a licence agreement.

Box: Example: Category B.II. settlement with a royalty-bearing licence

The generic company was on the verge of launching its generic product in several Member States without the originator company's consent. The latter, instead of litigating, decided to grant a non-exclusive, royalty-bearing licence to the generic company to market/import the product in the territory concerned.

(773) Three quarters of the settlement agreements including a licence agreement were limited in geographical scope (see Figure 114). Usually, the licences granted by the originator company only covered the geographic areas (fully or only partially) in which the two parties had been involved in litigation. Seven of these settlement agreements were not limited to a certain geographic area but granted a licence to the generic company for all the countries in which the originator company held the patent(s).

Figure 114: Percentage of licences that were geographically limited

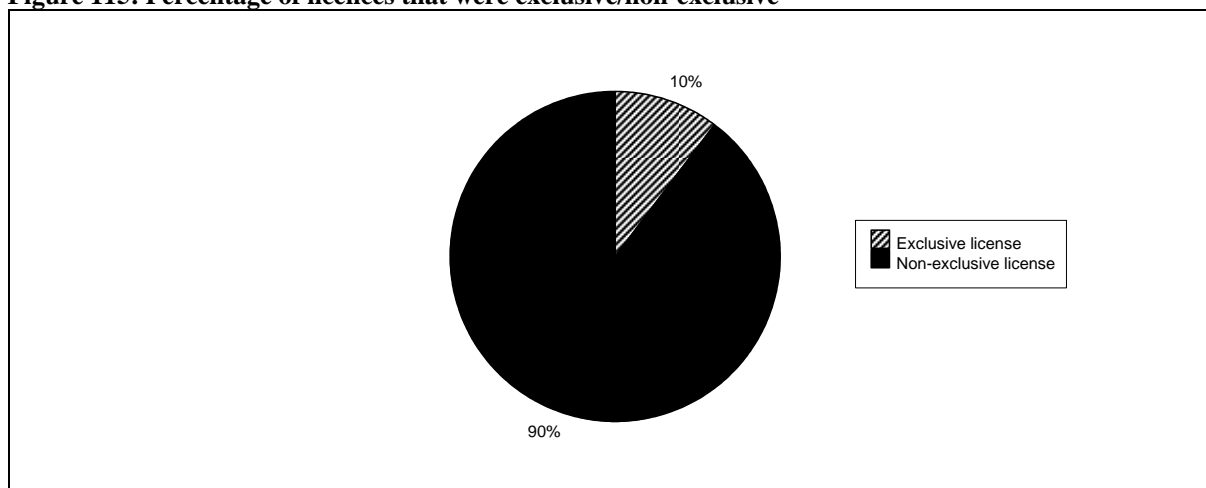


Source: Pharmaceutical Sector Inquiry

(774) A total of 26 of the 29 (90%) licences granted by the originator company in combination with a settlement agreement were non-exclusive (see Figure 115). In those agreements, the originator company thus maintained its rights to grant licences to other parties. In three settlement agreements the originator company granted an exclusive licence to the generic company. However, in all of these agreements, the exclusivity was territorially limited.

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Figure 115: Percentage of licences that were exclusive/non-exclusive



Source: Pharmaceutical Sector Inquiry

- (775) In nine of the B.II. settlement agreements the parties signed a supply and/or distribution agreement enabling the generic company to enter the market with one of the originator company's own products in a generic form. In some of these agreements, the originator company undertook to supply the generic company with the finished product (either itself or through a third party), whereas in other agreements the generic company was due to receive only the API (active pharmaceutical ingredient) from the originator company. In seven of these agreements the settlement agreement also included another form of value transfer to the generic company whereas in two instances it was the only value transferred to the generic company.

Box: Example: Category B.II. settlement with payment to the generic company and supply agreement

Generic company A, with which the settlement was reached, distributed generic products delivered from another generic company B in several EU Member States. The originator company sent a warning letter to company A claiming that the generic company's activities infringed its patent(s).

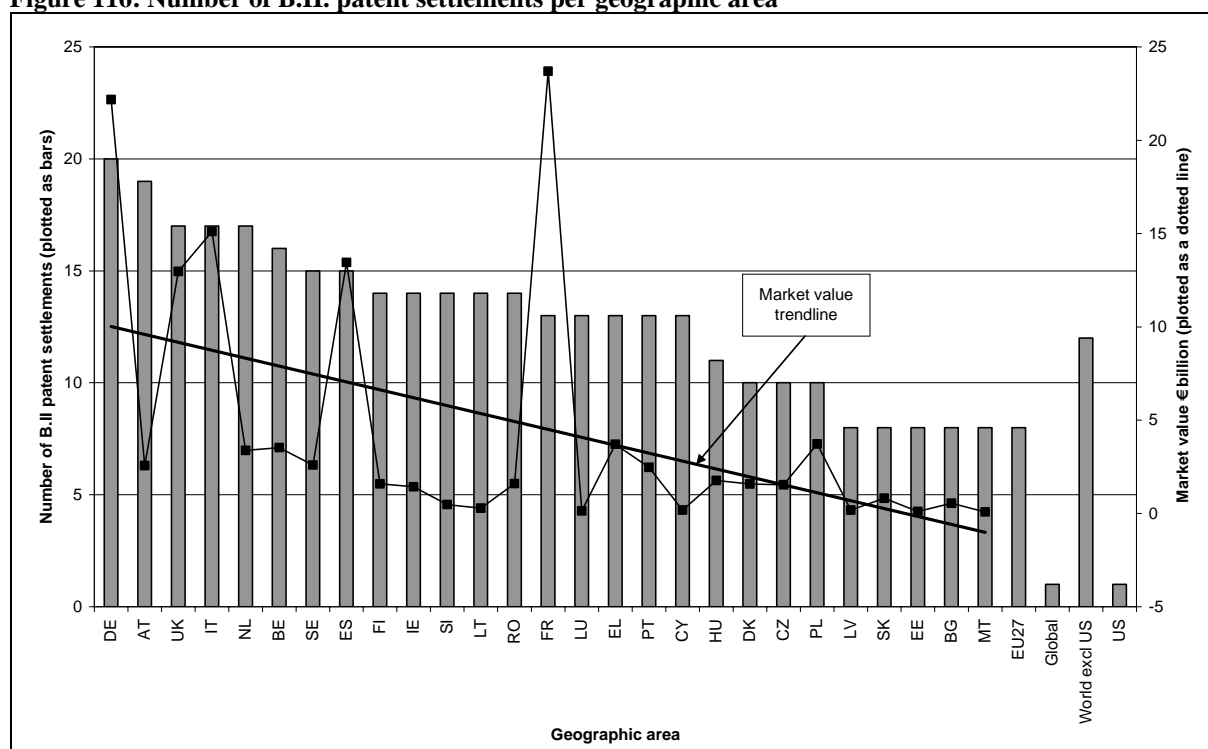
The parties decided to settle. Generic company A agreed to stop marketing the generic products subject to the payment of a lump sum by the originator company. Furthermore, generic company A agreed to use its influence on generic company B to stop it supplying generic products in several Member States during the term of settlement. In exchange, the originator company undertook to initiate no patent infringement action against generic company A and recognised this as full and final settlement for all its claims in the EEA. Furthermore, the parties signed a supply agreement under which the originator company would supply generic company A with the products.

- (776) Only one of the B.II settlement agreements included a 'side deal' – in the sense that it involved elements not directly related to the patent issue at stake – as value transfer to the generic company. In this settlement, the parties agreed to expand an existing clinical supply and development relationship, in order to include a potential API supply arrangement in respect of a product which was not subject to the patent litigation between the companies.

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(777) As was the case for the total number of patent settlements, a similar result emerges for the number of category B.II settlements covering various geographic areas (see Figure 116). Again, a correlation between the size of the market and the number of settlements is observed. The major difference here is that there are not substantially more B.II. agreements covering Germany and that France – which has the highest value sales of pharmaceutical products – dropped a few places in the ranking. Moreover, eight of the countries most covered by settlements are still found in the top ten when it comes to the conclusion of B.II. settlements, with Denmark being the only other country to drop down the list. Consequently, as was the case with the total number of settlement agreements concluded, there are more B.II. settlement agreements covering the most valuable geographic markets in the EU.

Figure 116: Number of B.II. patent settlements per geographic area



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

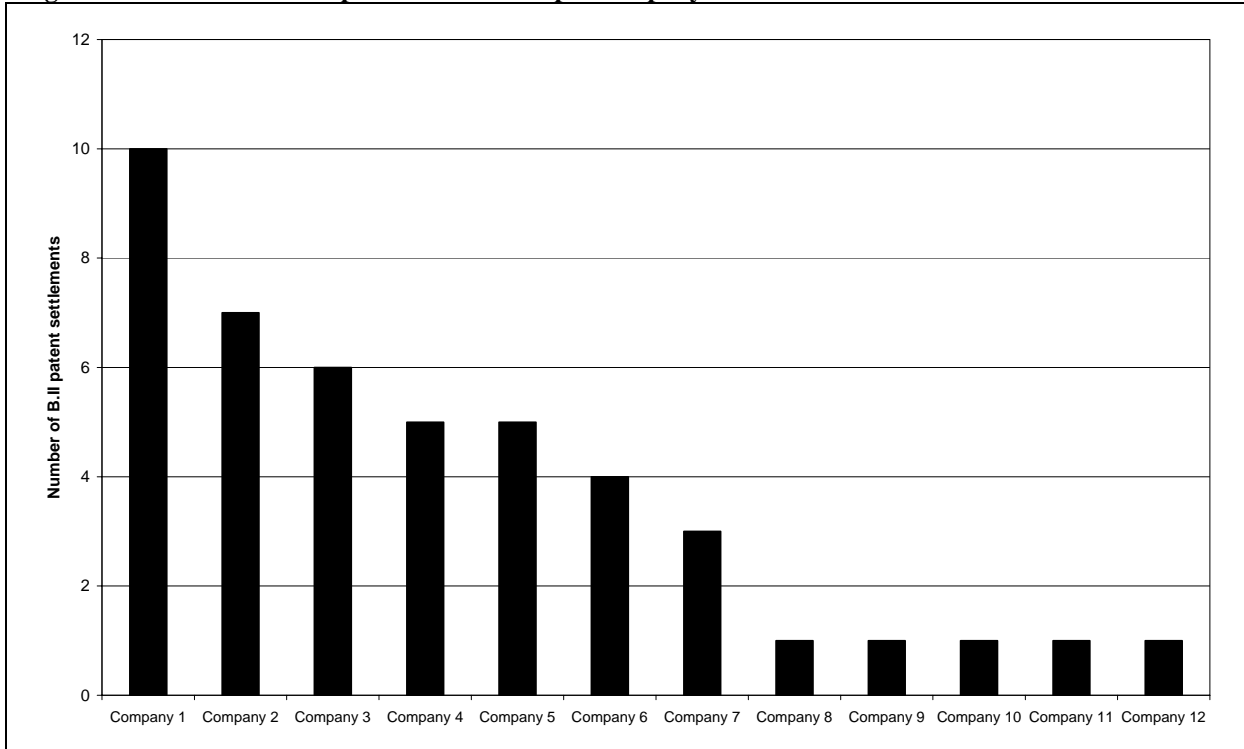
Note: Agreements covering more than one geographic area are counted for each area. The market value figures are for sales of prescription medicines for human use, at ex-factory prices. The black line shows a linear market value trend line for the dotted line indicating the total market value. Figures for Greece, Romania, Bulgaria, Slovenia, Cyprus and Malta include sales of non-prescription medicines. Sales data for Cyprus and Malta are from EPFIA.

(778) The 45 B.II. settlement agreements were concluded by 12 originator companies of which only 5 concluded one B.II. settlement agreement each. The two companies with the highest number of B.II. settlements concluded agreements in ten and seven cases respectively (see Figure 117).

(779) In total, the 45 B.II. settlements were concluded for 15 different INNs (see Figure 118). For nine of the INNs, only one B.II. settlement was concluded, while for the three INNs with the most B.II. settlements, ten and, in two cases, six settlements were concluded. Some 12 of the 15 INNs (80%) for which B.II. settlements were concluded, were in the initial selection of INNs, which the Commission's services made in the preliminary phase of the sector inquiry.

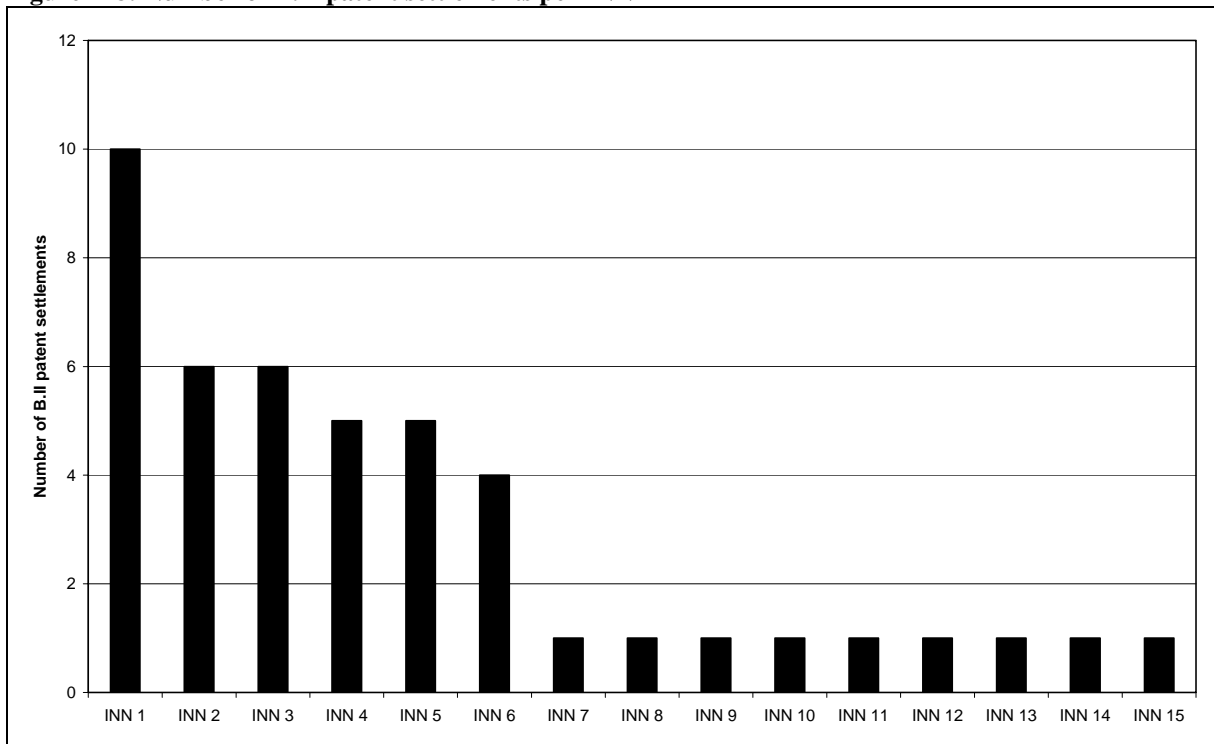
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Figure 117: Number of B.II patent settlements per company



Source: Pharmaceutical Sector Inquiry

Figure 118: Number of B.II patent settlements per INN



Source: Pharmaceutical Sector Inquiry

2.4.1.5. Patent Settlement Agreements in the USA

- (780) In the initial phase of the sector inquiry it was submitted that there were significant differences between patent settlement practice in the pharmaceutical sectors of the USA and the EU. This was alleged to be essentially due to the differences in the regulatory environments, which were said to encourage generic companies active in the USA to be the first challenger of a patent-protected product.⁴⁷⁶ By contrast, such incentives would not exist in the EU. Accordingly, the enforcement practice of the Federal Trade Commission (FTC) was deemed not to be transferable to the EU.
- (781) For the purposes of this report, it was therefore considered useful to provide an overview of USA settlement practice and to identify the common factors and the differences between the EU and USA systems. This section will first describe the USA enforcement practice on settlements, as evidenced by the Cephalon case and the recent Solvay case. Furthermore, it will describe important USA Court rulings on the issue of patent settlements and explain the newly proposed legislation in the USA that would prohibit certain types of settlements. A comparison will then be made between the patent settlement agreements concluded in the USA and in the EU during the past four years.
- (782) As was indicated at the outset of this Chapter C.2.4.1., its purpose is not to provide any guidance on the compatibility of settlement agreements with EC competition law. It would therefore not be appropriate to conclude that the USA enforcement practice – presented in this report – is automatically and fully transposable to the EU.

Enforcement Practice in the USA – In Particular by the FTC

- (783) Since 2004, pharmaceutical companies have been required to file certain settlement agreements with the Federal Trade Commission (FTC) and the Department of Justice (DoJ) within ten days of execution.⁴⁷⁷ Each year the FTC publishes a report summarising the number and types of agreements received during the previous fiscal year. Reports have been published since 2004, the most recent relating to 2007. The latest FTC report⁴⁷⁸ covers 45 settlement agreements which were notified to the FTC for the fiscal year 2007.
- (784) According to the FTC, "the [2007] report confirms that settlements with potentially anticompetitive arrangements continue to be prevalent".⁴⁷⁹ This has encouraged the FTC to go ahead with its enforcement action in the area of patent settlements, as

⁴⁷⁶ For an overview of the US regulatory framework, see Annex: US regulatory environment (Annexes to Chapter C).

⁴⁷⁷ For the sake of clarity, it has to be noted that no such reporting obligations exist in the EU.

⁴⁷⁸ See <http://www.ftc.gov/os/2008/05/mmaact.pdf>

⁴⁷⁹ See <http://www.ftc.gov/opa/2008/05/drug.shtm>

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shown by the Cephalon case and the recent Solvay case which is the latest in a long-lasting enforcement record.

Box: USA *Cephalon* case

In February 2008, the FTC sued Cephalon over its agreements with four generic companies for the narcolepsy medicine, Provigil (modafinil) which included exclusion payments. Cephalon entered into agreements with all four generic companies that planned to sell a generic version of Provigil. Each of these companies had challenged the only remaining patent protecting Provigil against generic entry. The FTC claimed that Cephalon was able to induce each of the generic companies to abandon its patent challenge and to refrain from selling a generic version of Provigil until 2012 by agreeing to pay the companies a total amount in excess of US\$ 200 million.

According to the FTC, "Cephalon prevented competition to Provigil by agreeing to share its future monopoly profits with generic companies poised to enter the market, in exchange for delayed generic entry. Such conduct is at the core of what the antitrust laws proscribe."

Box: USA *Solvay* case

On 2 February 2009, the FTC filed a complaint in the Federal District Court against the originator company Solvay Pharmaceuticals and the three generic companies: Watson Pharmaceuticals, Par Pharmaceuticals and Paddock Pharmaceutical. Watson and Par, via its partner Paddock, had sought regulatory approval from the FDA to market generic versions of Solvay's testosterone-replacement drug AndroGel. In their FDA filings, the companies certified that their products did not infringe the only patent Solvay had relating to AndroGel, and that the patent was invalid. The complaint alleges that Solvay, realising the devastating effect generic entry would have on its sales of AndroGel, acted unlawfully to eliminate this threat. According to the FTC, Solvay paid Watson and Par a share of its AndroGel profits to abandon their patent challenges and agree to delay generic entry until 2015. As a result, the complaint states that the defendants are cooperating on the sale of AndroGel and sharing the monopoly profits, rather than competing.

- (785) The general policy line of the FTC is that payments made by the originator company to the generic company are unlawful if they are combined with a restriction on the generic company from entering the market with its own product. The FTC submitted in this respect that "where a patent holder makes a payment to a challenger to induce it to agree to a later entry than when it would otherwise enter, consumers are harmed – either because a settlement with an earlier entry date might have been reached or because continuation of the litigation without settlement would yield a greater prospect of competition."
- (786) The USA DoJ supported the general view that patent settlements can amount to a violation of USA antitrust law. However, it stated that the mere presence of a payment from the originator company to the generic company was not sufficient to establish

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that the settlement was unlawful. For the DoJ, the appropriate legal standard is "the likelihood of success of the parties' patent claims, viewed ex ante."⁴⁸⁰ In this relation, it should be noted, however, that the position of the DoJ towards patent settlements is expected to change following the new USA Administration. In the Senate Judiciary Committee's nomination hearing, the newly nominated Assistant Attorney General for the Antitrust Division at the DoJ, Christine Varney, said she supported the FTC's efforts in bringing a patent settlement case to the Supreme Court. Furthermore, she mentioned that she would support a legislative proposal to ban such agreements – see below – if the courts should continue to disagree with the FTC and uphold settlements.⁴⁸¹

- (787) Taking into account the fact that the substantive standard for assessing the validity of settlement agreements is not spelled out in law, the discussions on the compatibility of patent settlements have also reached the judiciary. The judiciary has not taken a uniform line, but the 11th Circuit Court in particular has taken the opposite view to that of the FTC, as shown by the Schering Plough case:

Box: *Schering-Plough Corp. v. FTC*⁴⁸² – *Eleventh Circuit Court*

Schering-Plough was the patent holder for the medicine K-DUR 20. When two generic companies (Upsher and ESI) filed applications for marketing authorisation, Schering sued them for patent infringement. Subsequently, Schering-Plough settled the patent litigation with both generic companies. Both generic companies agreed not to market their generic products until specified dates in exchange for payment of US\$ 60 million to the first generic company and US\$ 15 million to the second. Furthermore, Schering-Plough agreed to license five of Upsher's products.

The FTC held that these arrangements were anticompetitive under the rule of reason. Schering-Plough and Upsher appealed the FTC decision to the 11th Circuit. The court first observed that the patent enjoyed a statutory presumption of validity. Further, under the agreement both generic companies were able to market a generic product 5 and 2 years respectively before the expiry of the patent. The 11th Circuit concluded that the licences granted by the generic company to Schering-Plough constituted adequate consideration for the payments made by Schering-Plough, rather than pay-offs to delay the introduction of generic competition.⁴⁸³

⁴⁸⁰ See case *FTC v. Schering-Plough Corp.* – described below.

⁴⁸¹ For information on the hearing see <http://judiciary.senate.gov/nominations/AssistantAttorneyGeneralAntitrust-ChristineVarney.cfm>

⁴⁸² 402 F.3d 1056 (11th Cir. 2005).

⁴⁸³ In the context of the public consultation, some stakeholders, relying on certain US case law, submitted that the legal test for assessing the legality of a settlement agreement should be whether the settlement agreement restricts competition beyond the exclusionary zone of the patent (unless the patent is a "sham patent") and that European competition authorities should adopt a similar approach. As mentioned above, this report does not aim to provide guidance on the legal assessment of certain agreements. Furthermore, it should be noted, as evidenced by the Cephalon and the recent Solvay case, that the FTC does not agree with such an approach. Furthermore, some stakeholders submitted, based on the US courts' decisions and

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- (788) At the same time as the FTC filed the complaint against Solvay, the Senate Judiciary Antitrust Subcommittee Chairman Herbert H. Kohl and Senator Chuck Grassley introduced legislation (S. 369) that would prohibit brand name pharmaceutical manufacturers from paying off generic drug companies to delay entry of a generic drug into the market. The proposed legislation would make it unlawful for a company to be a party to a patent settlement agreement in which (i) the generic company receives anything of value and (ii) the generic company agrees not to research, develop, manufacture, market, or sell the product concerned for any period of time. The proposal specifically mentions that patent settlement agreements in which the only value to the generic company is the right to market the product prior to the expiration of the patent are not unlawful.⁴⁸⁴ The "Preserve Access to Affordable Generics Act" is similar to legislation that was cleared by the Judiciary Committee in the last Congress but never enacted. That legislation (S. 316) was initiated in response to the Supreme Court's refusal to hear the Schering-Plough case.
- (789) It remains to be seen how the courts will react to the latest FTC cases concerning Cephalon and Solvay and whether the introduced legislation will become law. Jon Leibowitz, the newly appointed chairman of the FTC, has said that targeting patent settlements in which originator companies pay generic companies to delay entry will be the "highest priority" for the FTC.⁴⁸⁵

General Comparison of EU and USA Settlement Agreements

- (790) Quite apart from the enforcement practice by the USA authorities and courts, it would seem useful to compare the settlement practice in the EU and the USA. Figure 119 provides an overview of the general patent settlement practice in the USA and the EU in the years 2004 – 2007.
- (791) Figure 119 shows that, for the years 2004 and 2005, there were substantially more settlement agreements for the EU than for the USA. In 2006, the number of settlements was almost the same for the EU and USA, and in 2007 more settlement agreements were concluded in the USA than in EU. As a general trend it can be observed that in the USA the number of settlement seems to be increasing slowly, whereas in the EU the number of patent settlement agreements seems to be relatively stable. The only exception in the EU is – as mentioned above – the year 2005, when a significantly higher number of settlement agreements (compared to the previous and subsequent

the FTC's Cephalon case, that patent settlements should, if at all, be dealt with using Art. 82 EC and not Art. 81 EC. In this regard, it should be noted, however, that in its recent Solvay case, the FTC has lodged its complaint not only against the originator company, Solvay, but also against the generic companies, Watson, Par and Paddock.

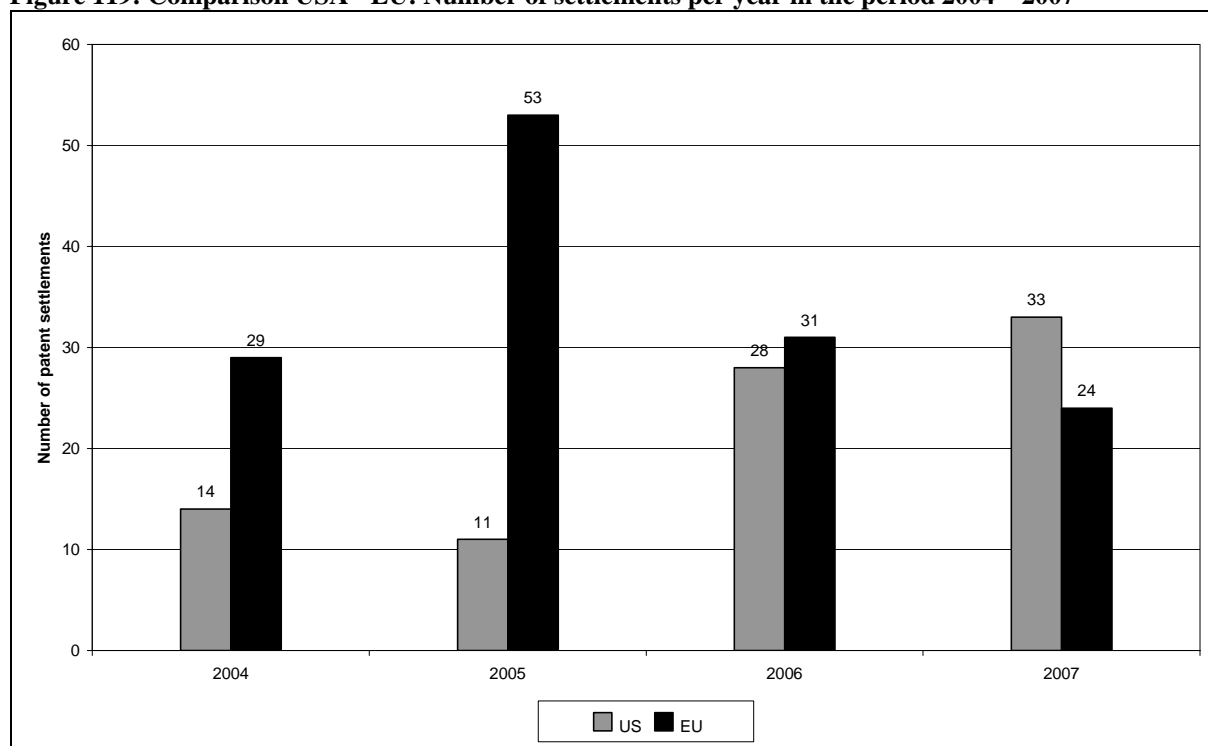
⁴⁸⁴ For the full text of the bill, please see: <http://thomas.loc.gov/cgi-bin/query/z?c111:S.369.IS>; A similar bill, H.R. 1706: Protecting consumer Access to Generic Drugs Act, has been introduced in the House of Representatives. The enactment of this bill was formally recommended by the U.S. House Energy and Commerce Committee's Commerce, Trade and Consumer Protection Subcommittee on 3 June 2009.

⁴⁸⁵ See "FTC's Leibowitz to prioritise scrutiny of generic pharma agreements", 27 March 2009, Robert McLeod, MLex market intelligence.

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years) were concluded – 53 in total. The reason for this was that a significant number of settlement agreements were concluded for two particular INNs, as shown in Figure 103.⁴⁸⁶

Figure 119: Comparison USA - EU: Number of settlements per year in the period 2004 – 2007



Source: Pharmaceutical Sector Inquiry, FTC annual reports on settlement agreements

- (792) The sector inquiry also confirmed that the underlying reasons to be considered when entering into a settlement agreement appear to be the same. On both sides of the Atlantic, companies have an interest in avoiding or ending litigation/disputes and there are various commercial criteria which are taken into account, such as: (1) the costs associated with the litigation, which is an issue of particular concern for generic companies; and (2) the prospects of winning the case, which are of particular importance for originators, especially if the market value of the product concerned is high.
- (793) Whilst one can thus observe a significant number of similarities between settlement agreements in the EU and in the USA, there are also some differences, resulting partly from the different regulatory regimes. For example, in the USA, the first generic company to file a paragraph-IV certification⁴⁸⁷ is explicitly rewarded by the legislator, while in the EU the first to market enjoys no statutory period during which he is

⁴⁸⁶ It should be noted that the number of settlements in the EU also reflects the fact that there are multiple jurisdictions in the EU. However, many of the settlements cover the entire EU or several Member States and are only counted once for this comparison.

⁴⁸⁷ See Annex: US regulatory environment (Annexes to Chapter C).

protected against market entry of a second, third or subsequent generic company. However, the first generic company also benefits from being the first entrant.

- (794) Another difference observed concerns the types of value transfer.⁴⁸⁸ As confirmed by the FTC report, one of the most important forms of value transfer in the recent USA settlement agreements appears to be the originator company's promise not to launch or sponsor an authorised generic for a given period of time after the entry of the generic company's product. This type of value transfer was not found in any of the settlement agreements concluded in the EU. In this regard, the FTC submits that the nature of USA settlements has evolved a trend which does not seem to have arrived in the EU. Likewise, an offer by the originator company of a 'side-deal' on a different product appears to be a normal type of value transfer in USA settlements, whereas on the basis of the material available, 'side-deals' do not appear to be a widespread form of value transfer in EU settlements.

2.4.2. Other Agreements between Originator and Generic Companies

- (795) The aim of this chapter is to describe the other agreements (besides patent settlements) relating to the sale or distribution of a generic product that were concluded in the EU between originator and generic companies during the period 2000 – 2007. More specifically, the chapter will provide a general overview of the extent to which such agreements exist, explain the different categories and present the general considerations for companies entering into such agreements, especially when this involves agreements leading to the launch of a generic product prior to the time when the originator company's product lost exclusivity. The purpose of this section is to complete the picture of the competitive environment between originator companies and generic companies, in particular highlighting early entry agreements. Therefore only the agreements between originator companies and independent generic companies are described in detail, i.e. excluding those agreements in which the generic product was launched by an affiliate of the originator company or the company itself.
- (796) It goes without saying that a generic company that enters into an agreement with an originator company is bound by the conditions of this agreement. The generic entry is thus "controlled" in some form or other. One therefore speaks about so called "authorised generics". The agreements include inter alia the granting of a licence to a generic company or otherwise authorising the launch of a generic version of the originator company's product, as well as the supply of a medicine containing the same active ingredient and its distribution through the generic company. An agreement that provides for the introduction of the medicine onto the market before the originator company's product lost its market exclusivity is hereafter referred to as an "early entry" agreement.
- (797) It should be noted, that the aim of this chapter is not to provide guidance on whether certain types of agreements can be considered compatible or incompatible with EC

⁴⁸⁸ Please note that the categorisation of settlement agreements used in this chapter is not necessarily the same as the one used by the FTC.

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competition law⁴⁸⁹. Such an assessment would require in-depth analysis of the individual agreement, taking the factual, economic and legal background into account.

2.4.2.1. Overview of Main Characteristics

- (798) For the purposes of the sector inquiry, both originator and generic companies were requested to indicate the agreements they have concluded for the sale/distribution of a generic product (including the sale of an active pharmaceutical ingredient or of a finished product) in at least one of the EU27 Member States in the period 2000 – 2007, where such agreements did not concern patent settlements agreements. The companies were requested to submit copies of all agreements in which the originator company still benefited from patent protection when the generic product at issue was launched.
- (799) These questions were designed to ascertain whether the practice of "authorised generics" exists in the EU and how often it is used by originator companies. The strategy of authorising the launch of a generic may be part of the tool-box used by originator companies to maximise revenue streams from existing products and to anticipate generic competition.⁴⁹⁰ The following quote illustrates some considerations of an originator company facing a generic entry:

"By entering into a supply agreement with [generic company], [originator company] could obtain a profit on its supply price and maintain some certainty of profits (although at a reduced level) on Distributed [INN name]. The alternative was to risk losing sales to [generic company] and to make no return on them at all."

- (800) Of the 43 originator companies that responded to the questionnaires during the sector inquiry, almost half (20 companies or 47%) had concluded an agreement with a generic company concerning the sale of a generic product. It has to be noted that, because the respondent companies did not provide a complete set of data on all the questions relevant to this section, the analysis in this section is based only on the information available. As a consequence, statistical analyses presented in figures are not always based on the same number of responses. Accordingly, the sample used in the statistical analysis may not always be of the same size. Precise information on sample size is given in the figures or in the accompanying text.

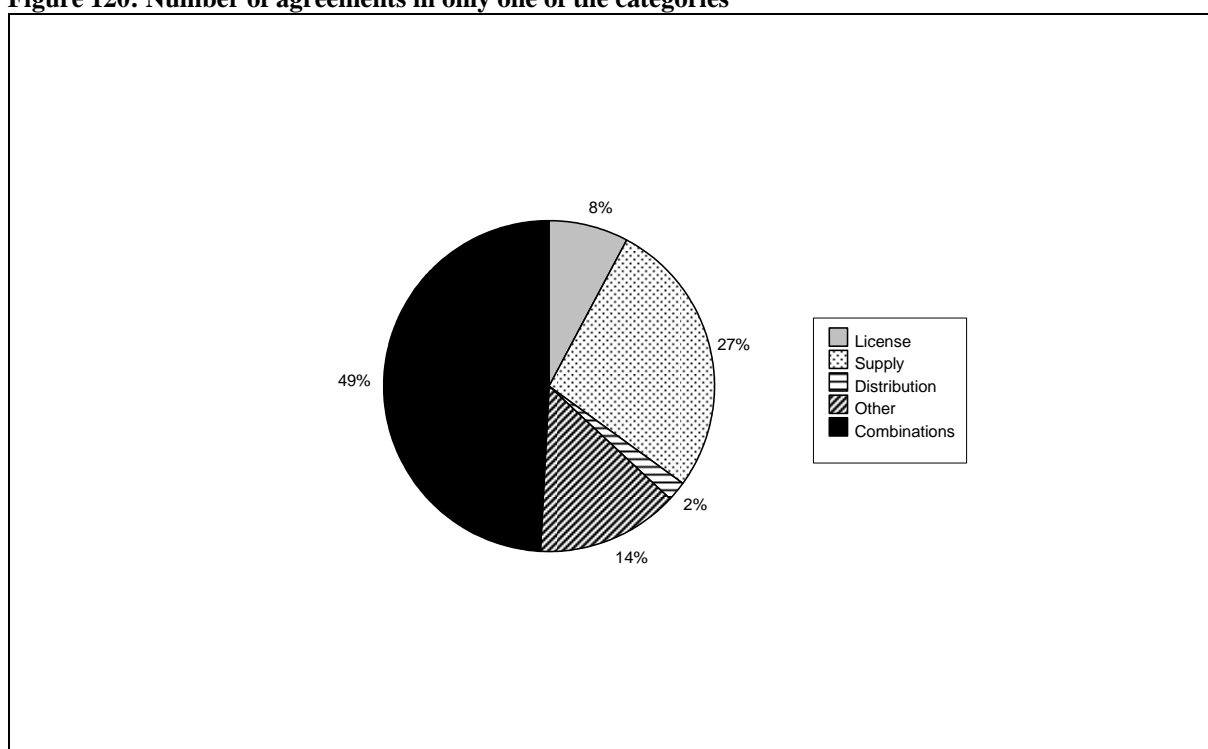
⁴⁸⁹ See Annex: EC Competition Law (Annexes to Chapter A).

⁴⁹⁰ During the public consultation it has been stated that the conclusion of a license or distribution agreement prior to patent expiration is pro-competitive since it creates a second independent source of supply for the product in question. Moreover, it has been submitted, that the conclusion of such agreements represents the exercise of the essential subject matter of the underlying patent rights. In this regard it is important to underline, as stated in the beginning of this chapter, that any assessment of whether a certain agreement could be deemed compatible or incompatible with EC competition law would require an in-depth analysis of the individual agreement, taking into account the factual, economic and legal background.

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- (801) In total, respondent companies indicated that during the period concerned 285 agreements⁴⁹¹ had been concluded relating to 74 INN. The agreements were analysed and grouped into categories depending on their subject and are described in detail below.
- (802) Based on the replies submitted by the originator companies, almost half of the agreements (140 or 49%) concerned a combination of different types of agreements, in particular licence, supply and/or distribution agreements in one or more EU Member States. Of the remaining 145 agreements (51%), 78 (27%) included only supply agreements. Five agreements (2%) concerned only distribution, whereas 22 agreements (8%) concerned only licences. The remaining 40 agreements (14%) included other types of agreements, such as transfer of marketing authorisations to generic companies or allowing early generic entry by a warranty or covenant not to interfere with the launch of a generic product before the date of loss of exclusivity (see Figure 120).

Figure 120: Number of agreements in only one of the categories



Source: Pharmaceutical Sector Inquiry

- (803) If the combination agreements are allocated among the specific categories, in total 211 of the 285 agreements provide for the supply of a product and 82 agreements provide for the granting of a licence. Further, the companies submitted that 80 agreements focus on the distribution of a product and 87 agreements contain elements that could not be categorised under licensing, supply or distribution (other agreements).

⁴⁹¹ This section and the contained figures have been revised following updates from the companies and further analysis of the agreements.

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- (804) Both originator and generic companies were asked to indicate those agreements that included an exclusivity and/or a non-compete clause. Both clauses should be understood as providing for some kind of exclusive relationship between the contracting parties, including exclusive supply obligations⁴⁹², exclusive sourcing⁴⁹³, exclusive licensing⁴⁹⁴ or any other kind of exclusivity⁴⁹⁵, and/or non-compete obligations⁴⁹⁶, regardless of whether they are directed at one partner or both partners. Based on the information available, 111 of the agreements provided for an exclusivity in the broad sense, whereas 131 of the agreements did not include any such clause (see Figure 121). For the remaining 43 agreements, no information was provided.

⁴⁹² For the purpose of the analysis, an exclusive supply obligation should be understood as any direct or indirect obligation agreed between the supplying originator company and the buying generic company that makes the former sell only to one buyer.

⁴⁹³ For the purpose of the analysis, exclusive sourcing (sometimes also referred to as "exclusive purchasing") should be understood as any direct or indirect obligation or incentive scheme agreed between the supplying originator company and the buying generic company that makes the latter purchase all of its requirements for a specific product exclusively from the designated supplier, but leaving the generic company free to buy and sell competing products.

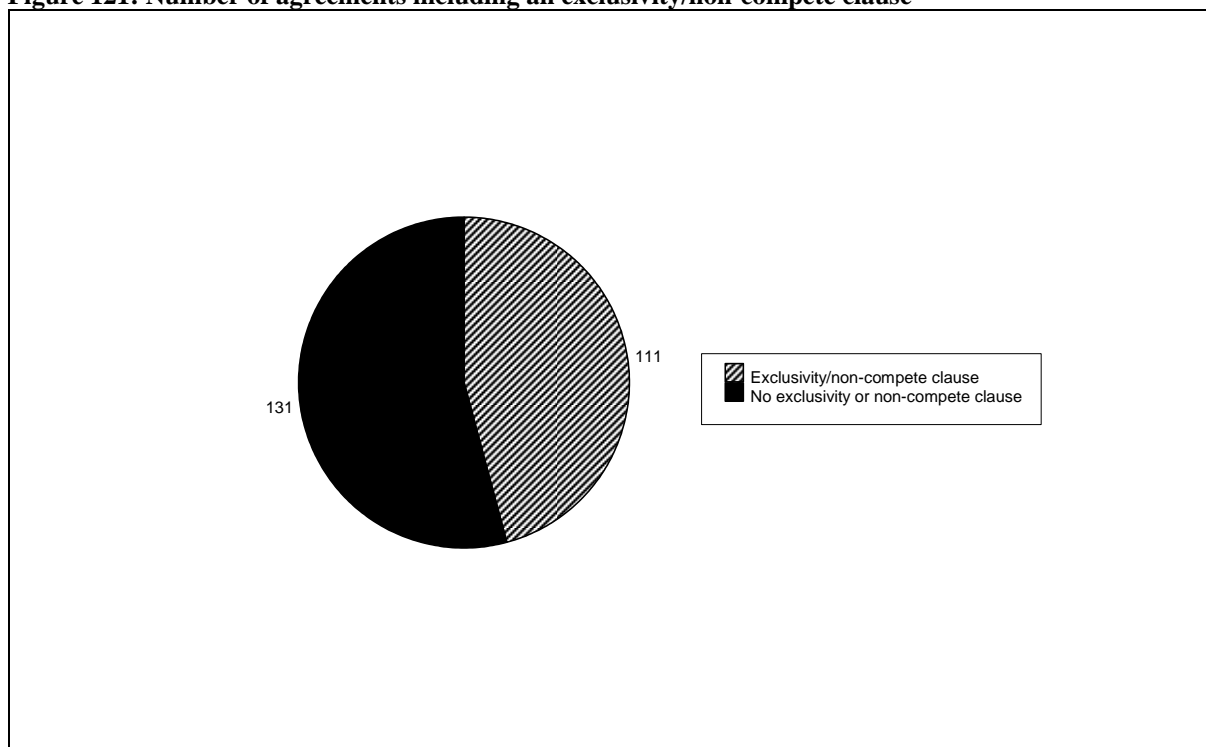
⁴⁹⁴ For the purpose of the analysis, exclusive licensing should be understood as any direct or indirect obligation agreed between the licensor and the licensee where the former limits his licensing to only one licensee (exclusive license) or a limited number of licensees (semi-exclusive license).

⁴⁹⁵ Those clauses were provisions under which the originator company agreed not to grant the same type of rights (e.g. warranties or covenants) to any other third party in the territory.

⁴⁹⁶ For the purpose of the analysis, a non-compete obligation should be understood as any direct or indirect obligation agreed between the supplying originator company and the buying generic company causing the generic company not to manufacture, purchase, advertise, market, sell or resell goods or services which compete with the contract goods or services.

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Figure 121: Number of agreements including an exclusivity/non-compete clause

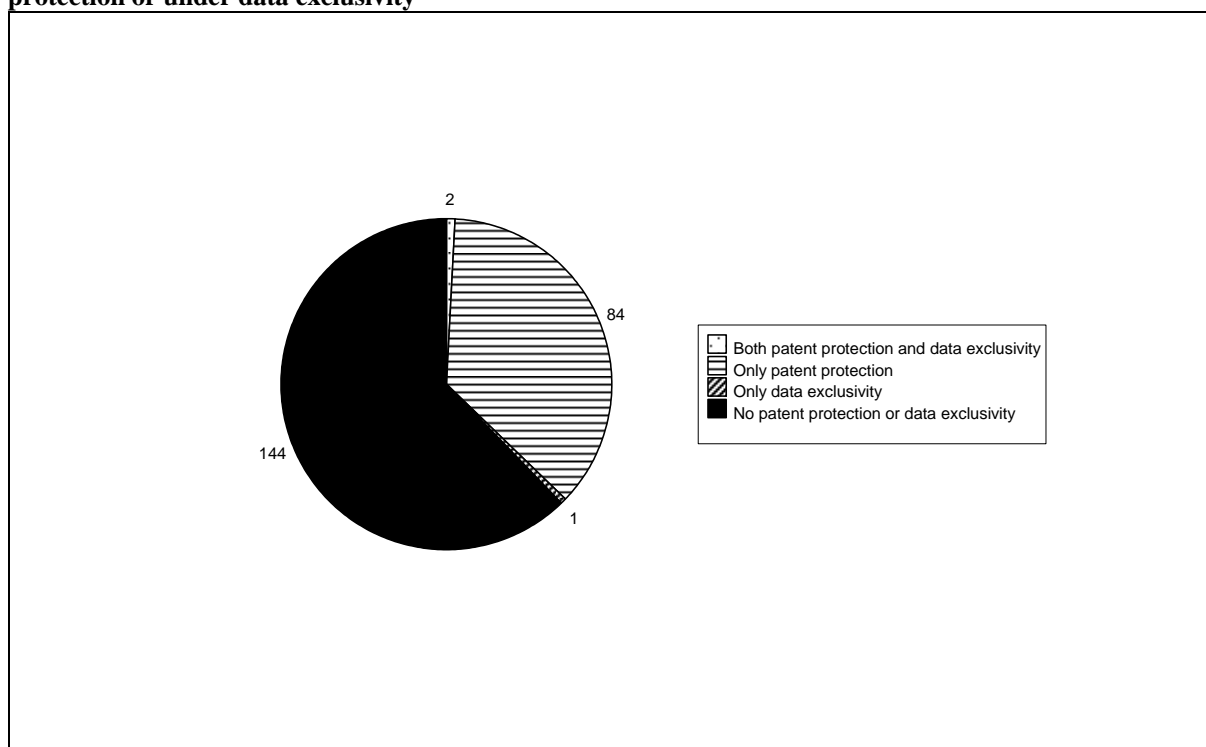


Source: Pharmaceutical Sector Inquiry

- (805) Originator companies were also requested to indicate whether, with a view to launching an own generic or a licensed generic, they had one or more generic companies as preferred partner(s). More than half of the respondent companies indicated that they had at least one preferred partner. In particular, some companies submitted that they mainly entered into agreements with generic companies with which they had already worked in the past. They also submitted that they look for partners that have a broad product portfolio (i.e. products from many different therapeutic areas, general practitioners and hospital products) and who therefore have a wide experience in the launching, marketing and distribution of any generic product.
- (806) Both originator and generic companies were requested to indicate and submit a copy of the agreements in which the originator company's product at issue was still under patent protection when the generic product concerned was launched. Figure 122 shows the number of these agreements. Based on the information available, the originator company's product benefited from patent protection in 86 agreements. In two of these agreements, the originator company's product was at the same time protected by data exclusivity. In one agreement, the originator company only benefited from data exclusivity. For the remaining 144 agreements, the originator companies indicated that their product was not protected by either patents or data exclusivity.

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Figure 122: Number of agreements in which the originator company's product was still under patent protection or under data exclusivity



Source: Pharmaceutical Sector Inquiry

(807) The 144 agreements concluded after the originator company's product had lost exclusivity concerned mainly supply and distribution agreements. These agreements will not be discussed further in this section. However, it should be noted that they are subject to the applicable EC competition law⁴⁹⁷.

2.4.2.2. Early Entry Agreements

(808) Based on the data submitted by originator companies, for the period 2000 – 2007, 87 "early entry" agreements⁴⁹⁸ were concluded between an originator and a generic company, i.e. agreements which led to the launch of a generic version of the originator company's product at a time where the originator company's product at issue was still benefitting from exclusivity. The 87 agreements were concluded by 16 different originator companies and covered 34 different INNs, of which 29 INNs (85%) were on the E75 list. Eleven of those agreements were entered into by one originator company pursuant to a commitment given to a national competition authority. Companies were requested to provide market information and market data for these agreements, to indicate whether other generic companies were present in the market at the time of launch of the generic and to provide a copy of any such agreements.

⁴⁹⁷ See Annex: EC Competition Law (Annexes to Chapter A).

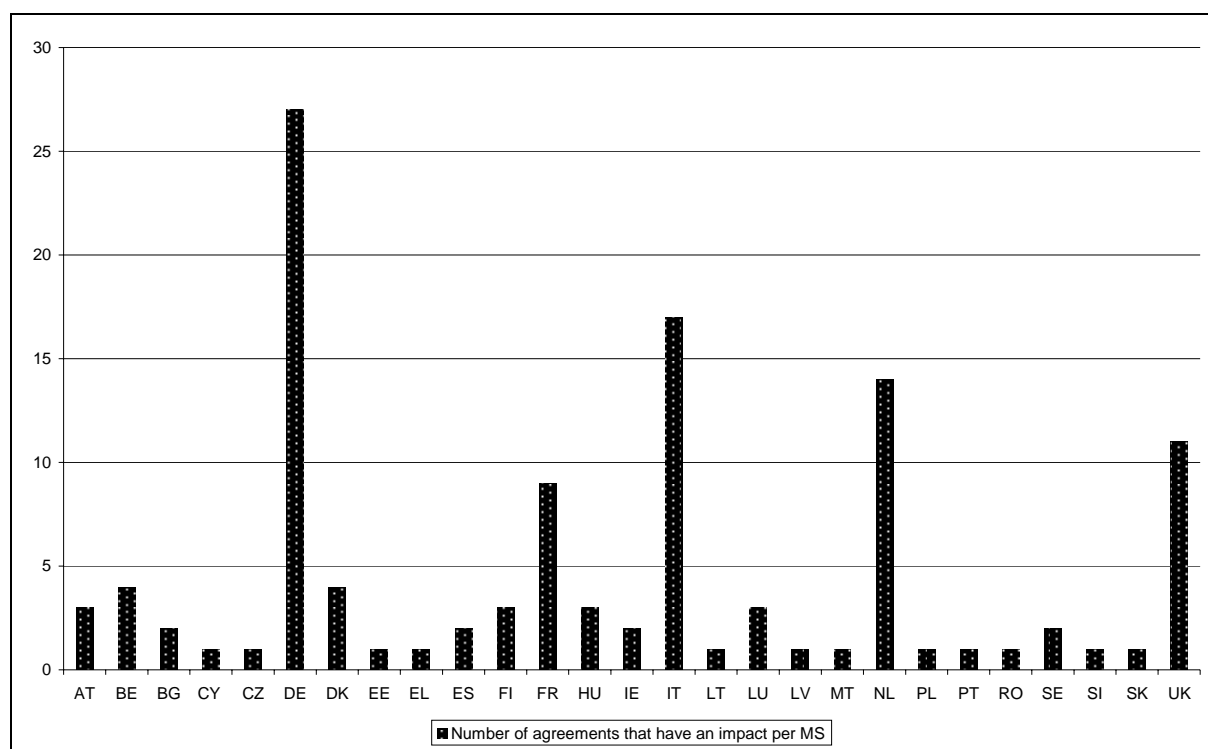
⁴⁹⁸ This section and the contained figures have been revised following updates from the companies and further analysis of the agreements.

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- (809) Early entry agreements are of a particular interest as one would normally expect the originator company to enforce its patent or data exclusivity rights before the date of loss of exclusivity. However, strategic documents of originator companies confirm that early entry agreements are used to anticipate generic competition by providing for a controlled market launch of a generic product. The early presence of a generic product limits the attractiveness of a market for other companies as the first generic product is likely to benefit from certain first-mover advantages. By fixing supply prices, originator companies could influence the sales prices of the generic products. As a consequence, early entry agreements could enable originator companies to preserve its sales volumes and, in particular if they contain certain provisions or restrictions, secure high revenues also beyond the date of loss of exclusivity. Furthermore, early entry agreements may be used to react to the presence of generics on the market, e.g. because it is difficult for the originator companies to enforce its patent rights. To understand the general rationale behind early entry agreements, originator companies were requested to explain their general considerations for entering into agreements with generic companies before the loss of exclusivity.
- (810) The information collected during the sector inquiry shows that originator companies generally take decisions on a case-by-case and a country-by-country basis when entering into early entry agreements with generic companies. Only four of the 87 agreements analysed covered more than one Member State. Figure 123 provides for an overview of the geographical coverage of the agreements by Member State. It indicates that in Germany, UK, Italy and the Netherlands early entry agreements are most frequently used, whereas for some Member States only very few or no early entry agreements were announced.

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Figure 123: The geographical scope of originator-generic agreements before loss of exclusivity by Member State



Source: Pharmaceutical Sector Inquiry

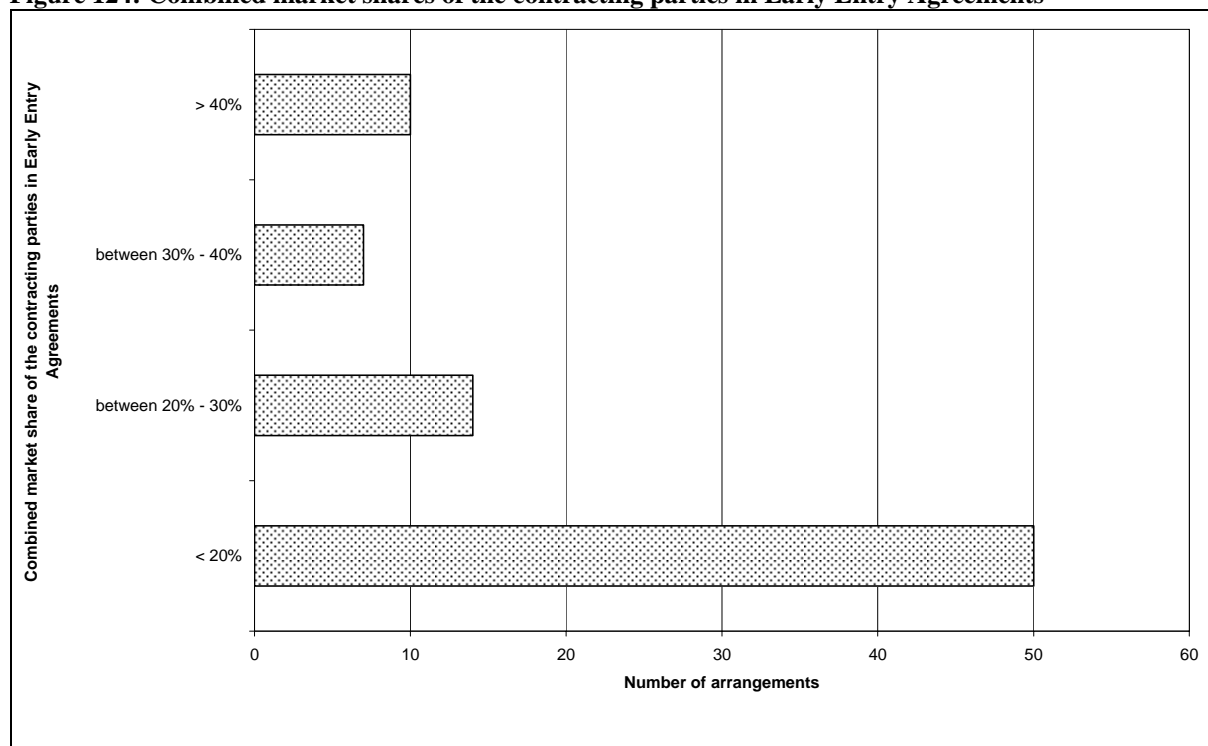
- (811) Originator companies were asked to describe the relevant product market for the products concerned in the agreements. Most companies submitted that the market coincides with the ATC 3 therapeutic classes in the ATC classification system⁴⁹⁹. For some agreements companies described the relevant product market according to ATC 4 therapeutic classes or gave other explanations. Based on their own submissions, originator companies provided estimates of their market shares and the market shares of their main competitors for the last calendar year before the agreement ended or, if it was still effective in 2008, for the year 2007. For some agreements, the companies referred to IMS data for the calculation of the market shares. For the other agreements, the source of information was not indicated by the companies. As the companies used different market definitions and divergent ways to calculate the market shares and the market data does not stem from the same time period, the data presented below does only give a first rough picture of the competitive constraints under which the product is marketed.
- (812) For ten of the 87 agreements the originator companies submitted a combined market share of the contracting parties (including their affiliates) exceeding 40% of the relevant market for the products concerned by the agreement. In seven agreements the combined market share was between 30% and 40%, and in 14 agreements the parties had a combined market share between 20% and 30%. For 50 agreements the originator

⁴⁹⁹ For an explanation of the ATC system see the glossary.

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companies submitted a combined market share below 20% (see Figure 124). For the remaining six agreements no estimates of market shares were available.

Figure 124: Combined market shares of the contracting parties in Early Entry Agreements



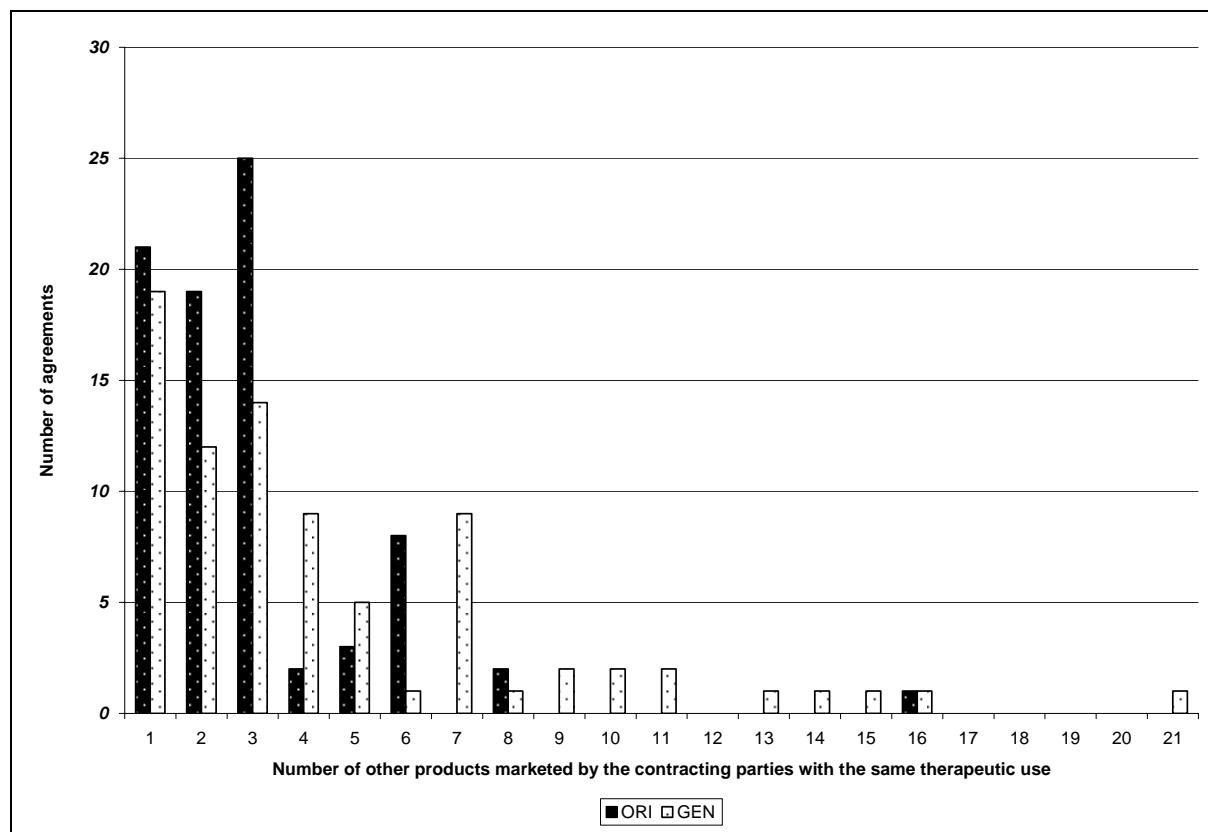
Source: Pharmaceutical Sector Inquiry

- (813) According to the information submitted, only for 15 agreements the originator company considered itself as the player with the highest market share in the respective product market. However, in 29 agreements the parties' combined market share was in excess of the market share of the largest competitor. The market data submitted suggests that originator companies use early entry deals with generic companies more often if they are not the strongest player in the market.
- (814) In 19 of the 87 agreements, the originator company claimed that it was not present at all or submitted a lower market share for itself than for the generic company in the relevant market. A reasonable explanation for this might be that the originator reduces its marketing efforts for a specific product after a generic entry. In particular generic companies with early entry deals are quite successful in gaining market shares. Another reason might be that companies often have more than one product within the same therapeutic use on the market. This is in particular the case for generic companies which tend to have a wider portfolio of products within a particular product market than originator companies.
- (815) The companies were asked to indicate other products with the same therapeutic use which the parties to the agreement had in their portfolio. According to the submissions, the originator company had on average 2.9 products with the same therapeutic use on the relevant market, whereas the generic company had on average 4.7 products on the

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particular market. Figure 125 provides for an overview of the number of products with the same therapeutic use marketed by the originator companies and the generic companies per agreement. It shows that in 80% of the agreements (65 of 81 agreements⁵⁰⁰) the originator company was marketing maximum three products with the same therapeutic use, whereas in 44% of the agreements (36 of 81 agreements) the generic company had more than three products on the market.

Figure 125: Number of other products of the parties with the same therapeutic use as the product concerned in the agreement



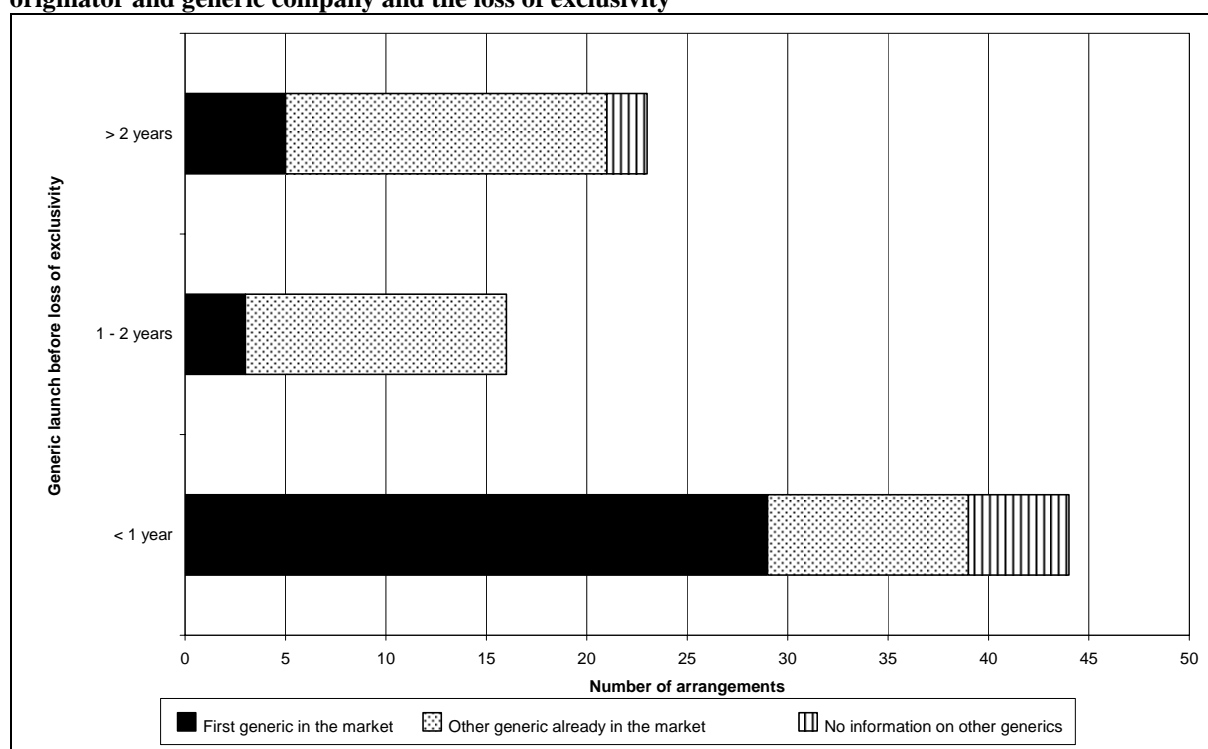
Source: Pharmaceutical Sector Inquiry

(816) On the basis of the information available, the timing of the generic entry was compared with the date of the originator product's loss of exclusivity in the following intervals: 0-1 year, 1-2 years and more than two years. Furthermore, Figure 126 shows whether the generic product launched as a result of the agreement was the first generic product or whether there were already one or more other generic products present in the market.

⁵⁰⁰ For 81 out of the 87 agreements, data was provided regarding other products with the same therapeutic use as the products concerned in the agreement.

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Figure 126: Period of time elapsed between the generic entry further to the agreement between the originator and generic company and the loss of exclusivity



Source: Pharmaceutical Sector Inquiry

(817) Based on the information gathered during the sector inquiry, Figure 126 shows that for 44 of the agreements the generic product brought to the market as a result of the agreement between the originator and the generic company was launched within the last year of the originator company's exclusivity. The duration of those agreements varied from an early entry period of 20 days up to an indefinite period subject to termination by either party giving not less than six month notice. Beside the five agreements for an indefinite period, the average duration of those agreements that were entered into for a fixed time period and that provided for an early entry of a generic product within the last year of the originator company's exclusivity was three years. This shows that parties tend to enter into agreements for a time period that exceeds the date of loss of exclusivity on average more than two years. According to the originator companies and based on the information made available, 29 of the 44 (66%) generic products launched were the first generic product on the market. In ten of the 44 agreements (23%), there was already another generic product on the market. For the remaining five agreements, no information on the presence of other generic products on the market was provided.

(818) Figure 126 further shows that 16 agreements led to the launch of a generic product one to two years prior to the loss of exclusivity. Three of these (19%) had already been launched as the first generic on the market and 13 at the same time or after the launch of another generic product (81%). In 23 agreements, the generic product was launched well in advance of the originator company's loss of exclusivity (more than two years in advance). Of these 23, only five products (22%) were the first generic in the market, whereas a clear majority – 16 (70%) – were launched after another generic was already in the market; for the remaining two agreements, no information on the presence of other generic products was made available. For four agreements, information on the

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period of the time elapsed between the generic entry and the loss of exclusivity was not provided.

- (819) Taking into account the agreements which led to the launch of a generic product less than one year before the originator company's product lost exclusivity, it seems that the originator companies wanted to anticipate generic competition by launching the first generic on the market. The timing of this strategy is well described by the following quote from a strategy document of an originator company:

"[...] we should plan for generics next year but wait before implementation of some activities ie supply agreements, trading deals etc until there is much more evidence that a generic [...] product will be launched."

- (820) On the other hand, for the majority of agreements concluded which led to the launch of a generic product more than one year before the loss of exclusivity, the generic product launched was not the first generic product on the market, which suggests that the originator companies were reacting to the presence on the market of one or more other generic companies.
- (821) As originator companies might use early entry agreements to control the marketing of generic products, the supply prices agreed on between the contracting parties were analysed. 63 of the 87 early entry agreements provided for the supply of a product to the generic company. Only six of the 63 agreements provided for an automatic reduction of the supply price after the loss of exclusivity. For the remainder, the supply price was fixed for the entire agreement or subject to renegotiations after certain time periods or material changes of the economic circumstances.
- (822) In the majority (45 of the 63 agreements), the supply price was a fixed amount specified in the agreement. In 31 of the 45 agreements, the supply price could be reviewed after a specific time period (between three month and two years) or more frequently if certain conditions were met. Usually, the contracting parties linked the review of the supply price to a change of the production costs. However, in 24 agreements the parties explicitly referred to a substantial change of the market circumstances or to the entry of another generic company or the impact of competitor's activities to trigger a review of the supply price.
- (823) In 18 of the 63 agreements the price to be paid to the supplier was fixed as a percentage of the generic company's selling price. The percentage of the selling price ranged from 6.5% of the net sales up to 90% of the actual average price charged to wholesalers. In 13 cases, it was combined with a floor price fixed in the agreement. In one agreement, the contracting parties agreed to share the net proceeds in equal parts.
- (824) The analysis suggests that originator companies might also use early entry deals to generate substantial profits on their product portfolio as supply prices are often not merely based on production costs, but rather on the market circumstances and the competitive constraints on the downstream markets. The parties generally entered into supply agreements for a single delivery of products or for a fixed time period between one month and seven years. However, five supply agreements were concluded for an indefinite time period. The supply agreements that were entered into for a fixed time period had an average duration of 3.5 years.

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- (825) As the first generic product on the market can benefit from certain first-mover advantages and, thus, is likely to capture the largest market share of the originator company's product, early entry agreements that also cover a period after loss of exclusivity might enable originator companies to extend a certain control over the sales for a large part of the market beyond loss of exclusivity. The impact on prices can be described with the following quote from a strategy document of an originator company:

"Launch [product name] via an early entry agreement with main players in the distribution channel, thus preventing disproportionate discounting of non-original [API name] containing products."

- (826) The 87 agreements concluded between originator and generic companies which led to an early entry of a generic version were also analysed with respect to the question whether they provide for any kind of exclusive relationship between the contracting parties, i.e. whether the agreement provided for an exclusive supply obligation, exclusive sourcing, exclusive licensing or any other kind of exclusivity, and/or a non-compete obligation.⁵⁰¹ Based on the submissions of the companies and the screening of the sample, the majority (64 agreements) contained a certain type or a combination of exclusive rights for either one or both partners. If one excludes the eleven agreements that were entered into by one originator company pursuant to a commitment given to a national competition authority and that contained no exclusivity or non-compete clause, one could say that 84% of the early entry agreements provided for a certain kind of exclusive relationship between the contracting parties.
- (827) Many early entry agreements contained restrictions on the side of the generic companies. Out of the 87 agreements, 29 agreements contained a non-compete clause and 17 fixed directly or indirectly annual minimum amounts that had to be purchased by the generic company. 45 of the 87 agreements contained a provision that obliged the generic company to purchase all of its requirements for the product concerned by the agreement from the originator company or a designated supplier (exclusive sourcing). Only 31 of the 87 agreements contained a clause that restricted the originator company's freedom to supply or license (i.e. exclusive or semi-exclusive licensing) the product to third parties.
- (828) The average duration of the agreements that contained an exclusivity and/or non-compete clause was 3.1 years. To enter into an exclusive relationship for a period in time that exceeds the products' loss of exclusivity may be reasonably explained by the originator company's interest to secure its sales or revenues in a longer term.
- (829) The agreements were also analysed whether they contain a non-challenge obligation on either one or both parties. Such a clause should be understood as any restriction on the parties' ability to challenge the validity of intellectual property rights which are relevant to the specific agreement. Only four of the 87 agreements (5%) analysed contained an explicit clause that the originator company is entitled to terminate the

⁵⁰¹ For an explanation of these clauses see para. (804).

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agreement if the generic company challenges the validity of the intellectual property rights that were concerned by the agreement. One of those four agreements had a duration of five years and provided for an entry of a generic version 23 months before the loss of exclusivity of the originator company's product. The other three agreements were licence agreements that each provided for an early entry of a generic product at least twelve years before the date of loss of exclusivity. One of those licence agreements had a duration of seven years, the other two agreements were supposed to be in force until the loss of exclusivity of the originator company's product.

- (830) The low number of non-challenge clauses in the sample suggests that generic companies generally prefer to pay royalties to originator companies and have limited incentives to challenge the validity of intellectual property rights after entering into early entry agreements. This is also supported by the fact that many agreements contain an explicit clause that obliges both the originator and generic companies to cooperate in the enforcement of the intellectual property rights. After entering into an early entry agreement, the generic companies participate in the exclusivity of the originator company's products. Challenging the intellectual property rights would also mean to possibly clear the way for other generic entries which would not seem to be in the interest of the originator company and/or the generic company.
- (831) Further, the 87 agreements were analysed whether they contain any restrictions on the parties' ability to carry out research and development. Four agreements were identified that contained an explicit clause that restricted the generic company's ability to develop new indications or dosages of the product concerned by the agreement or to develop new products containing the same active ingredient. Various agreements that also provided for a transfer of a market authorisation contained a clause that allowed the use of the market authorisation solely for the sale of the product in the specific territory, or a clause stating that the generic company needs the written consent of the originator company for any variations to the market authorisation transferred.

General Considerations of Originator Companies when Entering into Agreements with Generic Companies before the Loss of Exclusivity

- (832) Originator companies were asked to explain their general considerations for entering into agreements with generic companies regarding the sale of a generic product when the loss of exclusivity was not imminent, i.e. did not occur until at least one year after the launch of the generic product concerned. In particular, originator companies were asked to indicate the five most important considerations and to explain how this decision was taken.
- (833) Most of the originator companies that responded stated in their submission that they applied no general policy guidelines when entering into such agreements with generic companies, thereby taking a decision on a case-by-case basis. However, based on their replies, it is possible to identify some key factors which originator companies consider when entering into such agreements.
- (834) The rationale for concluding a supply agreement with a generic company before the loss of exclusivity is summarised in the following quote:

"An early entry of a generic product can almost never be excluded. [...] Entry of generic product means a rapid loss of market shares by the originator in volume."

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- (835) The most important consideration for originator companies seems to be the opportunity to maintain the revenues from the patent protected product for as long and as broad as possible. In fact, the launch of generic products may increase the overall market for the type of product in question and can contribute to a market expansion. Furthermore, the generic product that is launched first in the market can benefit from certain first-mover advantages. The opportunity to leverage the company's supply capacity and thus create additional revenue is likewise taken into account.

"The objective in entering into other arrangements with generic companies is to maximise the income from the products even when they are not sold by [our company] because they do not fit within the therapeutic franchises."

- (836) The above-mentioned statements and considerations appear surprising in a situation in which an originator company holds market exclusivity for a specific product. However, there are situations in which the originator companies have an incentive to enter into such early entry agreements, e.g. where the originator company becomes aware of the (imminent) market entry of another generic company and considers itself not able to enforce its patent rights.⁵⁰²
- (837) Another factor that originator companies find especially relevant when deciding to enter into such agreements is the importance of the product in question and its market size, including its price and sales potential. In this context, particular attention is paid to the company's commercial interests in the product, i.e. whether the company is able and/or intends to develop its "own" generic product in the near future. Originator companies also take into account the territory in which the agreement will apply and its importance in terms of sales.
- (838) Some originator companies stated that they carefully scrutinise the generic company before deciding whether or not to conclude an agreement with it. In this respect, they indicated that they take into account the market position of the generic company and its credit ranking, but also that they might perform a due diligence on the generic company. Some originator companies indicated that they conclude agreements with generic partners who have relevant expertise and are able to capture significant market shares in the market concerned. By using the generic companies' distribution systems and customer contacts, originator companies can maximise their profits.

"In view of the lengthy regulatory procedures, there's a need to start a partnership well before a possible early entry by a third party."

- (839) As far as the decision-making process is concerned, originator companies stated in their submissions that they decide to enter into such agreements on an *ad hoc* basis and on a country-by-country basis, taking into account the abovementioned considerations, without the need for any formal proceedings being in place. Some companies indicated

⁵⁰² During the sector inquiry it was also noted that originator companies concluded more than one early entry agreement relating to the same product and the same geographical market with more than one generic company.

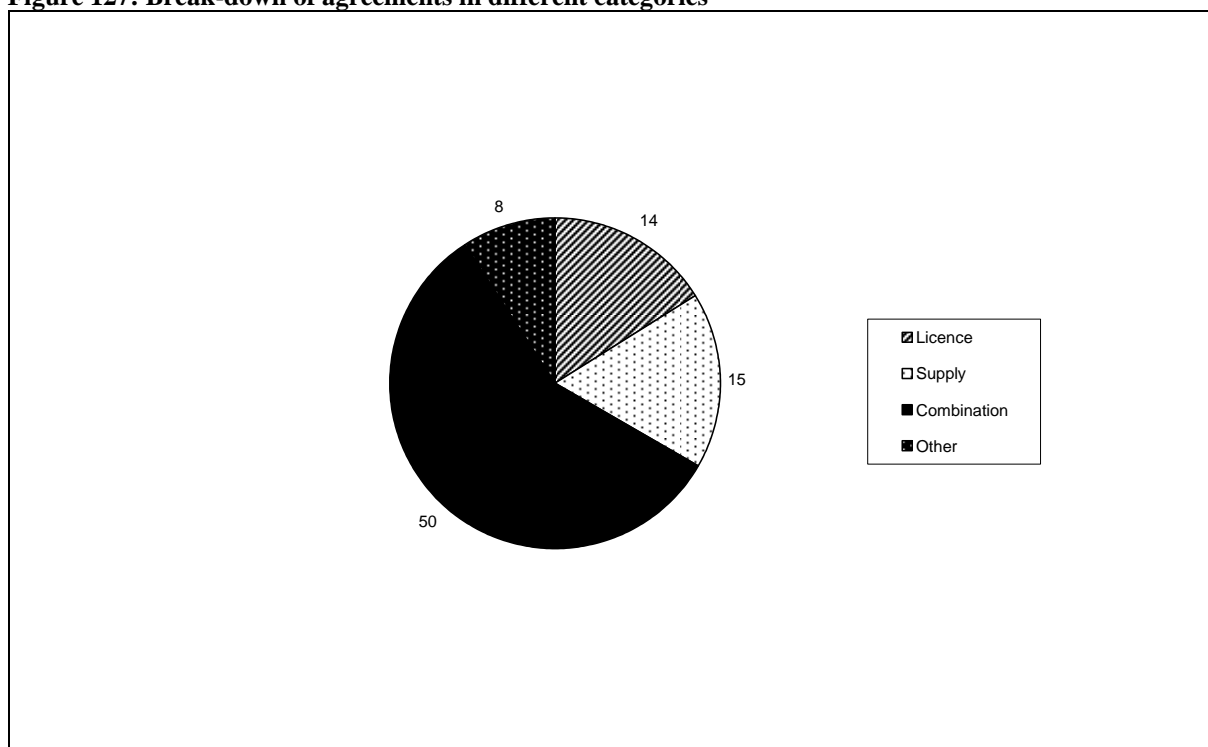
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that, in general, local/sub-regional management is responsible for building a business case, with the help of a number of regional experts (e.g. on health economics, legal issues, patents, regulatory and medical affairs).

Description of the Main Categories of Such Agreements

- (840) The early entry agreements were categorized on the basis of the companies' submissions. Taking all of the 87 agreements into account, fifteen (17%) concerned only supply and fourteen (16%) were licence agreements. The sample did not contain any (pure) distribution agreements as in the early entry agreements analysed, distribution elements were always combined with the supply of the product or a licence to manufacture and/or import the product. Eight agreements (9%) were notified as other agreements. Those agreements mainly provided for the transfer of marketing authorisation(s) or allowed an early generic entry by a warranty or covenant not to intervene with the launch of a generic product before the date of loss of exclusivity. The remaining 50 agreements (57%) could not be allocated into one single category as they included a combination of licence, supply, distribution and other agreements (see Figure 127). Hereinafter, the main categories of agreements, including those that contained a combination of different types, are explained in more detail.

Figure 127: Break-down of agreements in different categories



Source: Pharmaceutical Sector Inquiry

Distribution Agreements

- (841) Under the distribution agreements, the distributor generally obtained the right to distribute and market the generic version of the product concerned during the term of the agreement in the territory concerned.

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- (842) A distribution agreement was usually combined with a supply agreement or a licence agreement. In most cases, the generic company was supplied by the originator company or another undertaking designated by the originator company. Apart from the 11 agreements entered into by one originator company pursuant to a commitment given to a national competition authority, only four of the 87 agreements that provided for the distribution of a generic product contained a licence to the generic company to manufacture and/or import the product.

Supply Agreements

- (843) In 63 of the 87 agreements, the originator company agreed to supply to the generic company the product covered by the agreement in order to re-sell it in the territory concerned. The majority of the agreements were a combination of supply and distribution agreements. In some agreements the generic company was the holder of a marketing authorisation for a medicinal product although the product was still patent protected. In these cases only the originator company had the capability and capacity to manufacture the product and the parties agreed solely on the supply of the product.
- (844) As already stated above, in more than two thirds of the supply agreements (45 agreements) the generic company committed itself to purchase exclusively all its needs of the product(s) concerned from the originator company (exclusive sourcing) at a price determined within the agreement. The duration of the agreements containing an exclusive sourcing obligation varied between 3.3 month and seven years with an average of 3.7 years.
- (845) In most cases, the originator company reserved itself the right to sell the products freely to other third parties and/or market them itself in the territory concerned. However, in seven agreements, the originator company agreed not to appoint another distributor or to supply the product or API to other third parties and thereby making the generic company a sole distributor in the territory concerned. The agreements containing an exclusive supply obligation were concluded for a fixed period between 3.3 month and four years; the average duration of those agreements was 2.4 years. Two of the seven agreements provided for a tacit renewal.
- (846) In several supply agreements, the originator company also transferred its own or a duplex of its marketing authorisation(s) for the product(s) concerned or the product registration(s) to the generic company. In consideration for this transfer, the generic company usually paid a lump sum to the originator company. Some agreements contained an obligation on the generic company to transfer the market authorisation back to the originator company after termination of the agreement or after the generic company had obtained its own market authorisation. If the generic company had to apply for its own market authorisation, the originator company usually provided the generic company with the necessary documentation.
- (847) Almost half of the supply and distribution agreements (29 agreements) included a non-compete obligation for the generic company. Thus, the originator company was entitled to terminate the agreement if the generic company were to market an alternative product (containing the same active substance or any salt of it) or if the generic company were to purchase alternative competing products from another source in the territory concerned during the term of the agreement.

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- (848) A number of supply and distribution agreements (25 agreements) prohibited active sales outside the territory concerned. Accordingly, the generic company was not allowed to advertise or actively look for customers outside the territory covered by the agreement. One agreement also prohibited the sale to third parties within the territory for re-sale outside the territory concerned, and two agreements contained an obligation to communicate enquiries and orders from third parties located outside of the territory concerned to the originator company.
- (849) More common than the prohibition of active sales outside the territory concerned were provisions that restricted the use of the marketing authorisation or the underlying documentation. A large number of agreements that contained a transfer of a marketing authorisation contained at the same time a clause that limited the use of the marketing authorisation or the underlying documentation for the purpose of the specific agreement or to the sale and distribution solely in the territory concerned by the agreement.
- (850) In some agreements (17 agreements) the contracting parties included an obligation to order minimum quantities of the product concerned by the agreement or fixed minimum quantities of sales to be achieved by the generic company. In some supply and distribution agreements the originator company also assisted the generic company (e.g. by training the generic company's sales force) and/or contributed financially to the promotional information campaigns, at least at the beginning of the term of the agreement.

Licence Agreements

- (851) In the licence agreements, the originator company granted to the generic company a licence to manufacture, market, promote, distribute and/or sell a generic version of the products covered by the agreement in a certain territory. Some licence agreements contained a provision that prohibited any sublicensing or any other assignation or transfer of rights to another party without the written consent of the other party. The prohibition on the assignation or transfer of the rights under the agreement sometimes even included affiliates of the contracting parties.
- (852) Some agreements provided for either exclusive (six agreements) or semi- or co-exclusive licences (eleven agreements). However, most of the licence agreements contained a non-exclusive licence, i.e. the originator reserved itself the right to freely enter into similar relationships with other third parties.
- (853) Usually, the licence agreements were royalty bearing. However, the eleven agreements entered into by one originator company pursuant a commitment given to a national competition authority provided for a licence free of charge. Most of the licence agreements were concluded for a fixed time period between 1 month and more than fourteen years. The agreements usually do not provide for a tacit renewal, however, some licence agreements were entered into for an indefinite time period.

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Other Types of Agreements

- (854) A number of agreements which were not categorised as licence, supply or distribution agreements between originator and generic companies concerned the sale and transfer of marketing authorisation of the product(s) at issue from the originator company to the generic company in order for the latter company to be able to market the product(s) in the territory concerned. Some transfers were provisional and valid for a certain period of time, after which the generic company would transfer the marketing authorisation back to the originator company. In return, the generic company paid a lump sum agreed within the agreement to the originator company. These agreements were not combined with any supply or distribution agreements.
- (855) In six agreements the originator company granted the generic company an early entry right by a warranty or a covenant not to interfere with the launch of a generic product. In particular, the generic company was entitled to import, manufacture, market and sell its own product(s) in the territory covered by the agreement a few months before the originator company's loss of exclusivity. As compensation for this early entry right, the generic company paid a lump sum to the originator company. Those warranties or covenants are usually entered into on an exclusive basis.

Summary

The inquiry established that between 2000 and June 2008, more than 200 settlement agreements were concluded between originator and generic companies. They covered some 49 medicines, of which 31 medicines (i.e. 63%) were best-selling medicines that lost exclusivity between 2000 and 2007. The vast majority of the settlements was reached in the context of litigation cases, the remaining settlements were concluded in out of court disputes and/or in the framework of opposition proceedings.

In approximately half of the settlements in question the generic company's ability to market its medicine was restricted. A significant proportion of these settlements contained – in addition to the restriction – a value transfer from the originator company to the generic company, either in the form of a direct payment or in the form of a licence, distribution agreement or a "side-deal". Direct payments occurred in more than 20 settlement agreements and the total amount of these direct payments from originator companies to generic companies exceeded € 200 million. The latter type of agreement has attracted antitrust scrutiny in the USA.

Between 2000 and 2007, originator companies and generic companies entered into a large number of other agreements concerning the sale/distribution of generic medicines. One third of these agreements were concluded with generic companies before the originator company's product lost exclusivity ("early entry agreements"). One cannot exclude that these agreements could be used to anticipate generic competition or to react to the presence of a generic company. The majority of the early entry agreements contained clauses that provided for a certain type of exclusive relationship between the contracting parties.

Half of the early entry agreements were concluded in the last year before loss of exclusivity. The duration of these agreements exceeded the date of loss of exclusivity on average by more than two years. For most of those agreements, the generic products were the first generic products on the market and, thus, were likely to benefit from certain first mover advantages.

2.5. Other Practices Affecting Generic Entry

- (856) This chapter examines the strategies employed and actions brought by originator companies before regulatory bodies other than patent offices (such as those dealing with marketing authorisation, pricing and reimbursement) and vis-à-vis other stakeholders (such as doctors and pharmacists), including distributors and API producers. These originator companies act at different levels, before different authorities and using different means. The forms which this takes are sometimes informal (for example, informal contacts, lobbying, offering training, etc.), but companies also employ formal means such as litigation. In this chapter, their interventions are classified into, first, pre-litigation contacts/disputes and, second, litigation.
- (857) The chapter is divided into five sections. Section C.2.5.1. describes interventions brought by originator companies before marketing authorisation bodies. Section C.2.5.2. deals with actions before pricing and reimbursement authorities. Section C.2.5.3. outlines marketing and promotion strategies employed by originator companies and contacts with doctors and pharmacists. Section C.2.5.4. focuses on action vis-à-vis wholesalers/distributors and changes in the distribution chain. Finally, Section C.2.5.5. discusses arrangements between originator companies and API producers.
- (858) It should be stressed that Chapter C.2.5. deals with company conduct rather than any obstacles perceived by the regulatory framework itself. Any alleged shortcomings in the regulatory framework are described in Chapter D, in particular Sections D.2. and D.3.
- (859) It is not the purpose of this sector inquiry to provide guidance as to the compatibility of certain practices with EC competition law. The Commission will further investigate whether individual company behaviour may have fallen foul of the competition rules.

2.5.1. Intervention before Marketing Authorisation Bodies

- (860) Before they can place medicinal products on the EU market, generic companies must first obtain marketing authorisation.⁵⁰³ Although the conditions of quality, safety and efficacy for obtaining such authorisation are the same for generic and originator products, producers of generic medicines can file an "abridged application" (for details see Chapter B.2.2.). This means that the generic company must establish that the generic product is composed of the same substances – in qualitative and quantitative terms – and has the same pharmaceutical form as the originator product which has already been granted marketing authorisation, and that the generic product is shown to be bioequivalent to the reference product. In return, the generic company is exempted from the requirement to prove safety and efficacy through pre-clinical tests and clinical

⁵⁰³ Chapter B.2.2. provides an overview on the legal framework governing marketing authorisation for pharmaceutical products in the EU and of the procedures and bodies involved.

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trials and the competent authority relies on the tests and trials for the reference product (submitted by the manufacturer of the original product when seeking marketing authorisation), if the period of data exclusivity protecting the original product has expired. This is a significant advantage as the tests and trials are the main cost factor in the R&D process.

- (861) Originator companies intervene in different ways, at various stages of the generic application procedure and for various purposes before different authorities. The subsections below provide further details of the reasoning behind the interventions by originator companies, whether pre-litigation contacts and disputes or litigation.

2.5.1.1. Pre-Litigation Contacts Related to Marketing Authorisation

- (862) A number of originator companies contact marketing authorisation bodies to draw attention to their concerns about applications by generic producers.⁵⁰⁴ An adviser to an originator company described such approaches to marketing authorisation bodies as follows:

"Certain Health Authorities will provide [the originator company with] information about pending applications [of generic companies] for marketing authorisation: some formally [...], some informally. [...] Establishing a good rapport is essential – you are on their side! [...] separate functions of persuading/challenging if this helps."

- (863) A widespread practice by certain originator companies is to write to marketing authorisation bodies to express concerns about applications for marketing authorisation submitted by generic companies.⁵⁰⁵ The sector inquiry revealed that the most common allegations by these originator companies are, *inter alia*, that generic producers infringe patent rights, that the generic medicines are not equivalent to the original medicines or that the generic medicines pose certain health risks for patients. In their letters to marketing authorisation agencies, these originator companies sometimes also directly request that the marketing authorisation body does not grant authorisation or does not even start examination of a generic application before the loss of exclusivity (see below for a discussion of the legitimacy of such demands). Community rules on the marketing authorisation of generics do not foresee a verification of the patent status of the originator company; on the other hand, in the period 2000 – 2007 the applicable rules on data exclusivity did not allow submission of a generic application until data exclusivity had expired.⁵⁰⁶

⁵⁰⁴ Originator companies sometimes also contact consultants or scientific experts who advise marketing authorisation bodies on scientific topics.

⁵⁰⁵ It was submitted during the public consultation that interventions are also taking place concerning biosimilars.

⁵⁰⁶ For details see Chapter B.2.2.

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- (864) Moreover, the evidence gathered reveals that interventions before marketing authorisation bodies may, in certain instances, be a deliberate strategy pursued by some originator companies to delay generic entry. Actions at marketing authorisation level appear to be a standard instrument in the strategic tool-box of some originator companies, sometimes known as "generics defence strategies", "late life cycle management" or "brand protection strategies".
- (865) The following quotes illustrate originator companies' intentions to intervene systematically at marketing authorisation level:

"Actions aimed at interacting with the registration procedures of generics attempting to delay entry [...]."

"Examine potential for regulatory challenges on generic registration processes."

"Address the clinical risk of switching from [originator product] to a generic [...] rewrite the document into a white paper [...] which can be used towards Health Authorities."

- (866) The sector inquiry revealed that, for the sample of 219 INNs under assessment, a significant number of interventions is taking place every year, in particular in relation to high-turnover products.
- (867) As regards the frequency of pre-litigation interventions with marketing authorisation bodies, the originator companies reported 118 instances in which they intervened, concerning 28 INNs. Replying to the same question, the generic companies reported that they were aware of 83 instances in which a number of originator companies intervened, concerning 20 INNs. The overlap between these two universes is rather limited (five INNs). Adding the two universes leads to 195 interventions on 43 different INNs. It is noteworthy that one intervention can cover several generic versions and/or several dosages. Marketing authorisation bodies confirmed such interventions without being able to provide quantitative data as they do not keep systematic records of these interventions. Therefore, the total number of interventions is probably even higher than presented here.
- (868) Out of the 43 INNs subject to interventions, 23 INNs are part of the E75 and/or T50 list which consist of those INNs that face loss of exclusivity and/or top-selling products. Moreover, 40% of the pre-litigation interventions concerned only four INNs (see Table 23).
- (869) As Table 23 indicates, four INNs out of the 43 INNs where some originator companies intervened before the marketing authorisation bodies during a generic application are part of the top 10 INNs on which there were originator-generic pre-litigation contacts (for details see Chapter C.2.2.). In addition, 14 INNs out of the same 43 INNs are part of the top 20 most litigated INNs in the EU 27 (for details see Chapter C.2.2.).

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Table 23: Pre-litigation contacts and disputes per INN towards marketing authorisation bodies ⁵⁰⁷

INN	Number of contacts	Member States	Top 10 INNs for originator/generic company contacts ⁵⁰⁸	Top 20 most litigated INNs between originator and generic companies ⁵⁰⁹
INN 1	24	DK (1), NL (23)		X
INN 2	21	AT (4), BE (1), CZ (2), ES (1), FI (1), FR (1), HU (1), IE (1), IT (1), NL (1), PL (1), PT (3), SE (1), SK (1), UK (1)		
INN 3	17	AT (1), BE (1), DE (1), DK (1), EL (1), ES (3), FI (1), FR (1), LU (1), NL (1), IE (1), IT (1), PT (1), SE (1), UK (1)		X
INN 4	15	DE (4), DK (1), ES (1), FR (1), NL (3), PT (1), SE (2), SI (1), SK (1)	X	X
39 other INNs	>100	AT (1), BE (2), CY (1), CZ (7), DE (5), DK (3), EL (2), ES (26), FI (3), FR (7), HU (3), IE (4), IT (6), LT (2), LU (1), LV (1), NL (19), PL (6), PT (13), SE (2), SI (3), SK (4), UK (8)	X ⁵¹⁰	X ⁵¹¹

Source: Pharmaceutical Sector Inquiry

(870) The Member States where marketing authorisation bodies are often approached by a number of originator companies are: the Netherlands (47 occurrences), Spain (34)⁵¹² and Portugal (18).⁵¹³

⁵⁰⁷ Reliable data from marketing authorisation bodies were not available, as many marketing authorisation bodies have no systematic records of all contacts and disputes, partly because of their informal nature.

⁵⁰⁸ For further details see Chapter C.2.2.

⁵⁰⁹ Idem.

⁵¹⁰ Out of the 39 "other INNs", three INNs are part of the top ten INNs of originator – generic contacts.

⁵¹¹ Out of the 39 "other INNs", ten are in part of the top 20 most litigated INNs between an originator and a generic company.

⁵¹² During the public consultation, a Spanish association representing originator companies stated that the high number of contacts in Spain "must be read in the context of the difficulties faced by originator companies to obtain a preliminary injunction before the generic is ready for launch".

⁵¹³ Sometimes more than one intervention on an INN is brought in one country, i.e. against products of several generic companies. This can be explained by an originator company intervening in respect of several versions of a generic product or several dosages of the same product, e.g. 10 mg, 20 mg and 50 mg.

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Patent Linkage

- (871) As outlined in Chapter B.2.2., patent linkage is the practice of linking regulatory approval for a generic medicinal product (in this case, the granting of marketing authorisation) to the patent status of a substance. Certain originator companies allege that by granting marketing authorisation, the authorities willingly collude in the alleged infringement. These originator companies therefore argue that no marketing authorisation should be granted until the allegation of patent infringement has been settled. Occasionally, actions are accompanied by a threat to sue the marketing authorisation body for damages if marketing authorisation is granted.
- (872) Under EU law, linking the granting of marketing authorisation for a product to the patent status of an originator company's reference product is unlawful.⁵¹⁴ The task of marketing authorisation bodies is to verify whether a medicinal product is safe, effective and of good quality. Their main function is to ensure that the pharmaceutical products reaching the market are not harmful to public health. Other factors, such as the patent status of the product, should therefore not be taken into account when assessing the risk/benefit balance of a medicine.
- (873) This notwithstanding, a number of originator companies continue to raise arguments based on patent linkage with marketing authorisation bodies in most EU Member States. In some cases, the marketing authorisation body or the legal framework itself facilitate patent linkage. Table 24 provides a brief overview of patent linkage issues reported in the EU at marketing authorisation level during the sector inquiry.

⁵¹⁴ Article 81 of Regulation (EC) 726/2004 and Article 126 of Directive (EC) 2001/83 provide that an authorisation to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in the Regulation and the Directive. Considering that patent status is not included in the grounds set out in the Regulation and the Directive, it cannot be used as an argument to refuse, suspend or revoke a marketing authorisation. The Commission may launch infringement proceedings against any Member State which infringes the Directive.

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Table 24: Overview of patent linkage at marketing authorisation level in Europe in mid-2008

Member State	Level concerned	Alleged patent linkage issues
Hungary	MA legislation and implementation by agency	Article 7(9) of Decree 52/2005 of the Ministry of Health requires generic companies to submit a "patent declaration". This document contains a declaration that the company is not harming any patent right by applying for marketing authorisation for its product and will not market the product until the patent rights have expired.
Italy	MA legislation and implementation by agency, court level	Generic companies report that the marketing authorisation agency requests certification by the applicant that the application for marketing authorisation for a generic product does not infringe any patents. However, according to the information of the Commission services, the prepared Italian draft legislation was not adopted following a letter by the Commission services. Certain originator companies also take legal action against the MA agency and against producers of generics.
Portugal	Litigation against marketing authorisation decisions	Some originator companies challenge marketing authorisations granted to generic companies in court (see also case study below).
Slovak Republic	MA legislation and implementation by agency	Section 22(8) of Act No 140/1998 states that, where the subject of the decision is not the original medicinal product, the decision on a marketing authorisation for a medicinal product will enter into force the day after the patent protection of the medicinal product or active substance contained in it expires. However, according to the information of the Commission services, the provision mentioned was amended following a letter from the Commission.

Source: Pharmaceutical Sector Inquiry

Claims Related to the Safety or Effectiveness of Generic Medicines

(874) Originator companies often claim vis-à-vis other stakeholders that generic medicines are less safe, less effective or otherwise inferior. Nine originator companies reported the arguments they use when expressing concern about a generic product.⁵¹⁵

⁵¹⁵ This overview concerns claims made vis-à-vis regulatory bodies and other stakeholders. Out of the 43 originator companies that were asked, nine reported that they had expressed concerns about a generic product, 21 said that they had never expressed concerns and 13 replied “not applicable”.

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Table 25: Arguments used by originator companies when expressing concern about a generic product

Less safe	Less effective	Inferior	Subject to counterfeit
75%	30%	39%	1.4%

Source: Pharmaceutical Sector Inquiry

- (875) The nine companies which confirmed that they had expressed concerns about generic products used the argument that the generic product was less safe in 75% of the 211 cases reported. In 30%, the originator company described the generic product as less effective, in 39% the originator company argued that the generic product was inferior and in 1.4% that it was subject to counterfeit. Note that a single action may fall under one or more categories (less safe, less effective, inferior or subject to counterfeit) as companies sometimes express several concerns about the same generic medicine.
- (876) Note that the concerns expressed by the originator companies concentrate on a relatively limited number of INNs, around 10% of the INNs investigated in the sector inquiry (24 of the 219 INNs, of which 14 are in the E75 group). More strikingly, out of the 211 cases reported, 169 were about just six INNs.
- (877) Whereas the main European federation of originator companies submitted during the public consultation that claims regarding safety aspects are normally made in all Member States where a generic company has filed an application, the sector inquiry finds that interventions are taking place selectively in certain countries and not in all Member States. This is indirectly confirmed by a Spanish association of originator companies which stated that a higher number of contacts in Spain "must be read in the context of the difficulties faced by originator companies to obtain a preliminary injunction before the generic is ready for launch".

Data Exclusivity

- (878) Under pharmaceutical legislation, holders of original marketing authorisation benefit from data exclusivity for the pre-clinical and clinical data they have to submit to the national MA body or to the EMEA. As pointed out in Chapter B.2.2., during the period investigated the marketing authorisation holder benefits from six or ten years of data exclusivity.⁵¹⁶ Such data exclusivity is important as it prevents generic companies from relying on the data of an originator reference product during a certain period of time to obtain marketing authorisation. Once the data exclusivity period ended, a generic company can apply for marketing authorisation via the abridged application procedure. Chapter B.2.2. outlines the concept of data exclusivity in more detail.
- (879) Disputes regarding data exclusivity ensued between an originator company and a marketing authorisation body were reported for 26 of the 28 data exclusivity

⁵¹⁶ Applications for marketing authorisation of reference medical products filed after November 2005 (centralised procedure) or 30 October 2005 (national procedures) benefit from the following protection periods: eight years' data exclusivity plus two additional years for marketing exclusivity, which can be extended by one year for new indications. However, this provision is of no practical relevance for the period under investigation.

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interventions reported in the sector inquiry. The remaining two were against a generic company without a parallel action against the marketing authorisation body.

- (880) When a dispute on data exclusivity occurs, the originator company often claims, in addition to patent-related issues, that the generic marketing authorisation refers to the originator company's data which are still covered by data exclusivity. Another claim often made is that the wrong reference product has been chosen and that the correct reference product is still protected under data exclusivity. Typically, large originator companies make such claims. Moreover, most companies only intervene on one important INN in their portfolio.

Table 26: Summary of main data exclusivity contacts and disputes with a marketing authorisation body

Originator company	INN	Country	Disputes	Top 10 INNs for originator/generic company contacts ⁵¹⁷
Originator company 1	INN 1	AT (1), BE (1), CZ (1), DE (1), ES (1), FI(1), FR (1), HU (1), IE (1), PL (1), PT (1), SE (1) , SK (1), UK (1)	14	
Originator company 2	INN 2	BG (1), PL (3), SI (1)	5	
Originator company 3	INN 3	CZ (2), SK (1)	3	
Originator company 4	INN 4	PT (2)	2	X
Other	2 other INNs	LV (1), PL (1)	2	

Source: Pharmaceutical Sector Inquiry

- (881) Generally, originator companies bring separate actions in the same country against each generic version which uses the data on the originator product. Therefore, for most INNs the number of disputes is higher than the number of countries concerned. As Table 26 indicates, six INNs gave rise to disputes, of which two were on the E75 list and one was in the top ten INNs on which originator companies have contacts with generic companies. Interestingly, the vast majority of interventions by a number of originator companies were unsuccessful. Out of the 28 disputes reported, only five are still ongoing. In the other 23 cases, the efforts of these originator company failed, i.e. the generic company was allowed to use the data on the reference product for its abridged marketing authorisation application.

⁵¹⁷ For further details see Chapter C.2.2.

2.5.1.2. Litigation Related to Marketing Authorisation

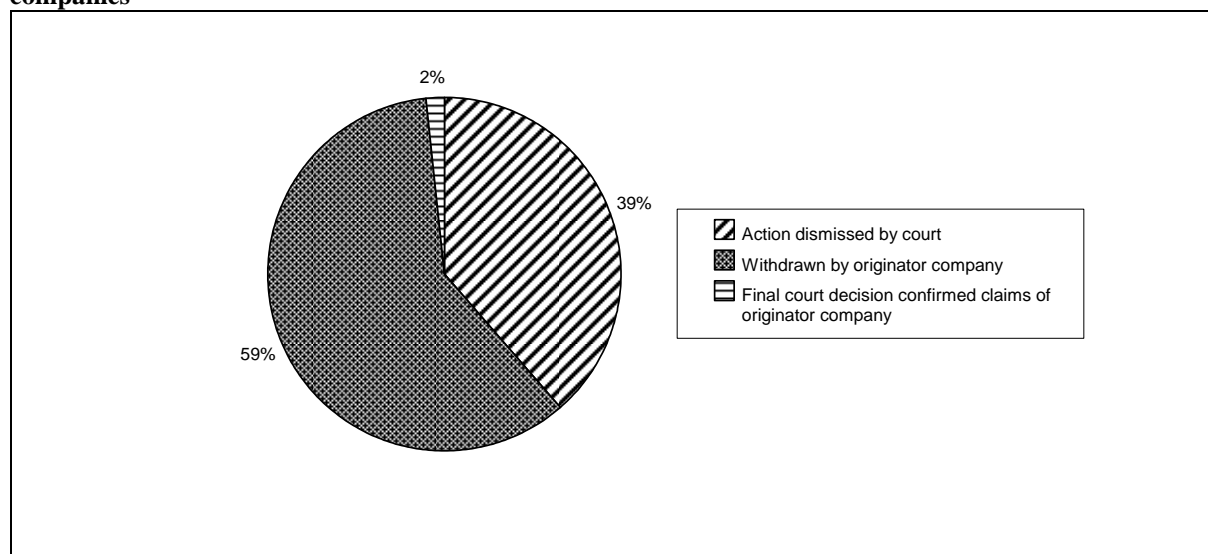
- (882) Originator companies also take legal action against the decisions of marketing authorisation bodies and against generic producers regarding their applications for marketing authorisations. For instance, interlocutory injunctions are used by some originator companies as a means to prevent presumed infringements of their patents. Such injunctions may be applied for before, or in conjunction with, the main infringement proceedings. Such actions can be brought before, but also after the decision by a marketing authorisation agency. In these litigation proceedings originator companies use arguments similar to those in their pre-litigation contacts, such as alleged patent infringements or alleged qualitative shortcomings of a generic medicine.
- (883) Based on the information gathered during the sector inquiry concerning only the INNs assessed, there are currently many pending litigation cases in which originator companies are challenging decisions by marketing authorisation bodies on the marketing authorisations of generic companies. For instance, in Portugal alone, more than 50 court cases initiated by originator companies against marketing authorisations concerning the products of generic companies are pending against the agency in charge of marketing authorisation.
- (884) Based on the data reported⁵¹⁸, the sector inquiry identified 137 litigation cases initiated by originator companies against marketing authorisation bodies alleging patent infringement and safety issues concerning marketing authorisations of generic companies. This excludes litigation concerning data exclusivity which is dealt with in the next section.
- (885) Whereas 75 cases were still pending (58 of which concerned Portugal), the courts rejected the claims of the originator companies in 24 final judgments and 37 legal actions were withdrawn by the originator company before a final judgment was made.⁵¹⁹ Only one final court judgement confirmed the claims of the originator company. In other words, in a large majority of cases the claims of originator companies were eventually not upheld by the courts and the originator companies lost their case, or alternatively, decided to withdraw their legal action. Figure 128 provides an overview.

⁵¹⁸ Data reported in mid-2008.

⁵¹⁹ Many withdrawals concern appeal cases where a lower court had rejected the claims of the originator company.

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Figure 128: Outcome of litigation initiated by originator companies against marketing authorisation bodies regarding patent infringement and safety issues concerning marketing authorisations of generic companies⁵²⁰



Source: Pharmaceutical Sector Inquiry

(886) As illustrated by Table 27, the sector inquiry also revealed that a high number of litigations are launched by the same originator companies in several Member States. Moreover, a number of originator companies generally concentrate their litigation effort on a few substances, generally on not more than three INNs in their portfolio.

Table 27: Overview of litigation cases initiated by originator companies against marketing authorisation bodies regarding patent infringement and safety issues (excluding cases concerning data exclusivity)⁵²¹

Originator company	INN	Country	Number of litigations	INN included in top 20 most litigated INNs between originator and generic companies ⁵²²
Originator 1	INN 1	BE, DE, DK, FR, UK, EE, NL, PT, SE, UK	> 70	X
Originator 1	INN 2	NL, ES	12	X
Originator 2	INN 3	CZ, HU, PT	8	X
Originator 3	INN 4	BE, NL, SE	7	X

Source: Pharmaceutical Sector Inquiry

⁵²⁰ This figure only includes cases where the final outcome was known in mid-2008. Consequently, cases where the proceedings are pending are not included. Also, the figure does not include litigation cases concerning data exclusivity, which are analysed in the next section.

⁵²¹ Litigation concerning data exclusivity is dealt with in the next section.

⁵²² For further details see Chapter C.2.2.

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Data Exclusivity

(887) The sector inquiry also sought to establish whether data exclusivity gave rise to litigation in the period 2000 – 2007. The inquiry identified 28 disputes and 42 cases of litigation for 43 originator companies surveyed. Litigation regarding data exclusivity is normally brought against national marketing authorisation bodies in the form of legal action against decisions issued by these bodies. This is confirmed by 30 of the 42 litigation cases reported by originator companies during the sector inquiry (see Table 28). Although the mechanism may differ from one country to another, the generic company which had previously obtained the marketing authorisation in question was normally involved in these litigations as an interested party. In the remaining 12 cases, the originator company litigated against the generic company over data protection (see Table 29). In six of the cases reported, parallel litigation was already ongoing against the agency which had issued the marketing authorisation for the generic product based on the originator company’s reference data.

Table 28: Summary of main data exclusivity litigation against a marketing authorisation body

Originator company	INN	Country	Litigations	Top 20 most litigated INNs between originator and generic companies ⁵²³
Originator company 1	INN 1	CZ (7), SK (2)	9	X
Originator company 2	INN 2	NL (4)	4	
Originator company 3	INN 3	BG (1), PL (1), SI (1)	3	
Originator company 4	INN 4	DE (1), SE (1), UK (1)	3	X
Other	5 other INNs	DE (2), FI (1), NL (1), PL (4), UK (3)	11	X

Source: Pharmaceutical Sector Inquiry

⁵²³ For further details see Chapter C.2.2.

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Table 29: Summary of main data exclusivity litigation against a generic company

Originator company ⁵²⁴	INN	Country	Litigations	Top 20 most litigated INNs between originator and generic companies ⁵²⁵
Originator company 3	INN 3	BG (1), PL (3), SI (1)	5	
Originator company 1	INN 1	CZ (1), SI (2)	3	X
Originator company 2	INN 2	BE (2)	2	
Other	2 other INNs	IT (1), SI (1)	2	X

Source: Pharmaceutical Sector Inquiry

- (888) Litigation on data exclusivity had been brought by one quarter of the originator companies which responded to the sector inquiry. Comparison of all the cases of disputes/contacts and litigation shows that some originator companies litigate without prior intervention. Conversely, not all disputes/contacts lead automatically to litigation. In fact, only 20% of disputes/contacts were followed by litigation.
- (889) As with contacts/disputes, companies appear to litigate in respect of one particular INN in their portfolio. Ten INNs were covered by the data exclusivity litigation, of which five were on the E75 list and five in the top 20 most litigated INNs between originator and generic companies. Although interventions take place in most EU countries, around 60% of all litigation mentioned by the companies surveyed were brought in the new EU Member States ("EU12").⁵²⁶
- (890) Considering that the same main companies and main INNs identified under data exclusivity disputes can also be found on the main list of data exclusivity litigation — albeit in a different ranking — the numbering of the INNs/companies is interlinked in this section. Three of the ten INNs subject to litigation on data exclusivity are also in the top 20 most litigated INNs between originator and generic companies (for details see Chapter C.2.2.).
- (891) As with contacts/disputes, each originator company will litigate separately in the same country against the marketing authorisation body for each generic version using the data on its product. Therefore, for most INNs the number of litigation cases is higher than the number of countries concerned.
- (892) Regarding the outcome of the 30 litigations brought against marketing authorisation bodies by originator companies in respect of data exclusivity, nine court proceedings are still pending. In the other 21 cases, the originator company's bid failed in 67% and

⁵²⁴ The originator companies represented by the numbers allocated in Table 28 (originator company 1, 2, 3 and 4) are the same in Table 29 and therefore have kept their respective number of Table 28.

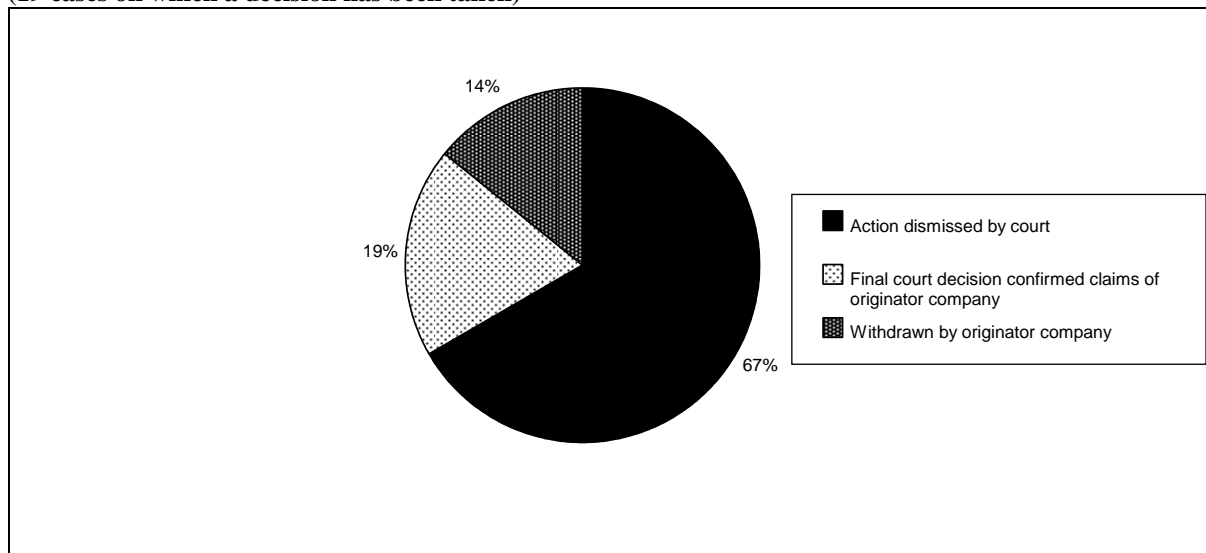
⁵²⁵ For further details see Chapter C.2.2.

⁵²⁶ Given the timeframe analysed in the report (2000 – 2007), it has been argued during the public consultation that certain litigations in the new Member States on data exclusivity might be the result of the transition regime resulting from the introduction of the Community acquis in the new Member States.

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the originator company withdrew its application in another 14%, i.e. the generic company obtained or maintained its marketing authorisation. In the remaining 19% (four out of 21 cases), the originator companies' efforts to litigate were a success and resulted in the generic producer losing its marketing authorisation. Figure 129 presents the findings, which show that originator companies won only a very limited number of cases.

Figure 129: Overview of outcome of litigation on data exclusivity against a marketing authorisation body (19 cases on which a decision has been taken)

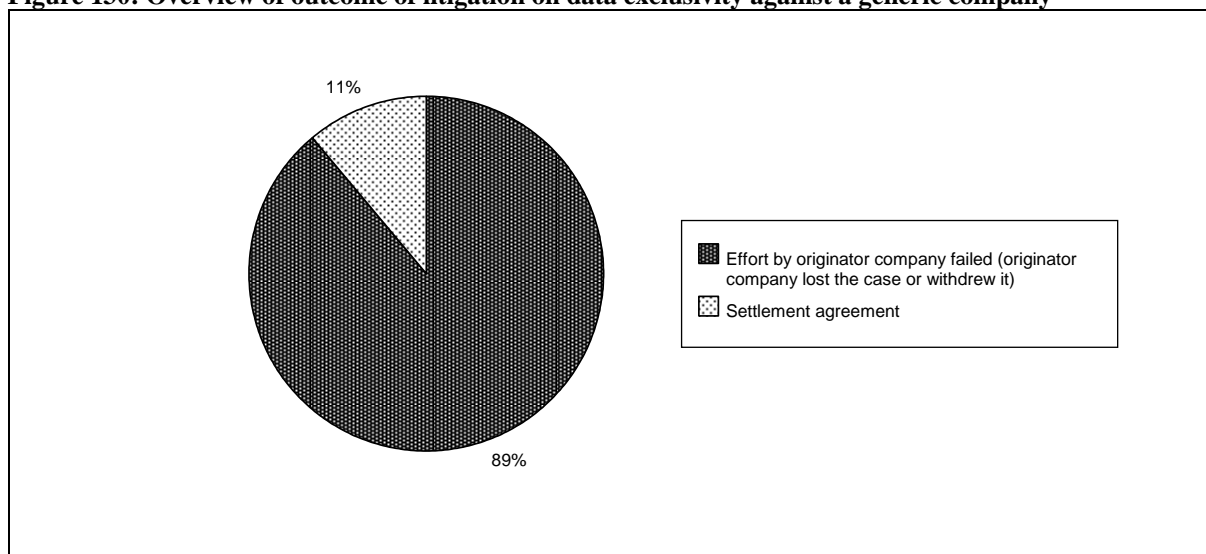


Source: Pharmaceutical Sector Inquiry

- (893) Out of the 30 data exclusivity cases involving an originator company litigating against a marketing authorisation body, three interim injunctions with suspension were granted by the courts in Finland and in the Netherlands. Only one of the three interim injunctions was followed by the marketing authorisation of the generic product ultimately being withdrawn.
- (894) A figure comparable to Figure 129 has also been prepared for litigation between originator and generic companies on data exclusivity. Three of the 12 cases brought against a generic company are still pending. Figure 130 shows the outcome of the other nine cases and clearly illustrates the very high failure rate for the originator companies which lost in eight of the nine cases (or 89%). The other case was settled in favour of the originator company, with the generic company withdrawing its application and not re-submitting it until after data exclusivity was lost.

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Figure 130: Overview of outcome of litigation on data exclusivity against a generic company



Source: Pharmaceutical Sector Inquiry

- (895) Out of the 12 data protection cases brought by an originator company against a generic company, at least five requests for an interim injunction were made to the court. However, none of these requests were granted. The Member States involved were the Czech Republic, Poland and Slovenia.
- (896) Figure 129 and Figure 130 demonstrate that originator companies are often defeated in court cases concerning data exclusivity. Nevertheless, even though most data exclusivity litigation cases ultimately have no impact on the marketing authorisation, they may still effectively delay market entry and can therefore have a financial impact on generic companies, health systems and patients. Table 30 provides an overview of the number of litigations begun in the period 2000 – 2007 and shows a peak in 2004 – 2005.

Table 30: Overview of data exclusivity litigations by year

Year	N.A.	2000	2001	2002	2003	2004	2005	2006	2007
Number of litigations	6	1	2	7	1	9	9	4	3

Source: Pharmaceutical Sector Inquiry

- (897) In conclusion, disputes and litigation in respect of data exclusivity are initiated by a number of originator companies. Whereas the geographic scope is wider for interventions than for litigation, there were more cases submitted of litigation than of intervention.⁵²⁷ A clear link can also be seen between INNs subject to litigation on data exclusivity and INNs subject to litigation in general as originator companies vigorously defend their commercial interests, in particular for their bestselling medicine.

⁵²⁷ The total number remains extremely low between one and nine cases per year.

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- (898) Whereas litigations may be used to clarify perceived legal uncertainty, the following quote illustrates that originator companies, under certain conditions, might also consider litigation when the chances of winning are low or minimal.

"Challenge of Generics MAs [marketing authorisations] [generic product name]

Third party objection based on safety concerns (additional expert opinion by [name of expert])

Third party action filed and fast track motion to re-establish suspensive effect

Motion dismissed by 1st instance (no third party right, appeal filed)

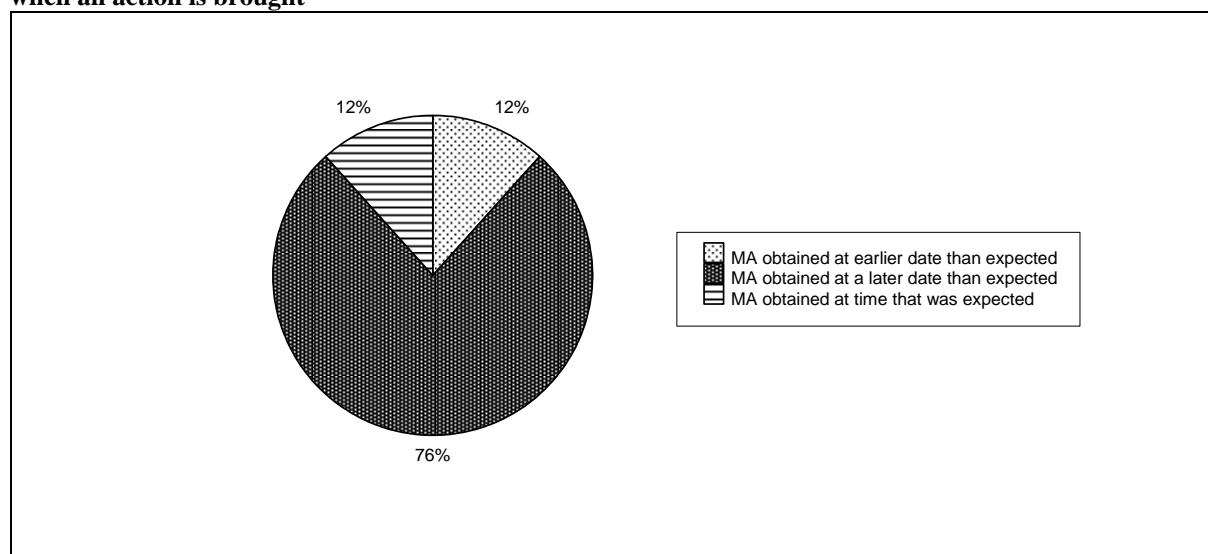
Chances: [of winning appeal] low"

2.5.1.3. Impact of Interventions before Marketing Authorisation Bodies

- (899) Returning to the above-mentioned 195 pre-litigation contacts/disputes brought by originator companies before marketing authorisation bodies indicated in Table 23, 52 of the 195 interventions reported to the Commission services were analysed as these were the only submissions for which data were available to allow comparison between the date when the generic marketing authorisation was obtained and the date when the generic company had initially expected to receive approval of its marketing authorisation. Figure 131 shows that in 40 of the 52 cases (76%), marketing authorisation was obtained at a later date than expected. In 12% of these cases, the marketing authorisation was obtained earlier than expected and in the remaining 12% at the time when the generic company had initially expected to receive it (i.e. within one month of the expected date).
- (900) When the marketing authorisation was obtained at a later date than expected, it took on average 11 months longer than foreseen. When the marketing authorisation was obtained earlier than expected, it was received on average three months before the company expected it. Some 60% of the products for which marketing authorisation was obtained earlier than expected were launched in Spain. However, there were also delays for the majority of applications reported in Spain. On average, it took 9.2 months longer than expected to obtain the marketing authorisation for each of the 52 analysed cases where intervention has taken place.

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Figure 131: Comparison of the expected and actual date of approval of generic marketing authorisation when an action is brought



Source: Pharmaceutical Sector Inquiry

- (901) It must be borne in mind that, when a marketing authorisation is obtained later than expected, other factors apart from the intervention could be responsible for the delay. This means that the data gathered does not establish causality between the interventions and the fact of obtaining the marketing authorisation at a later date than expected. However, the data shows a certain correlation as regards to the delays. When compared with a representative sample of other cases in which there was no intervention, the marketing authorisation was obtained on average "only" 5.3 months after the date it was expected, which is 3.9 months shorter than the 9.2 months in case intervention had taken place.⁵²⁸
- (902) During the sector inquiry, the Commission's services also came across cases where marketing authorisations were granted but their actual entry into force was suspended either by the marketing authorisation body or following legal action by originator companies. The economic effect of such a decision for a generic company is the same as a refusal to grant marketing authorisation: the generic product cannot be put on the market.

Box: Third-party motions leading to the suspension of marketing authorisations

In the course of the sector inquiry, it was submitted that a number of originator companies filed third-party oppositions against decisions granting marketing authorisation to a generic product. In some Member States, national administrative

⁵²⁸ A random sample of 164 representative cases where no action was brought by the originator company during appraisal of the application by the generic company for marketing authorisation was compared with a sample of 52 representative cases where actions had been brought. The first sample resulted in an average delay of 5.3 months between the dates when the generic company had expected and when it finally obtained marketing authorisation. When intervention had taken place, this delay increased to an average of 9.2 months per application.

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procedures allow such third-party motions. The objections raised may lead to the immediate suspension of the marketing authorisation of generic medicines due to national administrative law or by order of the marketing authorisation body. Generic companies reported several cases in Germany where, following third-party motions, a marketing authorisation body temporarily suspended the marketing authorisation of a generic company until a final decision was reached either by a court and/or by the marketing authorisation body itself. In all German cases reported to the Commission, the administrative courts eventually dismissed the objections and ordered the immediate execution of the marketing authorisation. Generic companies have pointed to the delays caused by these third-party motions. Originator companies pointed to the specificities of the respective cases.

- (903) The results of successful actions are also recorded by the originator companies. One originator company summarised the results of actions before health authorities as follows:

"Interchangeability issues were used in [several countries] to limit generic erosion [...] Outcome: extra [originator] product sales of USD 61m in 2 years compared to expected generic erosion. [...]"

"Delayed market entry of [generic product] due to requirement for more robust efficacy and safety data. Delay of entry of [...] results in USD 350m extra [...] sales [...]"

- (904) Apart from the impact on the business of generic companies, the delays can have significant consequences for public health budgets and ultimately consumers as the lower prices could only be introduced later than expected.

2.5.2. Interventions before Pricing and Reimbursement Bodies⁵²⁹

- (905) As price and reimbursement levels for prescribed pharmaceutical products are set at national level in most EU Member States, pharmaceutical companies have to reach an agreement concerning pricing and reimbursement for their products with the relevant authorities before launching their product on the market in the Member States concerned. This applies to both originator and generic products. Besides interventions at marketing authorisation level, originator companies are bringing an increasing number of actions before pricing and reimbursement bodies against generic products.
- (906) Based on the information received during the sector inquiry, certain originator companies either write to the pricing and reimbursement bodies or take legal action against them. This might well lead to delays in generic products obtaining pricing and reimbursement status.
- (907) When bringing actions, originator companies often base their arguments on safety issues, bioequivalence and "patent linkage". One claimed that certain generic tablets

⁵²⁹ Figures have been revised in this sub-section.

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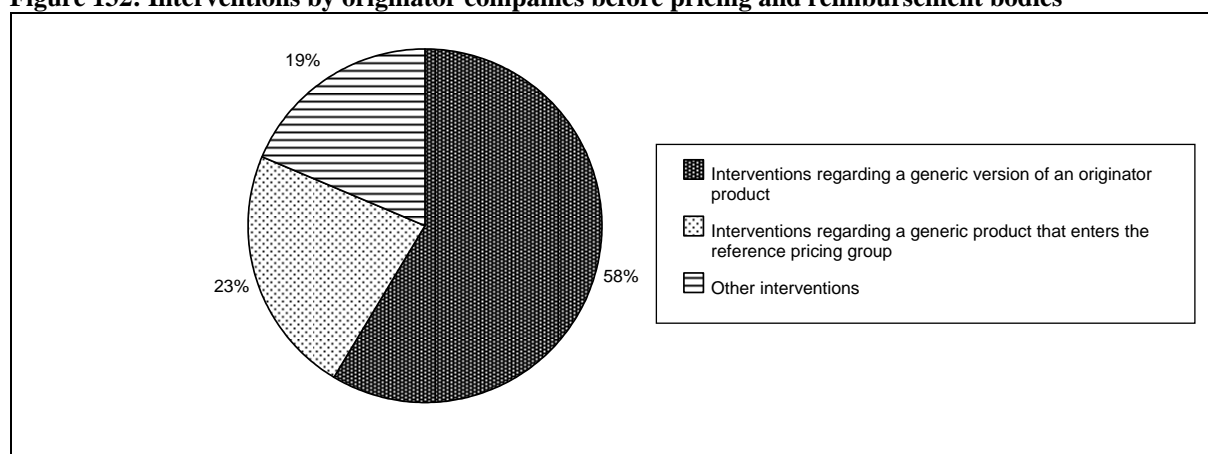
were less safe than the originator company's product, when taken, for example, with alcohol. Another argument sometimes put forward by a number of originator companies is that although the active ingredient of a generic medicine is the same, its effectiveness can be influenced by the production procedure.

- (908) Under the applicable EU directive, decisions on prices must be adopted and communicated to the applicant within 90 days of receipt of a valid application.⁵³⁰ The national authorities cannot extend this time limit, unless the information supporting the application is incomplete or inadequate. Suspending the price approval procedure for any other reason than the ones indicated in the Transparency Directive is considered as a breach of the Directive. Another 90 days are allowed in the Directive for deciding on the reimbursement status.

2.5.2.1. Pre-Litigation Contacts and Disputes with Pricing and Reimbursement Bodies

- (909) Originator companies intervene before pricing and reimbursement bodies on various issues. Figure 132 classifies the 66 actions reported in the sector inquiry.⁵³¹ Just over half of them (40 cases) concerned the pricing status of generic versions of an originator company's product. The remainder were split between actions against a generic product entering the reference pricing group⁵³² (thirteen cases) and on other issues (thirteen cases).

Figure 132: Interventions by originator companies before pricing and reimbursement bodies



Source: Pharmaceutical Sector Inquiry

⁵³⁰ Article 2(1) of Directive 89/105/EC.

⁵³¹ The 66 cases are based on the interventions that were reported by the originator companies which have been cross-checked with data from national pricing and reimbursement bodies.

⁵³² A reference pricing group can comprise a basket of reference countries used to determine the price or reimbursement status of a medicine (cross-border referencing) or comprises a group of medicines with a comparable therapeutic effect that attract the same price or reimbursement (for details see Chapter B.2.3.).

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(910) In some cases, one intervention concerns several generic companies and several versions of a generic product (such as dosages). For the purposes of the following overview, they have been counted as one intervention.

Intervention Regarding Pricing Status of Generic Versions

(911) The 40 interventions dealing with a generic version of an originator company's product were brought by twelve large originator companies. Table 31 below gives an overview of these 40 actions:

Table 31: Overview of interventions by originator companies before pricing and reimbursement bodies against a generic version of a medicine

Originator company	INN	Interventions	Minimum number of products/dosages concerned	Country
Originator company 1	INN 1	1	31	PT (31)
Originator company 2	INN 2	7	22	ES (17), HU (1), LV (1), RO (1), SK (1), SI (1),
Originator company 3	INN 3	5	22	AT (5), FR (14), HU (1), LV (1), IT (1)
Originator company 4	INN 4	2	14	FR (14)
Originator company 5	INN 5	2	14	EE (1), PT (13)
Five other originator companies	14 other INNs	23	More than 47	AT, BE, BG, FR, HU, IT, LV, PT, SE

Source: Pharmaceutical Sector Inquiry

(912) As can be seen in Table 31 above, these originator companies rarely intervened against only one generic version or one specific dosage of their product. Instead, the 40 actions concerned more than 150 generic versions/dosages of originator companies' products. Moreover, all 40 dealt with just 19 INNs, of which eight are on the E75 list. Six of the top 10 INNs on which originator companies had disputes with generic companies (for details see Chapter C.2.2.) appear among the 19 INNs concerned by the 40 interventions.

(913) Regarding the geographical scope, all 40 interventions were brought in a total of 15 countries, of which more than 60% took place in Portugal, France and Austria. In almost all these cases (34 out of 40), these originator companies alleged patent linkage, i.e. that no pricing and reimbursement status should be given as long as the reference product was still patent-protected.

(914) The data gathered during the sector inquiry suggest that a number of originator companies often intervene in parallel at both marketing authorisation and pricing and reimbursement levels. In at least eleven of the 40 cases mentioned in the previous paragraphs, these originator companies intervened before pricing and reimbursement bodies in parallel with a request for interim injunctions to obtain suspension of the marketing authorisation of the generic product. Especially in Portugal, the pricing decision is often suspended due to interim injunctions that have been filed against the marketing authorisations (for details, see case study in box). The pricing decision remains suspended until the court has ruled on the marketing authorisation.

Intervention Regarding Reference Pricing

- (915) The thirteen intervention cases regarding reference pricing⁵³³ that were identified for the 219 selected INNs may also have an (indirect) impact on generic products. When an originator company applies for a price and reimbursement of its product, some authorities calculate a price by taking a reference group of products. When generic products come on the market and enter such a reference price group, the price and reimbursement of the originator company's product might be adjusted (downwards). Therefore, originator companies may have a commercial interest in keeping generic products out of the reference price group for their products. The generic producers, on the other hand, will endeavour to be included in the reference price group as their presence could well expand the market for their products. Therefore, if originator companies succeed in excluding the generic products from the reference pricing by means of litigation/interventions, they may create obstacles for generic companies. However, the analyses of the thirteen relevant interventions clearly showed that none of the attempts by originator companies to raise concerns about inclusion of the generic products in the reference price group succeeded. Some resulted in a compromise on a price cut for an originator company's product after inclusion of one or more generic products in the reference price group.

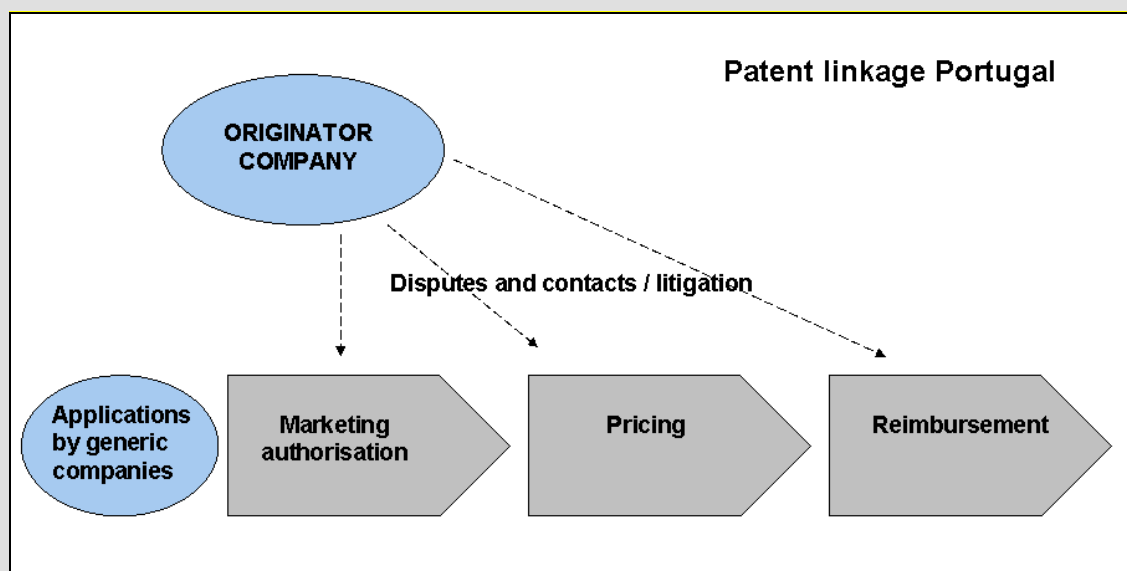
2.5.2.2. Litigation against Pricing and Reimbursement Bodies

- (916) Whereas some originator companies intervene directly before the pricing and reimbursement bodies, some will also litigate against these authorities. If a pricing and reimbursement body is brought to court, several arguments are used by those originator companies. They relate to patent linkage, irregularities in the registration file for the generic medicine, concerns about equivalence or non-compliant promotional material. Portugal is a special case, in that most claims there are based on patent infringement only. Under EU law, patent protection is not a criterion to be considered by the authorities when approving prices or granting reimbursement status.
- (917) As described earlier in this section, patent linkage occurs in several EU Member States. By way of example, the following case study takes a closer look at the issues at stake:

⁵³³ For further details on reference pricing see Chapter B.2.3.

Box: Case study on patent linkage in Portugal

Clusters of cases involving patent linkage were observed in Portugal during the sector inquiry. A number of originator companies pursue deliberate actions, including litigation, creating administrative difficulties for generic companies which might result in delays in generic entry. The flowchart below illustrates such actions usually coinciding with the price application by a generic company to the authorities responsible for marketing authorisation and pricing and reimbursement.



A number of marketing authorisations issued by the Portuguese Medicines Agency (INFARMED) for generic medicinal products have been challenged in the administrative courts by some originator companies, on the grounds that the reference products are still protected by a patent. These legal actions have affected the pricing process for the generic products concerned. Indeed, the Direção-Geral das Atividades Económicas (DGAE) in the Ministry of Economic Affairs and Innovation reportedly suspends the price approval process for generic medicines when originator companies launch legal proceedings based on an alleged patent violation.⁵³⁴ Several requests for approval of prices for generic medicines were suspended in 2007 and 2008, pending the judgments of the administrative courts to which the cases had been referred. Altogether, more than 70 court cases related to eleven molecules are currently pending.⁵³⁵ The court proceedings take a long time. In one case, price approval has been delayed for almost 18 months. Furthermore, in several cases the administrative courts decided to suspend the marketing authorisations granted to generics until the patents expired or until the patent litigation was resolved by the commercial courts.

(918) Figure 133 classifies the 38 litigations reported by originator companies: just half of them (19 cases) dealt with a generic version of the originator company's product. The

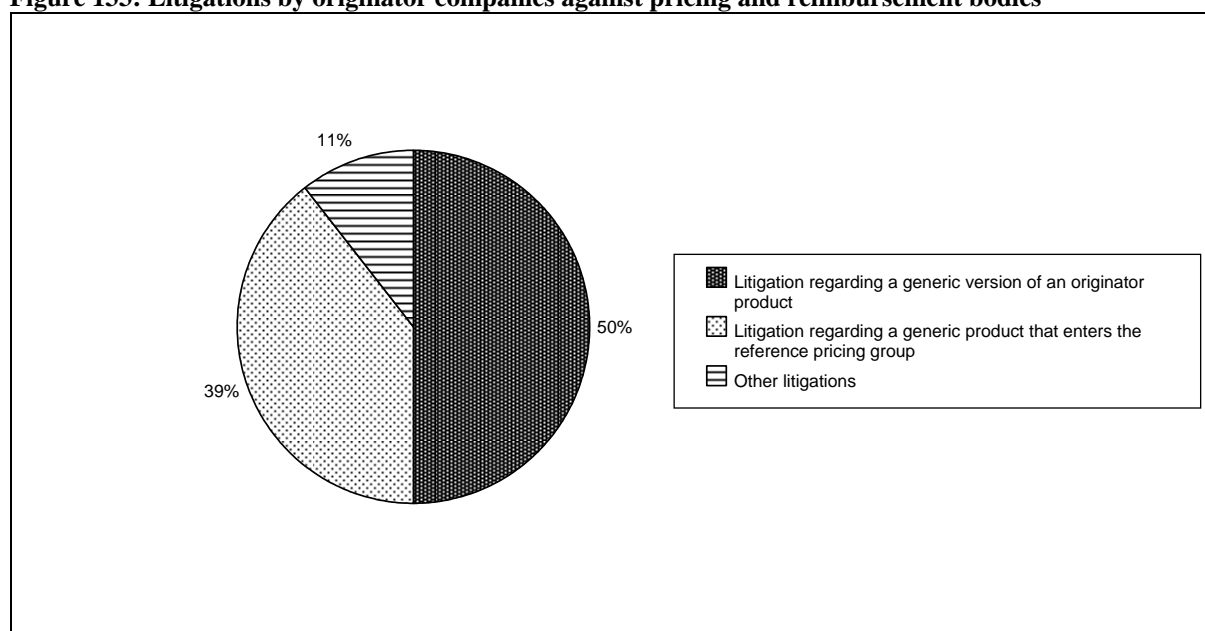
⁵³⁴ In mid-2008, the price approval process for more than 120 generic products was suspended. Some of the applications for price approval had been filed as long ago as May 2007.

⁵³⁵ Six of the eleven molecules on which 70 court cases are pending are part of the T50 list.

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remaining actions were divided between litigation against a generic product entering the reference pricing group (15 cases) and other types of litigation (four cases).

Figure 133: Litigations by originator companies against pricing and reimbursement bodies



Source: Pharmaceutical Sector Inquiry

Litigation Regarding Generic Versions

(919) The 19 litigation cases reported which dealt with a generic version of an originator company's product concern eight large originator companies. Out of the 19 litigations, eleven deal with a patent infringement. Table 32 gives an overview of these 19 litigations.

Table 32: Overview of litigations brought by originator companies against pricing and reimbursement bodies regarding a generic version

Originator company	INN	Litigations	Number of products/dosages concerned	Countries
Originator company 1	INN 1	1	45	PT (45)
Originator company 2	INN 2	2	17	PT (17)
Originator company 3	INN 3	2	17	IT (17)
Originator company 4	INN 4	1	13	PT (13)
Originator company 5	INN 5	1	5	PT (5)
Three other companies	8 other INNs	12	15	BE (5), IT (1), LT (4), PT (5)

Source: Pharmaceutical Sector Inquiry

(920) As can be seen from Table 32, these originator companies rarely litigate in relation to only one generic version/dosage of their products. Often, the originator company litigates against the pricing and reimbursement body regarding more than one generic version/dosage in one court case. However, some companies litigate against the pricing and reimbursement body separately for each generic version. The litigation cases

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between originator companies and pricing and reimbursement bodies on generic versions of products concerned 44 different generic companies.

- (921) The 19 reported litigations regarding generic versions of originator company's products brought against a pricing and reimbursement body dealt with thirteen INNs, of which four are on the E75 list. Four of the top 20 most litigated INNs between originator and generic companies (for details see Chapter C.2.2.), feature amongst the thirteen INNs concerned in the 19 litigations.
- (922) Regarding geographical scope, reported litigations were brought in four countries. Nine of the cases concern Portugal, four were reported in Belgium, three in Italy and three in Lithuania.
- (923) As far as the outcome of the litigations is concerned, seven settlements have been agreed (only for cases other than patent infringements), while in six cases the main action is still pending (after failure to obtain a preliminary injunction in some cases), for five the pricing process has been suspended and for one a preliminary injunction has been issued and is currently under appeal.

Litigation Regarding Reference Pricing

- (924) The 15 litigation cases regarding reference pricing concern four companies and four INNs in two countries. Apart from one case in Sweden, all the others occurred in Italy. In every case, these originator companies claimed that no off-patent product should be included in the reference price group of their patented product, as this would violate their patents. In only two instances did the court agree with the originator company. However, appeals might still be lodged by the pricing and reimbursement body. The court ruled against the originator company in five other cases and the remaining eight are still pending.
- (925) While no final conclusions can be drawn without court outcomes, it is already clear that this practice of litigating against the pricing and reimbursement bodies on the part of the originator companies affects the generic producers as interim injunctions lead to suspension of the pricing and reimbursement status of the generic product until after the court outcome.

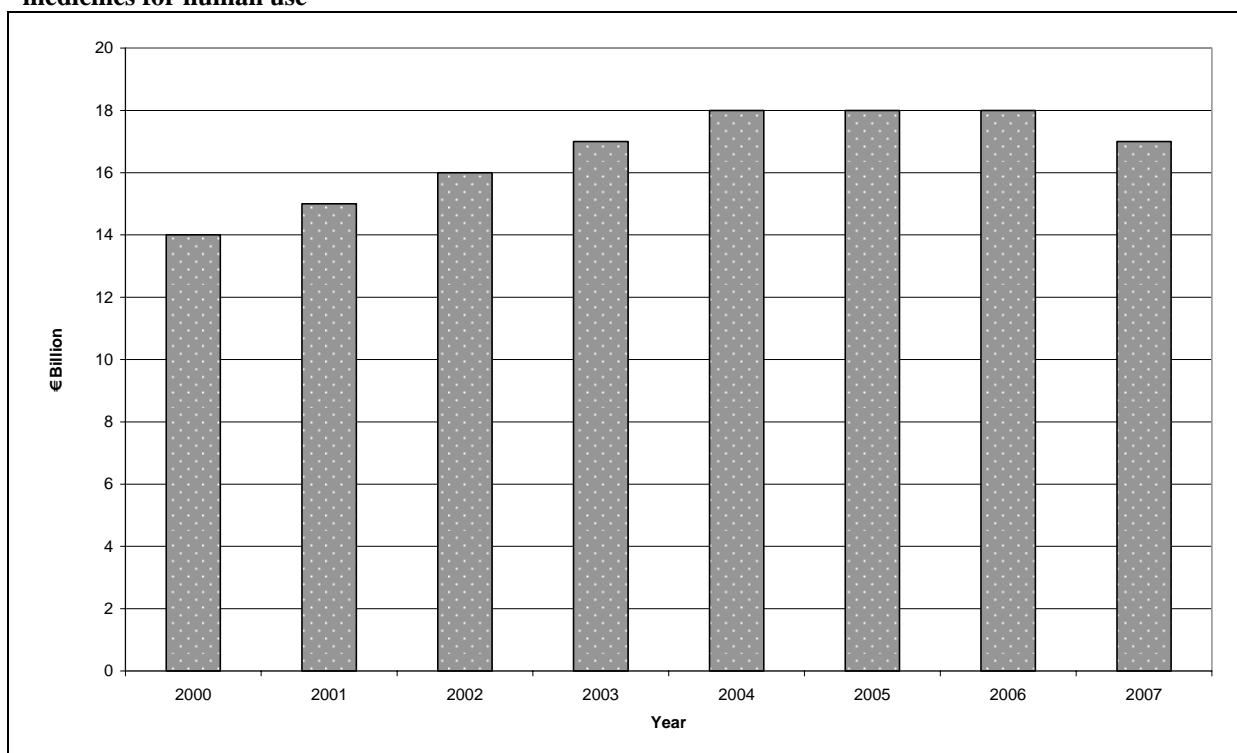
2.5.3. Marketing and Promotion Strategies of Originator Companies Affecting Generic Entry

- (926) Originator companies incur high costs when developing new medicines and it is essential that their presence on the market is successful if they are to secure a return on their investments. As outlined in Chapter B.1.2. originator companies consider marketing and promotion very important in bringing their medicines to patients and doctors. They argue that providing information to doctors about new products is essential to ensure, *inter alia*, continuous product innovation.
- (927) The budgets which originator companies earmark for marketing and promotion are therefore considerable and exceed the amounts spent on R&D. Figure 134 provides an overview of the annual marketing and promotion costs in the EU for prescription medicines for human use. Over the period 2000-2007, the annual marketing and

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promotion costs increased and were in the range of between 20 and 25% of total turnover.

Figure 134: Annual marketing and promotion costs in the EU of 35 originator companies for prescription medicines for human use⁵³⁶



Source: Pharmaceutical Sector Inquiry

- (928) Based on the strategy documents of pharmaceutical companies submitted during the sector inquiry, business decisions are clearly taken at multiple levels within the respective companies. Whereas the overall strategy for products and most decisions before market launch are taken at global level, companies generally switch to a more regional approach once the product has been launched. Although coordinated, marketing and promotion strategies are customised to the relevant national markets. One originator company put this choice of a more regional/local approach down to the wish:

"[...] to take advantage of local growth opportunities with sales forces mirroring local healthcare systems to the largest extent possible".

- (929) Marketing and promotion strategies of originator companies are closely aligned with the "life cycle management" frameworks with a tool-box of instruments and tactics for products which lose exclusivity (see Chapters C.2.6. and C.2.7.).
- (930) Both originator and generic companies target health professionals with promotional activities aiming at increasing sales of their pharmaceutical products. The form and

⁵³⁶ Companies with incomplete data sets have been omitted. The largest originator companies are included in the sample.

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manner in which medicines are marketed and promoted can vary considerably. The next few sections will look at promotion and information strategies employed by originator companies to present the advantages of their own products (such as sponsoring conferences or providing training for health professionals), strategies involving next-generation products and "evergreening" combined with an information policy pointing out alleged disadvantages of generic products.

2.5.3.1. Promotion Strategies and Information Policy Presenting the Advantages of the Originator's Own Products

- (931) "Marketing and promotion" has a legitimate purpose and is considered in the report as all techniques used by companies to promote and sell their own product(s). One major marketing challenge for pharmaceutical companies is to convince doctors to prescribe their products. As outlined in Chapter B.2.1., the most important activity in terms of budget is "detailing", i.e. visits by sales staff to doctors and pharmacists. Detailing is recognised as the most useful means to ensure that doctors are kept up-to-date with scientific knowledge (as not all doctors participate in scientific congresses) and is also the main channel for pharmaceutical companies to collect pharmacovigilance data. Pharmaceutical companies also undertake other promotional activities, including meetings, sponsorship, financing travel costs and participation in conferences, gifts/grants/donations, promotional material and training.

Training and Sponsoring of Conferences

- (932) Promotion of originator products to doctors can sometimes be undertaken in a covert manner, for example in the form of training sessions (co-)organised by originator companies. A recent case in Germany concerning on-line training for doctors is described below.

Box: German online training case

According to press reports,⁵³⁷ in 2008 the German competition agency opened an investigation into on-line training for doctors organised by a number of originator companies and endorsed by the German doctors' associations (Landesärztekammer and Bundesärztekammer). Objective product information provided on the Internet is a useful and necessary tool for health professionals and consumers. However, in a letter to the Bundesärztekammer, the competition agency expressed concerns that the free on-line training offered by a number of originator companies and endorsed by the doctors' associations contained hidden advertising of these originator companies' products. Hidden advertising of pharmaceuticals is forbidden under German law. This free on-line training also had an impact on independent commercial providers of training which were allegedly excluded from the market. In that respect, the German competition authority expressed concern that the doctors' associations had abused their dominant position when certifying the courses offered by the originator companies. Following a warning letter sent by the German competition authority, one of the originator companies concerned stopped offering on-line training.

- (933) Pharmaceutical companies generally spend significant resources on sponsoring conferences, training sessions and other events. Scientific conferences aim to address one or more medical or other scientific issues in one or more fields of science and are therefore important drivers for research and for discussing advances in medicine. The data received during the sector inquiry show that not all companies are systematically spending large amounts of money to promote their products and corporate image by means of conferences. Whereas the expenditure of some pharmaceutical companies on conferences and other events is limited, others (in particular certain large originator companies) sponsor hundreds or even thousands of conferences and/or training sessions in the EU every year.⁵³⁸ Many companies cover the travel and participation costs of doctors, pharmacists and scientists attending these events.
- (934) Spending by pharmaceutical companies on marketing and promotional activities (also applicable to trainings, conferences or gifts) is governed by a number of European directives, national regulations and codes of practice. Two applicable directives are the Directive on the Community code relating to medicinal products for human use,⁵³⁹ which sets out the rules for placing on the market, production, labelling, classification, distribution and advertising of medicinal products for human use, and the Misleading

⁵³⁷ Ärztezeitung online, 3 July 2008, Fortbildungskurse: Kartellamt prüft Verstoß gegen Wettbewerbsrecht and Spiegel online, 15 October 2008, Macht der Pharma-Portale erbost das Kartellamt.

⁵³⁸ During the sector inquiry companies reported that they sponsor many conferences/seminars, as illustrated by the following representative examples: one originator company sponsors more than 2 500 conferences and seminars a year in EU-27 (excluding pure promotion events); another reported that it had sponsored more than 50 000 events over the period 2000-2007.

⁵³⁹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use (OJ L 311, 28.11.2001, pp. 67-128).

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and Comparative Advertising Directive.⁵⁴⁰ The Community code relating to medicinal products for human use prohibits the advertising to the general public of medicinal products subject to prescription, but allows advertising to persons qualified to prescribe or supply such products, subject to the conditions laid down in the Directive.

- (935) As regards self-regulation by the industry, the Joint Declaration of the CPME (Standing Committee of European Doctors) and EFPIA (European Federation of Pharmaceutical Industries and Associations) was adopted in June 2005. The CPME and EFPIA considered it essential to establish a framework that could serve as guidelines at both European and national level for the relationship between the medical profession and the pharmaceutical industry. Companies should normally implement this code of practice (although, strictly speaking, it is not legally binding) by means of clear in-house policies and procedures which aim at ensuring that the Joint Declaration and national pharmaceutical regulations are strictly followed in all marketing and promotional activities.⁵⁴¹
- (936) Out of the 43 originator companies surveyed, two were unaware of the Joint Declaration of the CPME and EFPIA, whilst a third company had only heard of the code. The 40 companies that were aware of the Joint Declaration replied that they follow these rules.
- (937) According to these 40 companies, up to the end of 2007 there had been a number of violations since the Joint Declaration was signed. These could take the form, for instance, of providing inappropriate leisure activities to doctors or including inaccurate or incomplete information in promotional material. Out of the 43 companies questioned, 23 gave figures, whereas eight just said that some violations had occurred but had no data. A total of 629 alleged violations of the Declaration were reported to the Commission.
- (938) Most companies stressed that violations resulted in appropriate action to remedy them, including disciplinary measures, changes to marketing material, additional training and adaptation of compliance processes. Nevertheless, some marketing and promotion practices of a number of originator companies are often interpreted differently by consumers.
- (939) BEUC explained:

"We believe that these promotional activities, often breaching the existing legislation and codes of conduct can be detrimental for consumers as they can have an undue

⁵⁴⁰ Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (OJ L 376, 27.12.2006, pp. 21-27). The Commission is currently preparing a proposal for legislation on information to patients to ensure good-quality, objective, reliable and non-promotional information on prescription-only medicinal products to citizens and to harmonize the existing situation in Member States in this area. See: http://ec.europa.eu/enterprise/pharmaceuticals/patients/patients_key.htm

⁵⁴¹ In addition, it was submitted during the public consultation that all EFPIA member companies are obliged to follow the EFPIA Code of Practice.

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influence in prescribing behaviours, create a distortion in the doctor/patient relationship and ultimately lead to irrational drug use by consumers".

- (940) Promotional activities aim not only to inform and convince doctors about specific products, but also to create product loyalty as pharmaceutical companies want to secure continued sales of their products. However, certain strategies targeted on product loyalty may contribute to creating obstacles for competing medicines, including generic products.

2.5.3.2. Information policy on alleged risks and disadvantages of generic products

- (941) Apart from general promotion and marketing strategies, a number of originator companies also appear to engage in practices that could be seen as calling into question the equivalence and/or quality of generic products. The sector inquiry confirmed that such information policies are indeed adopted by several originator companies, particularly during the launch of a competing generic product. One widespread practice on the part of originator companies is, for example, to send warning letters to pharmacists, wholesalers, hospitals or doctors about the generic versions of their product. Some originator companies or associations of originator companies also launch marketing campaigns which could be viewed as pointing out the disadvantages of generic products.

Warning Letters

- (942) The sector inquiry confirmed that originator companies follow a certain pattern when sending warning letters. Often, these originator companies start to send warning letters to generic producers when they become aware that generic companies are preparing to launch a generic version of their product.
- (943) As one originator company notes in an in-house strategy document:

"Draw up standard letter to send to companies planning to launch generic [product] to warn for potential patent infringement. Draw-up follow-up letter with stonger text. [...]"

- (944) This practice is further described in Chapter C.2.2. After they have sent warning letters to generics companies and health authorities (see above), it is not uncommon for originator companies to start sending letters to doctors. Pharmacists also receive letters from originator companies but, based on the information received during the sector inquiry, to a lesser extent as they are not the ones who prescribe the medicines.

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- (945) In the course of the sector inquiry, many examples of such letters were received. In certain cases, originator companies sent letters to thousands of doctors, pharmacists and hospitals.⁵⁴²
- (946) The sector inquiry revealed that in communications with doctors and pharmacists, some originator companies will mention ongoing court cases and alleged infringements of patent rights. Doctors and pharmacists are given the impression that they would be infringing patent law if they were to prescribe or dispense the generic product while the court case is still pending. A significant number of letters even mention the possibility of damage claims against doctors and pharmacists prescribing/dispensing the generic product, as can be seen from the following quote from a letter from an originator to pharmacists:

"We reserve the right to hold you [pharmacist] responsible for damage [our company] might suffer by substitution of [our product] by [the generic version]".

- (947) Some of the letters sent to doctors and pharmacists by certain originator companies mention that research and development is primarily undertaken by originator companies and that only those companies offer added value to doctors and their patients. If the originator companies criticise the generic product in their letter, their main arguments are once again based on the generics being less safe, less effective, inferior and unsuitable as substitutes.
- (948) The warning letters sent by a number of originator companies to pharmacists are not always unsuccessful, as can be seen from a pharmacist's reaction after receiving a letter from an originator company (however, this might be an exceptional case):

"I have recently been informed by [name of an originator company] of [your generic company's] illegal methods of doing business [= offering a generic version of product X with alleged patent infringement]. [...] [As a consequence of this] [...] you are no longer welcome to make presentations of your products [in this pharmacy]."

- (949) It must be added that the originator company which sent the original letter to the pharmacist was eventually unsuccessful in the patent infringement case referred to.
- (950) Hospitals are also targeted by originator companies. The letters sent by originator companies to hospitals do not primarily discuss the product characteristics of a generic medicine but place greater emphasis on the alleged legal uncertainty concerning the generic product, as do the letters sent to doctors and pharmacists.

⁵⁴² In one case in Germany, an originator company reported that it had sent about 164,000 letters concerning one product in a relatively short period: approximately 84,000 to doctors about the new formulation, approximately 60,000 to doctors about the terms of reimbursement and approximately 20,000 to pharmacies about the terms of substitution.

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Information Campaigns

- (951) Certain originator companies or their associations use an indirect way of influencing public opinion towards trusting originator medicines ahead of generic medicines. The message that these originator companies tend to send is that generic products are not of good pharmaceutical quality and are less effective. There are also campaigns by generic companies and associations in favour of generic medicines, sometimes supported by public health authorities.
- (952) In Spain, for example, a national press campaign was mounted in June 2007, sponsored by Farmaindustria, the Spanish association representing the originator industry. A full-page advertisement was published in the leading newspapers featuring a single unlabelled bottle of pills followed by a sentence which read "¿A que la marca sí es importante?" ("The brand name is also important, isn't it?"). By way of illustration, two versions of the Farmaindustria campaign are reprinted below.⁵⁴³



Source and copyright: Farmaindustria (Spanish industry association)

- (953) Negative advertising by a number of originator companies also appears in scientific journals. A certain originator company used the slogan "Do not consider my original

⁵⁴³ It has been argued during the public consultation that the advertisement was intended to address the discriminatory effect of the Spanish law that states that where generics and branded products are equally priced, the generic must be dispensed.

product X to be equal to the generic products." without mentioning any scientific reference. Again the main message being conveyed is that generic products are not "equivalent", even though the marketing authorisation agencies had confirmed bioequivalence.

- (954) It has to be emphasized that all medicinal products (whether originator or generic) authorised for placing on the Community market are subject to the same requirements of quality, safety and efficacy. The difference between originator and generic products resides in the procedure to prove safety and efficacy (the originator through its own tests and trials, the generic by showing bioequivalence to a previously authorised originator medicine), but not in the public health standards applied by the authorities. Any campaigns which put this fact in question ignore the key principles for marketing authorisation of the Community code on medicinal products for human use and may mislead the public.
- (955) A recent case in France illustrates how some originator companies may adopt a very aggressive commercial strategy during the launch of a generic medicine.

Box: Commercial practices by an originator company in France

One originator company facing the launch of a competing generic product systematically criticised the generic product via its sales staff (alleging, *inter alia*, lack of effect, inferior quality and a negative impact on patients' health). At the same time, the originator company switched its distribution channel from wholesalers to direct-to-pharmacy, including strong commercial incentives to dispense the originator's product (long payment terms, rebates and remunerated questionnaires) in order to fill pharmacy shelves. As a result, penetration by the generic product was not particularly successful. Entry was blocked and the market share of the generic medicine kept below 10%, which was unusual as normal market penetration would have been expected to have been around 50%. The generic company complained to the French competition authority which granted an interim measure.⁵⁴⁴ The originator company was ordered to publish a statement in the professional press that the generic product is fully equivalent to its product and is absolutely safe.

2.5.4. Interventions vis-à-vis Wholesalers/Distributors and Changes in the Distribution Chain

2.5.4.1. Pre-Litigation Contacts and Disputes with Wholesalers

- (956) Originator companies also contact wholesalers about ongoing legal actions against generic companies pursuing alleged patent infringements. Wholesalers have reported several cases where they have been made aware of such legal proceedings and requested not to distribute the generic medicines concerned as long as the litigation is

⁵⁴⁴ Press release at:
http://www.conseil-concurrence.fr/user/standard.php?id_rub=211&id_article=865.
Judgement of the Cour de Cassation of 13 January 2009, Pourvoi no. P 08-12.510

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pending. Often harshly worded letters request wholesalers to inform the originator companies whether the generic products have already been received or distributed. In some cases, originator companies also requested the wholesaler to sign a written declaration not to distribute the generic medicines. Wholesalers report that these practices may create considerable uncertainty on the market and mentioned cases where distribution of generic drugs had been severely impeded or blocked.

- (957) In all, nine of the originator companies surveyed reported more than 500 disputes with wholesalers on alleged patent infringements.⁵⁴⁵ All the disputes reported concerned just 16 out of the list of 219 INNs. Twelve of these 16 INNs are on the E75 list.
- (958) Germany, the Netherlands and Spain are especially prone to approaches by originator companies to wholesalers to draw their attention to their patents. Most of the approaches reported were made in the form of warning letters sent by certain originator companies or their legal advisers.⁵⁴⁶

2.5.4.2. Litigation against Wholesalers

- (959) A number of originator companies also take wholesalers to court over patent infringements if wholesalers (plan to) distribute generic medicines on which patent disputes or litigation are pending between the originator company and a generic company. This is illustrated by the Danish case described below.

Box: Litigation against a wholesaler in Denmark

An originator company applied for interim injunctions against a wholesaler over its distribution agreements with generic companies in Denmark.⁵⁴⁷ This wholesaler acted as a distribution warehouse for a number of generic companies. The originator sought and obtained an injunction against the wholesaler for its alleged intention to distribute products infringing its patent rights, even though each of the generic companies which use the wholesaler had confirmed that it had no intention to import the product concerned. The Danish court granted the injunction against the wholesaler on the basis of the marketing authorisations issued to the generic companies ruling that the existence of the marketing authorisations was a sufficient threat to constitute an infringement of the patent rights of the originator company.

⁵⁴⁵ Another 200 interventions were reported by originator companies regarding parallel imports. However, as parallel trade does not fall within the scope of the sector inquiry, these cases are not assessed in this report.

⁵⁴⁶ During the public consultation, an association of originator companies argued that sending notice letters on patent infringement was actively encouraged by courts with a view to preventing "needless litigation". Moreover, this association claimed that such notice letters were a procedural precondition for enforcing patents. However, no evidence was submitted that such letters are indeed a procedural precondition for interim injunctions. Such letters can however be taken into account in subsequent damage actions.

⁵⁴⁷ Danish District Court case number FS 1-13061/2007. The case is currently under appeal.

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(960) However, most of the court cases deal with patent infringements. The sector inquiry revealed that out of the 15 litigation cases between an originator company and a wholesaler in EU27 over the period 2000 – 2007, twelve were about patent infringements. Table 33 gives an overview of the 15 litigations reported:

Table 33: Overview of litigations against wholesalers

INN	Number of litigations	Member States	Top 20 most litigated INNs between originator and generic companies ⁵⁴⁸
INN 1	6	DK (6)	X
INN 2	3	DK (2), HU (1)	X
INN 3	2	IT (1), LV (1)	X
INN 4	2	ES (2)	X
INN 5	2	DK (1), SI (1)	X

Source: Pharmaceutical Sector Inquiry

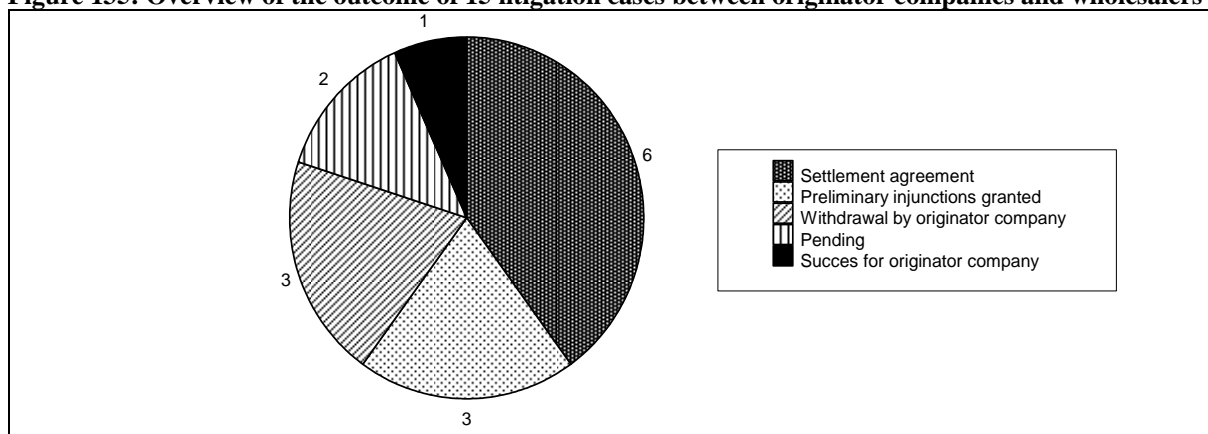
(961) The 15 court cases against wholesalers were brought by four large originator companies on a total of five INNs, all of which are in the top 20 most litigated INNs between originator and generic companies (for details see Chapter C.2.2.). The Member States where wholesalers were brought to court are Denmark, Hungary, Italy, Latvia, Slovenia and Spain. A high number of litigations were reported from Denmark where nine out of the 15 reported court cases were brought.

(962) Several of the court cases against wholesalers (six out of 15) were settled, as can be seen from Figure 135, which gives an overview of the status/outcome of the 15 litigations. The settlement agreements are often linked to other legal proceedings and sometimes involve a payment to the generic company that supplied the wholesaler with the products concerned, mostly for damages claimed by the generic company. In three court cases, a preliminary injunction was granted and distribution of the generic product was prohibited. Another three cases were withdrawn and two are still pending. Only one court case was won by an originator company, with the result that the generic product was withdrawn from the market until the patent expired.

⁵⁴⁸ For further details see Chapter C.2.2.

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Figure 135: Overview of the outcome of 15 litigation cases between originator companies and wholesalers



Source: Pharmaceutical Sector Inquiry

(963) To conclude this section, a brief overview of stakeholders who have received letters from originator companies and of the main arguments used in them, as reported during the sector inquiry, is set out below.

Table 34: Overview of the typical arguments used by originator companies vis-à-vis the main stakeholders

Stakeholders	Typical arguments used
Generic producers	The originator's product is covered by various intellectual property rights, such as patents, data exclusivity, etc.
Marketing authorisation pricing and reimbursement body	The generic product is less safe or not bioequivalent. Possible patent infringement.
Doctors	Legal situation: Prescribing the generic version will be considered an infringement of our patent rights. Safety issues. "We do the research."
Pharmacists	Legal situation: Selling the generic version will be considered an infringement of our patent rights. Safety issues. "We do the research."
Hospitals	Legal situation: Until court cases produce a final outcome, refrain from buying generic products that might infringe patent rights. Safety issues.
Wholesalers	Wholesalers will be brought to court if they (plan to) distribute generic medicines on which patent disputes or litigation are pending.

Source: Pharmaceutical Sector Inquiry

2.5.4.3. Direct-to-Pharmacy (DTP) Distribution

- (964) The traditional model of pharmaceutical distribution in Europe is changing, as major manufacturers switch to a direct-to-pharmacy (DTP) approach. The recent adoption of this model by some of the industry’s largest players in the UK could be a sign of a new trend that could spread across Europe.
- (965) In the majority of EU Member States, disregarding sales to hospitals, the distribution system operates on the basis of a manufacturer—wholesaler—retailer model. Wholesalers purchase medicines from manufacturers and supply the medicines to pharmacies at a margin. As indicated in Chapter B.1.1., there are broadly two types of wholesalers: those who deal in the full range of medicines marketed in a particular country, known as full-line wholesalers, and those specialising in a limited range, known as short-line wholesalers.
- (966) In DTP distribution, the pharmaceutical company sells the medicines directly to the pharmacist. The medicines are delivered by a logistics service provider, which is generally paid a delivery fee per pack and, unlike under the current wholesaler arrangements, does not acquire ownership of the medicine. Typically, an originator company selects one of the large wholesalers to act as its logistics provider.
- (967) As regards the forms of DTP system, a distinction can be drawn between exclusive DTP systems and semi-exclusive DTP systems. In exclusive DTP systems, all orders and deliveries are handled by one exclusive logistics service provider. This can be either the full range of prescription products or individual products. In semi-exclusive DTP systems, all orders and deliveries are handled by two or three logistics service providers. In both cases, all other wholesalers are denied access to the medicines covered by the DTP system.

How widespread is DTP currently?

- (968) As can be seen from Table 35, DTP has already been introduced in the UK by several originator companies with a total market share of approximately 30%.⁵⁴⁹

Table 35: Overview of DTP systems already introduced in the UK

Company	Start date	Products affected
Originator 1	March 2007	All prescription medicines are exclusively available from one logistics provider.
Originator 2	November 2007	Certain medicines are available from only one logistics provider.
Originator 3	February 2007	All products are available from only two logistics providers.
Originator 4	October 2007	All products are available from only three logistics providers.

Source: Pharmaceutical Sector Inquiry

⁵⁴⁹ Based on the figures given by the OFT (2007) report: Medicines Distribution. An OFT market study, p. 22. http://www.of.gov.uk/shared_of/reports/comp_policy/oft967.pdf.

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- (969) Following detailed examination, on 11 December 2007 the UK Office of Fair Trading (OFT) published a report on DTP arrangements in the UK.⁵⁵⁰ The OFT found that, although DTP did not contravene competition rules, there was a significant risk that such arrangements would result in higher costs to the National Health System (NHS). According to the OFT, pharmaceutical companies adopting DTP schemes have the power to reduce the discount given to pharmacies under the traditional wholesale model. Whether this conclusion could apply elsewhere in the EU may depend on the particular features of supply-chain remuneration in a Member State.
- (970) Moreover, according to a wholesalers association, its model includes cross-subsidisation between high-value, high-volume medicines and low-value, low-volume medicines. One possible effect of DTP could be that full-line wholesalers are left with the economically less "attractive" product segment, whereas the economically attractive products are distributed by DTP and short-line wholesalers. Hence, the current cross-subsidisation would be undermined, thereby creating upward pressure on the distribution margin and leading, ultimately, to higher prices in the low-value, low-volume product segment and, possibly, to a deterioration in service levels.
- (971) The OFT announced that it would carefully monitor the exclusivity of medicine distribution arrangements, in order to assess competition in the sector and to take action if necessary.
- (972) In its reply to the sector inquiry questionnaires, one major originator company argued that DTP is necessary to improve the security of the supply chain and reduce the risk of penetration by counterfeit medicines. Once the pharmaceutical product leaves the manufacturer, it can pass through a number of intermediaries before arriving at the pharmacy. This would make it easier to introduce counterfeit medicines into the legal supply chain. However, other stakeholders in the distribution chain claim that the underlying motive for originator companies to switch to DTP is not to stop counterfeit medicines reaching the shelves, but to limit parallel trading of medicines.

Future Developments

- (973) The sector inquiry received information indicating that DTP is currently spreading to several Member States, most prominently Poland and Portugal. However, it has been argued that in certain Member States, such as Portugal, it would be difficult to reconcile DTP systems with the public service obligations that wholesalers must meet.⁵⁵¹ Although pharmaceutical companies are free to choose the distribution methods they deem appropriate, possible anticompetitive aspects of certain

⁵⁵⁰ http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft967.pdf

⁵⁵¹ "The obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question." Article 1(18) of Directive 2001/83/EC on the Community code relating to medicinal products for human use, amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ L311/67 p.67). See also the section on wholesalers in Chapter B.1.1.

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arrangements are and will be carefully scrutinised by the competition authorities in the EU.

Impact of DTP on Market Participants/Distribution of Generics

- (974) Many of the generic companies consulted during the sector inquiry either gave no firm opinion on DTP arrangements or found it too soon to judge their effects. However, a significant number expressed the view that DTP could have negative effects on their business, in particular in the long run. Some respondents stated that widespread adoption of DTP could lead to small manufacturers, both originator and generic companies, experiencing distribution difficulties as distribution costs would increase. In addition, there could be lower discounts to pharmacies, resulting in an increase in medicine prices. Another consequence of DTP highlighted by generic and originator companies alike is that it would lead to concentration at wholesale level, reducing competition in the sector.

One of the generic companies notes that:

"The 'direct to pharmacies' strategy introduced by several originator companies is the materialisation of the will of a number of companies to increase their economic aggressiveness to maintain their sales volume, mainly to face generic competition. In itself, it is a legitimate move as long as these companies do not use the monopoly products they own to improperly bundle sales with other products, namely products which face generic competition."

- (975) Some market participants have also reported that a number of smaller wholesalers have closed down in the UK following the introduction of DTP arrangements.⁵⁵²

Impact of DTP on the Availability of Medicines

- (976) Some associations representing pharmacists and wholesalers expressed doubts about whether the present service levels can be maintained under a DTP system, where orders for medicines must be placed directly with the manufacturer.
- (977) In their opinion, DTP could lead to supply delays and, consequently, difficulties for patients. They also claim that if the viability of the traditional distribution model is seriously affected, those wholesalers who remain in the market may be forced to reduce levels of service, which again could lead to availability difficulties.
- (978) According to one association, DTP also allows manufacturers to limit the supply of medicines to individual pharmacists on a quota basis. This could give rise to supply limitations driven by the desire to exclude parallel trade, but which do not reflect local

⁵⁵² In the context of the public consultation, it has been reported that as a consequence of DTP those full line wholesalers operating in the UK which have not entered a DTP agreement are re-orientating their business model towards home care, hospital services and parallel trade.

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or individual requirements based on patient needs. In the view of this association, there could be increases in demand from pharmacists, dictated by changes in prescribing patterns or policies, and in such circumstances quotas could lead to supply shortages.

2.5.5. Arrangements between Originator Companies and API Producers

- (979) One important component of any medicine is the active pharmaceutical ingredient (API). An API is the substance which provides the therapeutic effect of a medicinal product. A medicinal product can include only one or a mixture of several APIs.
- (980) In order to launch a generic product on the market, a generic company needs to have access to the API in the medicine. The generic company can choose either to produce the API itself or, alternatively, to purchase the API from a third party. A number of companies specialise in producing APIs for the pharmaceutical sector, which they offer to both originator and generic companies.
- (981) As supplying API is one of the upstream links in the supply chain of pharmaceutical companies, the generic companies were asked whether, over the period 2000 – 2007, they had suffered from any discontinuation of supply from an API producer, e.g. following acquisition of the API producer by an originator company or due to an agreement (e.g. patent settlement or licence) between an originator company and the API producer.
- (982) Only six of the generic companies questioned had been in such a situation on one or more occasions. Four of them responded that they had encountered a discontinuation of supply following acquisition of the API producer by an originator company. The same number (not the same companies) responded that a settlement with an originator company had led an API producer not to commence supplying the agreed API or to cease its supply to their company. Finally, one generic company responded that one API producer had terminated its supply after an originator company had acquired a stake in it.
- (983) The Commission also asked originator companies whether they had acquired control over an API producer in the period 2000 – 2007 and, if so, what their reasons for the acquisition had been. Only four of the originator companies questioned responded that they had acquired an API producer. These companies gave several different underlying reasons for the acquisitions, such as the need to secure continuity of supply, the ability to enter new markets and the ability to expand their own business in the market for production of APIs. Furthermore, the Commission's services asked the originator companies whether the acquisition had led to discontinuation of supply from the API producer to generic companies. Only one of the four originator companies admitted that an acquisition had an impact on the supply to generic companies.
- (984) A number of other originator companies responded that they had acquired companies producing APIs but where this was not considered to be their core business. All these originator companies explained that their acquisition(s) had not been based on the API production activity of the company acquired.
- (985) Furthermore, originator companies were asked whether, during the period 2000 – 2007, they had concluded agreements (e.g. patent settlements or licences) or had

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contacts with API producers which had led to discontinuation of the supply of an API from that producer to generic companies. Two companies responded that they had concluded settlement agreements with API producers which had subsequently led the API producer to cease the supply to generic companies. According to both, the API producer had infringed the originator company's patent(s) and the settlement concluded the parties' litigation.

- (986) Generic or chemical companies may also request a licence to manufacture an API directly from the originator company instead of trying to purchase the API from other API producers. An example of such a request which was refused by the originator company and subsequently attracted the Italian competition authority's attention is explained in the box below.

Box: Glaxo Group – Refusal to grant a licence

In February 2006, the Italian Competition Authority (AGCM) concluded that Glaxo Group had abused its dominant position by refusing to grant a licence to Frabbrica Italiana Sintetici SpA (FIS) for the manufacture in Italy of the active ingredient *Sumatriptan Succinate* – used in the production of generic drugs known as triptans for the treatment of migraine – for use in other Member States in which Glaxo no longer held any patent rights. The AGCM found that Glaxo, in addition holding a quasi-monopoly on the production of *Sumatriptan Succinate* worldwide, occupied a dominant position in the Spanish and Italian markets for the production and marketing of triptans sold through hospitals. The AGCM concluded that Glaxo's refusal hindered the production of an active ingredient needed by producers of generic drugs in order to access national markets where Glaxo did not have any exclusive rights.

Despite having ascertained the abusive nature of the conduct, the Authority did not impose a fine as Glaxo had granted the licences to FIS and allowed FOS to make up the time which had been lost because of the original refusal thereby enabling FIS to offer the active ingredient to manufacturers of generic drugs as early as if the refusal had never occurred. As a result, well before the conclusion of the proceedings, a producer of generic drugs had succeeded in entering the Spanish market.⁵⁵³

⁵⁵³ In another refusal to licence case, the Italian Competition Authority (AGCM) in November 2006 accepted Marck Sharp & Dohme (MSD) commitment to offer free licences to manufacture and sell the active ingredient *Finasteride*. In June 2005, as part of the same case, AGCM adopted interim measures obliging MSD to issue licences authorising the production in Italy of the active ingredient *Imipenem Cilastatina*.

Summary

Apart from originators' medicines obtaining patent protection, all medicines, whether originator or generic, need to obtain a marketing authorisation and in most Member States also pricing and reimbursement status before they can be put on the market. A number of originator companies intervened before marketing authorisation and/or pricing and reimbursement bodies when generic companies applied for marketing authorisation and pricing/reimbursement status for their medicines, claiming that generic products were less safe, less effective and/or of inferior quality. Certain originator companies also argued that marketing authorisations and/or obtaining pricing or reimbursement status could violate their patent rights, even though marketing authorisation bodies must not take this argument into account according to EU legislation.

From the litigation reported, the claims of these originator companies were upheld in only 2% of the cases concerning marketing authorisation, suggesting that the arguments submitted by these originator companies in many cases could not be substantiated. Originator companies had also a low success record in cases concerning data exclusivity, i.e. when they claimed that marketing authorisation for a generic product cannot yet be granted due to data exclusivity rules protecting the originator product. The final court judgements confirmed claims of originator companies in 19% of those cases.

Intervention and litigation by originator companies in administrative proceedings for generic medicines can lead to delays to generic market entry. In relation to a sample that was investigated, the inquiry showed that marketing authorisations were granted on average four months later in cases in which an intervention took place. The sector inquiry produced evidence that such practices generated significant additional revenues on a number of originator products.

Originator companies devote a significant part of their budgets to marketing of their products with medical doctors and other health care professionals. The sector inquiry produced indications that some originator companies sought to put into question the quality of generic medicines, as part of a marketing strategy, and even after the generic product was authorised by the relevant authorities and was available on the market.

Finally, there are indications that a number of originator companies attempted to influence wholesalers preparing for the supply of generic products. Also some generic companies complained about interventions at supply sources for the active pharmaceutical ingredients needed to produce the generic medicines in question.

2.6. Life Cycle Strategies for Follow-on Products

2.6.1. Introduction

- (987) Incremental research is important as it can lead to significant improvements of existing products in different steps, also from the perspective of the patients. These may include the discovery of new therapeutic uses for a given product, which may represent important innovations in terms of public health protection, or certain categories of changes to the products formulation within the same indication. Most originator companies do research for incremental innovation for top-selling products in their portfolio to ensure further development of their products, sometimes leading to "second generation products" and the continuity of their revenue stream.
- (988) The reason why the inquiry looked into the issue of follow-on products is not to put into question incremental innovation as such. Rather it is suggested that the launch of a second generation product can be a scenario in which an originator company might want to make use of instruments that delay the market entry of generic products corresponding to the first generation product. The companies have an incentive to do so in order to avoid, for the second generation product, exposure to competition stemming from generic versions of the first generation product. Therefore, the purpose of this section is to analyse the use of the toolbox in a situation where "second generation" or "follow-on products" are launched.
- (989) Originator companies often launch second generation or follow-on products shortly before loss of exclusivity of the first generation product, which is sometimes combined with the withdrawal of the initial product from the market. This is accompanied by intensive marketing efforts, such as detailing, in order to switch a substantial part of prescriptions, and patients to the new product.⁵⁵⁴ As a result, generic companies may encounter some difficulties to sell their generic version of the previous product. This chapter will show that sometimes follow-on products are part of a life cycle strategy that goes beyond the pure patent strategies and that in addition involves marketing and promotion strategies, as well as other practices discussed in previous chapters.⁵⁵⁵
- (990) For the purpose of the following analyses, second generation or follow-on products are defined as products that result from follow-up R&D essentially based on that of an existing product ("first product") and have essentially a similar mode of action. These second products may have the same INN as the first product (e.g. second products involving *inter alia* new formulations, crystalline forms, particle sizes or medical uses) or a different one (e.g. combinations, individual stereoisomers separated from mixtures or the identification of metabolites of an existing INN).

⁵⁵⁴ For further details see Chapter B.1.2.

⁵⁵⁵ For further details see Chapters C.2.1. and C.3.1.

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- (991) This section will first give a general overview of the rationale of follow-on products and their market relevance before examining mechanisms of switching from the first to the second generation products, including patenting of these products. This will be followed by an examination of timing and economic considerations concerning these switches. The analysis will then turn to practices employed by originator companies to facilitate switches of patients from the first to the second generation product. The section will conclude by looking at the effects of such switches on generic entry.
- (992) It is not the purpose of this sector inquiry to provide guidance as to the compatibility of certain practices with EC competition law. The Commission will further investigate whether individual company behaviour may have fallen foul of the competition rules.

2.6.2. Rationale of Follow-on Products

- (993) Originator companies maintain that even small incremental innovation within a product may result in products that satisfy unmet/differentiated needs of consumers. These are, for example, the need to enhance compliance (e.g. once daily, once weekly administration), to facilitate administration of the pharmaceutical (e.g. through tablets that are easier to swallow or transdermal patches) or to facilitate administration in conjunction with another substance, as in the case of added vitamins or combination products.
- (994) Several generic companies and their industry associations and consumer associations have, on the other hand, strongly criticised life cycle strategies leading to second generation products. They refer to these practices as "evergreening" and have raised concerns about their effects, in particular when there are no improved therapeutic effects. They claim that some of the new products show little if any innovation and limited if any additional benefits, and that they serve primarily to retain the revenue streams of the first generation product.
- (995) It is logical from an economic perspective to focus incremental innovation on the top-selling products which meet most therapeutic demand but also face a threat for potential competition. The present report does not question the appropriateness of follow-on products themselves. Yet, the circumstances associated with the introduction of follow-on products to the market suggest that originator companies may sometimes use different means in an endeavour to prevent the follow-on products being confronted with competition, most notably from generic versions of the first product which lost or is about to lose exclusivity.
- (996) Strategies for launching follow-on products are in some cases valued for their potential of preventing competition from generic companies, as is suggested by the following quote of an originator company:

"[Our second generation product] represents the most effective strategic initiative to counter generic [versions of the first generation product] [...]"

- (997) Another originator company highlighted the purpose of launching its second generation product in the following way:

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"[Our second generation product] is a new formulation of [our first generation product], launched initially as a line extension to maintain the growth momentum of the product."

(998) A statement by a national authority corroborates this:

"In our point of view the originators companies have [...] developed several strategies to create barriers to the fully [sic] development of generics. The most common of these strategies are: [...] the development of new formulations or new combinations of active substances already on the market; the development of new active substances that are isomers from the already approved and reimbursed ones."

(999) Similarly, a wholesaler considered that:

"Originator companies do occasionally introduce a second generation patent in an attempt to forestall the introduction of generic products. [...]"

2.6.3. Market Relevance of Follow-on Products and Mechanisms for Product Switches

(1000) The data used in this section was gathered by focussing on second generation products as defined above and which are marketed within the three largest national markets in the EU: France, Germany and the UK. Furthermore the collection of data was restricted to switches from first to second generation products where at least one of the products was included within the 219 INNs on which in-depth analysis was carried out in the sector inquiry. Originator companies were asked to complement the previously submitted data if it turned out that only one of the products was in the INN list.

(1001) It should be noted that the originator and generic companies questioned did not have the same view as to what products could be considered as second generation products. The originator companies reported 38 INNs whereas the generic companies identified 72 INNs for which a second generation product has been developed. The overlap between these two universes consisted of 22 INNs (hereafter called the "FP22 universe") meaning that in total 88 INNs (hereafter called the "FP88 universe") were reported for which a second generation product has been developed. It is noteworthy that some widely published examples of second generation products were not reported by the originator companies despite the fact that the first or second generation product was in the INN list.

(1002) The scope of the data analysis of the section on market relevance of the follow-on products and of the originator companies' practices facilitating product switches uses the FP88 universe, while the section on patenting as well as the one on the timing of product switches uses the FP22 universe.⁵⁵⁶

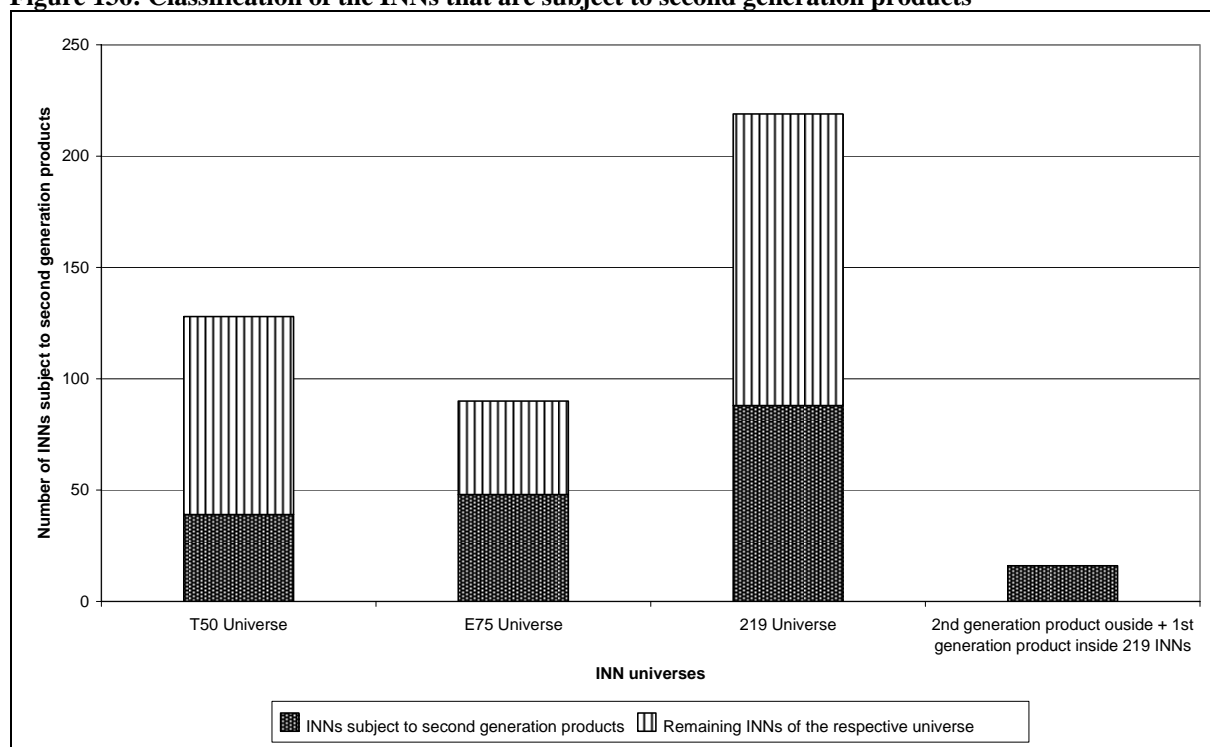
⁵⁵⁶ It has been argued during the public consultation by the originator industry that the Commission ought to have used a wider sample for this analysis. However, the FP22 universe constitutes a conservative sample, as it comprises cases of product switches recognised by both the originator and generic

2.6.3.1. Market Relevance of Follow-on Products

(1003) The FP88 universe represents 40.1% of the 219 INNs covered by the sector inquiry. It is also noteworthy that 39 INNs of the FP88 universe are part of the top selling "T50 list" (i.e. 30.4%). In addition, 48 INNs of the FP88 universe also fall within the E75 scope which represents a list of top selling products which lost exclusivity in the period 2000 – 2007 (i.e. 53.3%). For 16 INNs of the FP88 universe, the second generation INN fell outside the scope of the 219 INNs covered by the sector inquiry when the first generation INN fell inside that scope. Figure 136 gives an overview of these classifications:

(1004) It is also interesting to see that for 24 INNs out of the FP88 universe, the second generation product creates a new INN compared to the first product. For the other INNs, the first and second generation products refer to the same INN. Within the 24 instances where a change in INN could be detected, in 18 cases the new INN was a combination, in three cases a single enantiomer and in the remaining three cases a metabolite. For two other reported INNs, on top of the previously mentioned 24 instances, the second generation product was characterised as a new salt form of an existing INN.

Figure 136: Classification of the INNs that are subject to second generation products



Source: Pharmaceutical Sector Inquiry

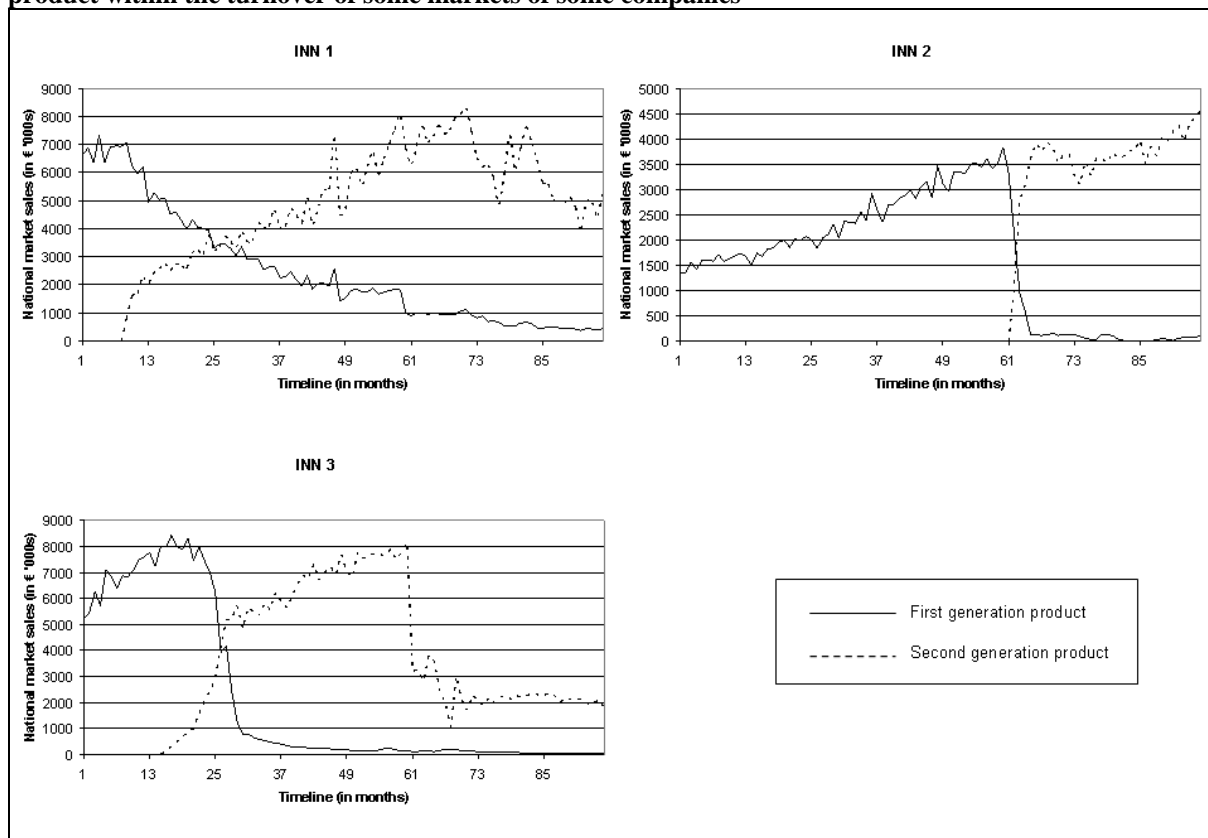
(1005) Often, the second generation products launched by originator companies relate to those first generation products that constitute a big part of a company's turnover. An example

companies, which makes it a relevant sample to be analysed, while still representing 10% of all investigated INNs.

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of a successful way of switching patients to the second generation products shown by the sales of a few high turnover INN from the FP22 universe have been represented below in Figure 137. The three graphs represent three different INNs in three different geographical markets whereby month 1 stands for January 2000 and month 96 for December 2007. It can be seen that patient switching was successful as the sales of the first product decreases and is replaced by the sales of the second generation product within a fairly short timeframe. For the three examples, the turnover of the second generation product represents between 10 and 20% of the company's turnover.

Figure 137: Examples of how the sales of a second generation product take over the part of the first product within the turnover of some markets of some companies⁵⁵⁷



Source: Pharmaceutical Sector Inquiry (based on IMS data)

(1006) In conclusion, for many commercially important INNs, second generation products come onto the market. In this context patient switching is a major challenge for the originator company to preserve a high turnover.

⁵⁵⁷

It has been argued during the public consultation that no trend can be seen from Figure 137 as the curves are very different in the three cases. The curves are indeed different as sales value evolutions are product and market specific. However, all three cases do have an important common characteristic: the level of sales of the 2nd product reaches the same level as the first product after the switch has taken place, while the sales of the 1st product plunge to marginal levels. In addition, it was questioned that a switch to a follow-on product is successful as sales for INN 3 drop at month 60. However, this sudden drop in sales was due to supply problems from the side of the originator company.

2.6.3.2. Mechanism for Product Switches

- (1007) Where a company takes the strategic decision to counter the loss of exclusivity of the first product with a launch of a second generation product, it will need to engage in a series of activities, spanning from the underlying incremental R&D to the final launch of the follow-on product, and even beyond.
- (1008) Patenting of originator incremental innovation is a very important, although not the only stepping stone for this strategy. But it is essential, as it will provide for the necessary exclusivity of the follow-on product. To do so, the timing of such patenting must ensure that the exclusivity of the follow-on product will extend beyond the protection period of the first product. In addition, a broad patent portfolio may be created around the follow-on product to secure effective exclusivity, and possibly also around the first product to prevent generic entry before the launch of the follow-on product.
- (1009) Next stage is the product development, the course and extent of which may diverge significantly depending on whether new clinical trials will be necessary or not in order to obtain the marketing authorisation.
- (1010) Timing the launch of a follow-on product is crucial for originator companies. If cheaper, generic versions of the first product come on the market before or simultaneously with the switch to the follow-on product, the originator company may incur considerable value losses both in terms of smaller volumes and reduced prices. Therefore, it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity.
- (1011) This means that very often accompanying measures are taken by the originator company to facilitate the switch. Such measures typically aim at effective channelling of demand from the first product to the follow-on product, but may in certain cases also attempt to delay or prevent generic entry for the sensitive period of the product switch.

2.6.3.2.1. Patenting for Second Generation Products

- (1012) Most originator companies do research for incremental innovation for top-selling products in their portfolio to ensure further development of their products, sometimes leading to "second generation products". In order to preserve the revenue streams from such a top-selling product, the second generation product needs to be protected by the same kind of exclusivity. This subsection will look at patent exclusivity for incremental innovation, while the issue of data exclusivity will be touched upon in the subsequent one.
- (1013) In any event, efficient patent protection is crucial in order to maintain exclusivity of the second generation product. This means that an originator company will have to file patent applications early enough to ensure continuous exclusivity of its products but

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also, as in the case of the first product, to create several layers of patent protection making it difficult for generic companies to develop a generic version of the follow-on product without infringing any patent.⁵⁵⁸

- (1014) As demonstrated earlier,⁵⁵⁹ originator companies continue patenting throughout the life cycle of the first product. Moreover, the data gathered in the sector inquiry shows that patenting activity often re-intensifies in the period close to the loss of exclusivity. Such patents may be used to buttress the exclusivity of the first product throughout the expected patent protection term, and possibly even beyond, as well as to protect a possible follow-on product.
- (1015) Patent protection for a second generation product may be sought through the filing of either new primary patent applications, e.g. for combinations, or through the filing of a secondary patent application relating to the first product, e.g. a reformulation, or different dosage regimes.
- (1016) Originator companies claim that second generation products are the result of incremental innovation. Most originator companies with second generation products asked within the framework of the sector inquiry stated that these products were developed to address unmet patient needs and offered clinical benefits vis-à-vis the old product. If this was not the case, they argued, patients and doctors could not be convinced to use them.⁵⁶⁰ This is summarised most comprehensively by the following answer of an originator company:

"[...] "Second pharmaceutical products" have to meet the expectation of the customers and thereby heavily compete with the "first pharmaceutical product" and/or its generic competitors. Consequently, it is ultimately the customer who makes the choice between the existing products, its generic equivalents or "second pharmaceutical products". The latter will fail if they do not add therapeutic advantage."

- (1017) At the same time, concerning a second generation formulation product, another originator underlined its potentially impeding effect for generics:

"While this formulation will not prevent the entry of generics into the [...] market (once exclusivity for the first product has expired), it is expected to protect a good portion of the business for several reasons:

a) The formulation technology and manufacturing process are patented [...], and [our company] has the exclusive license to this technology for use in [this product category]. [...] Again these elements will not prevent a generic to enter the market but will make it less attractive."

⁵⁵⁸ For a more detailed discussion on patent clusters see above Chapter C.2.1.

⁵⁵⁹ For further details see Chapter C.1.2.

⁵⁶⁰ It should be noted that patents protecting the results of incremental research must meet normal patentability requirements of novelty, inventive step and industrial application.

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(1018) In this context, the European consumer association, BEUC, claimed to be:

"[...] very much concerned by the phenomenon of so-called "evergreening", which describes a specific tactic used by originators to extend patents by seeking to obtain as many patents as possible during the development of the product and the marketing phase, and to obtain a patent extension for new manufacturing processes, new coating and new uses of established products. [...] Originators can also slightly change an active ingredient and present an old medicine as a new product and register a new patent. We consider that these practices are anticompetitive and prevent generics entry into the market means. They also incur higher health care expenditures and/or higher prices for consumers."

(1019) Equally, when asked about their perceptions of originator companies' patent strategies, a number of national authorities replied that they considered the way originator companies used patents for second generation products as part of a strategy to create obstacles to market entry by generics, as illustrated by the following quote of one such authority:

"In fact, there are special strategies linked to patents, which can constitute barriers to entry for generics. A quick legal research allowed [us] to supply a few examples:

- Modification of composition of the pharmaceutical specialty*
- Extension of therapeutic indication [...]*
- launching of an enantiomer*
- registering a patent as regards a new formulation, which is presented as more efficient."*

2.6.3.2.2. Development and Marketing Authorisations of Follow-on Products

(1020) Once a patent basis is established for follow-on products, the originator companies will proceed with the development of the compound with a view to marketing it. Follow-on products are typically based on incremental innovation.

(1021) Similarly, one wholesaler pointed to the timing in relation to follow-on products:

"[...] originator companies have attempted to reduce the impact of pending generic competition by introducing apparent last minute improvements to products, or by changing the galenic form of their molecule."

(1022) In this context it has to be noted that changes in the strength, pharmaceutical form, administration routes, presentations, as well as any variations and extensions will not trigger a new period of data exclusivity as the corresponding marketing authorisations will fall under the global marketing authorisation whereby only the initial data

exclusivity period will apply.⁵⁶¹ Therefore, if a second generation product would be based on any of the previously mentioned changes, in order to preserve exclusivity the originator company would have to seek protection via the patent system as no extension of the data exclusivity period would be granted.

(1023) When second generation products rely on a new INN (e.g. via combination, single enantiomer or metabolite), new clinical trials would in principle be necessary. This would on the one hand imply a longer product development as compared to products that fall under a global marketing authorisation. On the other hand, the originator company will enjoy a new data exclusivity period if the second generation product is considered to contain a new active substance.⁵⁶² Hence, such follow-on products would be able to find protection via data exclusivity as well as via the patent system.

2.6.3.3. *Timing and Economic Considerations of Product Switches*

(1024) Irrespective of the type of patent protecting a second generation product, the patent will usually provide the company in question with further patent protection in addition to the exclusivity enjoyed for the first product, provided that the company can switch patients from the old product to the new one. This would allow the originator company to maintain the market share by retaining comparable volume levels as well as preventing a price decline which usually occur with generic market entry. Such a switch of patients to second generation products may, however, not be easy if generic versions of the old product have already entered the market before or simultaneously with the follow-on product.⁵⁶³ Where a clear-cut therapeutic advantage is either not apparent or cannot be communicated, the success of the follow-on product might be constrained by more cost-effective generics.

(1025) Hence, once generics are on the market, it becomes more difficult to switch patients to second generation products, as observed by an originator company:

"If [generics] come together with or prior to [second generation product] the switch rate is dramatically reduced. [...] Once [generics] come in it becomes more difficult to get switches from [old original product]"

(1026) In this context the importance of the price level – and the fall of prices following generic entry is – illustrated by the following remark by a generic company:

⁵⁶¹ Directive 2001/83/EC Art 6 as amended by Directive 2004/27/EC Art. 1.5 (a).

⁵⁶² This will be the case if a new form of an active substance (e.g. isomer, mixture of isomers, a complex or derivative or salt) differs in properties with regard to safety and efficacy from the substance previously authorised.

⁵⁶³ For further details see Subsection C.2.5.3.2.

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"A pre-patent expiry entry of the second generation product enables the Innovator to switch patients in a pricing climate where the first generation product price is stable. The second generation product may be priced at or slightly below the first product, and positioned as being 'better and similarly cost effective'. If the prescriber is prepared to accept this Innovator argument and switch prescribing, he is unlikely to go back subsequently to the first generation product when a generic is available. If the second generation product appears after patent expiry of the original product, then the pricing climate will be different. The generic will have caused the market price to fall, and thus to switch to the newer product will likely incur a cost penalty to the physician budget, something he is likely to resist unless the second generation is a compellingly better product. This is seldom if ever the case."

- (1027) There are several possible reasons why the switch of patients to a new originator product is more difficult once generic versions of the old product are used. Some of the explanations derive from obligations by the regulatory framework, generic substitution by physicians or prescription inertia of physicians. The latter is suggested by the following quote of an originator company:

"[...] not all physicians are equally amenable to switch programs. In general the [therapeutic class] market is a slow switch market and physicians do not see the (our) urgency for actively switching their patients. [...] getting general agreement is "easy", actual and immediate behavioural changes however are hard to achieve."

- (1028) Originator companies are aware of their competitive advantage if they manage to switch patients to the second generation product before loss of exclusivity for the first product:

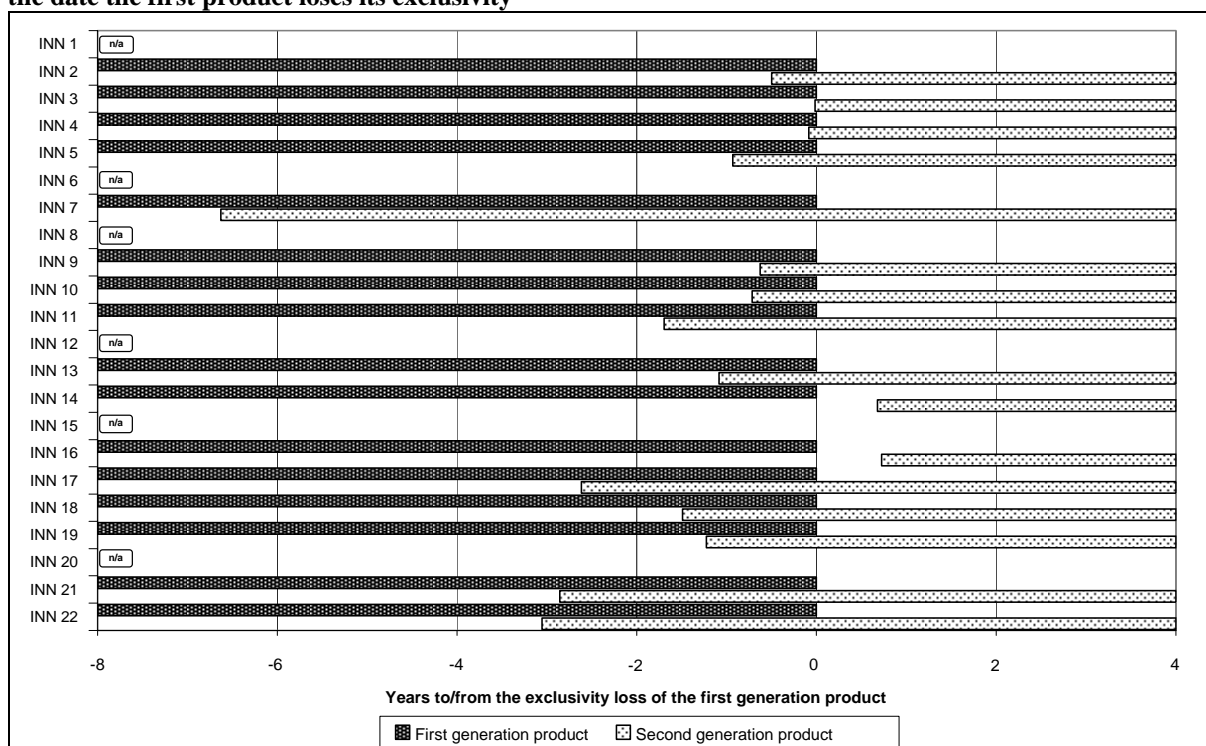
"The launch of [our second generation product] is a challenge, not experienced until now, as generics firms, [...] press onto the market with all force and as we have to fear the loss of our patent [...]. This means each patient that is not switched quickly enough to [our second generation product] is forever lost to the generics. Once the patient is switched to [our second generation product] the physician does not have to, cannot and will not switch him to a generic, and what is more important: the pharmacist cannot substitute!! "

- (1029) The above quotes also indicate that, to optimise the product switch, originator companies need to flank the launch with significant accompanying activities aiming at adapting the prescribing behaviour to the benefit of the follow-on product. More generally, the need to secure the switch to the new, follow-on product before the onset of generic versions of the old one may prompt the originator companies to resort to other life cycle instruments. This would especially be the case where generic entry could pre-date, or coincide with the launch of the follow-on product. Practices that originator companies resort to in order to facilitate product switches in the critical time span sensitive to generic entry ("bridging strategy") will be examined further below.
- (1030) The actual timing of second generation product launches seems to confirm the originator companies' need to launch before generic entry. An overview of the above-mentioned FP22 universe regarding the launch date of the second generation product in comparison with the date the first product loses its exclusivity has been given in Figure 138 below. The dark grey bar represents the exclusivity period of the first

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product whereby at time zero loss of exclusivity occurs. The light grey bar shows when the second generation product has been launched.

Figure 138: Comparison for the FP22 universe of the launch date of the second generation product with the date the first product loses its exclusivity⁵⁶⁴



Source: Pharmaceutical Sector Inquiry

(1031) For the INNs on which data were submitted, Figure 138 shows that for at least ten of the INNs, the launch date of the second generation product was close to the date of loss of exclusivity of the first product. The average time a second generation product would be launched ahead of loss of exclusivity of the first product is around one year and five months according to the reported data. For at least three of these ten INNs, the first products were withdrawn shortly (in most cases a few months) after the launch of the second generation products (this is not depicted in Figure 138).

2.6.3.4. Practices Employed by Originator Companies to Facilitate the Switch

(1032) In view of the above, it is clear that the timing of the launch of generics and of next generation originator products for the same indication becomes crucial for the market success of both originator companies and generic companies. This further emphasizes that delays in the crucial market introduction phase of generic medicines can make or break a business case.

⁵⁶⁴ Where more than one of the three markets concerned was reported for a given INN, the average time of launch date and exclusivity has been calculated. In other cases only one market was reported.

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(1033) Where a company encounters difficulties to switch from a first to a second generation product, it may need to resort to its tool-box to delay generic entry until the switch took place. A clear case of bridging the potential gap between patent expiry of an old product and the effort to switch patients to the new generation product by delaying market entry of generic versions of the old product is the AstraZeneca case, decided by the Commission in 2005.⁵⁶⁵ Here, the originator company AstraZeneca (AZ) employed several tactics in order to prevent entry of generic omeprazole when its patent for the relevant original product Losec was about to expire. This included instigating the withdrawal of the marketing authorisation for AZ's own old product, thereby removing the reference pharmaceutical, which generics needed at the time to obtain their market authorisation. This strategy succeeded in part in certain countries in keeping generics off the market for an additional period during which the company would aim at switching patients from the first generation product omeprazole to its patent protected second generation product esomeprazole:

"Indeed, the primary aim of AZ's Losec Post Patent Strategy is to facilitate the switch from its omeprazole based products to its esomeprazole based products at as high a reimbursement price as possible, in particular through exclusion of generic omeprazole prior to the launch of the new generation product. This emerges clearly from AZ's national strategy documents for Denmark, Norway and Sweden".⁵⁶⁶

(1034) The underlying strategy was confirmed by the following quote from an internal document of AstraZeneca for the Danish market, cited in the decision, pointing out the necessity to block generic entry until a successful switch has occurred:

"Total omeprazole market share will probably be quite stable, but a big part of the Losec market share will most likely be taken over by generics in 2000-2001. [Esomeprazole] is scheduled for launch August 2000. It will be very difficult to launch [esomeprazole] successfully, since Astra by this time will not be the market leader and the price gap between [esomeprazole] and generics will be large..."⁵⁶⁷

(1035) In this context the sector inquiry sought to establish whether originator companies involved in the practice of such life cycle strategies simultaneously used other instruments to delay generic entry such as interventions at regulatory bodies and litigation or expressing concerns about generic versions of their products. This would be of particular interest if the companies apply a so-called "bridging strategy" to confront the situation where the life cycle of the original product comes to an end before the successful launch of a new generation product.

⁵⁶⁵ Commission Decision of 15 June 2005 (Case COMP/A. 37.507/F3 - AstraZeneca); currently under appeal currently pending before the Court of First Instance (T-321/05).

⁵⁶⁶ Commission Decision of 15 June 2005 (Case COMP/A. 37.507/F3 - AstraZeneca) para. 532.

⁵⁶⁷ Commission Decision of 15 June 2005 (Case COMP/A. 37.507/F3 - AstraZeneca) para. 299.

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(1036) As outlined below in Chapter C.2.7., there is a high correlation between the different strategies and practices as originator companies combine the use of different instruments in their "tool-box" for the same product.

Marketing of the first and follow-on product

(1037) Switching patients from a certain product to a second generation product does not happen automatically and needs a lot of marketing and promotion efforts. Especially a strong sales force will be needed in order to convince the physicians of the merits of the follow-on product and to switch their prescription behaviour towards the second generation product.

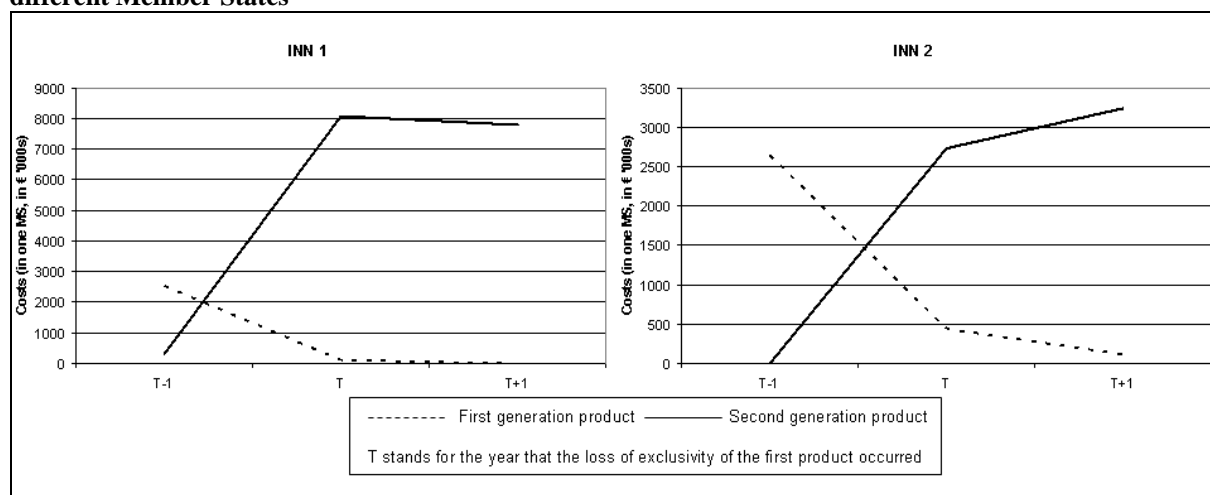
(1038) When asked about the means used to confront generic products eroding second pharmaceutical products most originator companies highlighted the necessity of bringing the advantages of second generation products to the attention of patients and doctors, in particular clinical benefits or the satisfaction of unmet patient needs, e.g. ensuring patient compliance or facilitating administration of the medicine. Thus the companies emphasised substantial improvement of the second generation product vis-à-vis the old one. However, when some originator companies that had launched second generation products were requested by the Commission services to submit separate information on their marketing expenses for their first products and for the second generation products many of those companies replied that they were not able to split the marketing costs of the first products from those of the second generation products as is illustrated by the following quote:

"[Our company] does not record its marketing costs separately for the different products sold under the [...] brand. Marketing costs are only recorded for the brand as a whole."

(1039) The analysis of the information that was submitted by some originator companies showed a decrease regarding marketing and promotion costs for the products that were about to lose exclusivity. Especially in the year before loss of exclusivity of the first product, one could see a switch of the marketing and promotion budget towards the second generation product. Two real-life examples of switching marketing and promotion budgets from the first to the second generation budget can be seen in Figure 139 below whereby year T stands for the year that loss of exclusivity of the first product occurs.

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Figure 139: Marketing and promotion costs for first and second generation products for two INN in different Member States



Source: Pharmaceutical Sector Inquiry

Litigation against generics vis-à-vis patent infringements concerning the first product

(1040) Out of the 68 INNs that were subject to litigation between originator and generic companies (for details see Chapter C.2.2.), 31 INNs were among the FP88 universe of INNs that have been reported as being subject to second generation products. More specifically, more than 405 of the 698 litigation cases that have taken place between originator and generic companies dealt with an INN subject to a second generation product. The outcome of these 405 litigation cases shows similar results as the conclusions that have been drawn for the total set of 698 litigation cases (i.e. that around 60% of the outcome of the cases were in favour of the generic producer).

Withdrawals of marketing authorisations for the first product

(1041) Generic companies reported that for at least nine INNs, the withdrawal of the marketing authorisation has caused problems in the past to launch the generic version. All of these INNs were among the FP88 universe of INNs that have been reported as being subject to second generation products. After a revision of Directive 2001/83/EC the withdrawal of the marketing authorisation of the reference product does not form a problem anymore for the producer of a generic version referring to it.⁵⁶⁸

Intervention at marketing authorisation bodies as regards generic versions of the first product

⁵⁶⁸ See revised Art.10(1) of Directive 2001/83/EC stating that reference under the abridged procedure must be made to a product which "is or has been authorised."

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(1042) Out of the 43 INNs that were subject to pre-litigation contacts and disputes with marketing authorisation bodies (for details see Chapter C.2.5.), 22 INNs were among the FP88 universe of INNs that have been reported as being subject to second generation products. More specifically, 97 of the 195 reported intervention cases that have taken place between an originator company and a marketing authorisation body dealt with an INN subject to a second generation product.

Intervention at pricing/reimbursement bodies as regards generic versions of the first product

(1043) The same observation can be made for intervention at pricing and reimbursement bodies where for the 19 INNs that were subject to pre-litigation contacts and disputes with pricing and reimbursement bodies (for details see Chapter C.2.5.), 11 INNs were among the FP88 universe of INNs that have been reported as being subject to second generation products. More specifically, 29 of the 40 reported intervention cases that have taken place between an originator company and a pricing and reimbursement body dealt with an INN subject to a second generation product.

Settlements

(1044) Out of the 49 INNs that were subject to a settlement between an originator and a generic company (for details see Chapter C.2.4.), 21 INNs were among the FP88 universe of INNs that have been reported as being subject to second generation products. More specifically, 108 of the 207 reported settlements that have taken place between an originator and a generic company dealt with an INN subject to a second generation product.

Withdrawals of first generation products

(1045) Furthermore, generic companies report that originator companies withdraw first generation products from the market and switch to second generation products. They claim that such withdrawals before generic market entry leave doctors and patients with no other choice than to switch to the second generation product. As already mentioned above three such withdrawals of first-generation products were reported among the FP22 universe after a second-generation product had been launched. These withdrawals were carried out shortly (in most cases a few months) after the launch of the second generation products and before loss of exclusivity of the first generation product.

2.6.4. Effects of follow-on product switches on generic entry

Success rate of switching in products examined

(1046) In six INNs out of the FP22 universe, originator companies stated that they succeeded in switching nearly 100% of the patient base from the first to the second product. In all other cases companies claimed that they could not give percentage estimates of successfully switched patient basis, as explained illustratively by the following quote:

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"[...our company] considers that it would not be possible to identify the proportion of the patient base (in terms of market volume) that switched from the first to the second product at any time in the relevant period because it is not possible to identify those patients that switched from the first to the second product as distinct from those that commenced on the second product."

Delay of generic entry into the market

- (1047) Switching patients to the next generation product before patent expiry may have an effect on the market entry of generic versions of the first generation product, as one generic company explained:

"In some cases we develop a product [...] but by the time we come to launch [...] the market has completely gone or switched to another molecule / form and our opportunity has diminished."

- (1048) These strategies are also reported to exist by authorities as one national pricing and reimbursement authority observed:

"There are a number of examples where the introduction of a second generation – patent protected-version of a product prior to such generic entry and at the same time withdrawal of the first (or previous) generation of that originator product from the market [...] caused a shift of budgets towards the second generation patent protected, therefore no generics, [...]"

- (1049) A similar experience was mentioned by another generic company:

"[T]he market situation was not favourable to generic versions due to the introduction of a new pharmaceutical form by the originator company, which would [make it] difficult for generics to achieve a reasonable market share."

Summary

Incremental research is important as it can lead to significant improvements of existing products, also from the perspective of the patients. Amongst others these may include the discovery of new therapeutic uses for a given product, which may represent important innovations in terms of public health protection, or certain categories of changes to the products formulation within the same indication. Patents protecting the results of incremental research must meet normal patentability requirements of novelty, inventive step, and industrial applicability. In the course of the sector inquiry generic companies and consumer associations sometimes questioned the actual improvement of certain categories of changes, in particular with respect to their therapeutic benefits.

The findings of the inquiry suggest that for 40% of the medicines in the sample selected for in depth investigation, which had lost exclusivity between 2000 and 2007, originator companies launched second generation or follow-on medicines. Nearly 60% of the patent related litigation cases between originator and generic companies examined in the context of the inquiry concern medicines that moved from first to second generation products.

The launch of a second generation product can be a scenario in which an originator company might want to make use of instruments that delay the market entry of generic products corresponding to the first generation product. The companies have an incentive to do so in order to avoid generic exposure for the second generation product.

In this respect the inquiry indicates that in order to successfully launch a second generation medicine, originator companies undertake intensive marketing efforts with the aim of switching a substantial number of the patients to the new medicine prior to the market entry of a generic version of the first generation product. If they succeed, the probability that generic companies will be able to gain a significant share of the market decreases significantly. If on the other hand generic companies enter the market before the patients are switched, originator companies may have difficulties in convincing doctors to prescribe their second generation product or in obtaining a high price for the second generation product.

On average the launch took place one year and five months before loss of exclusivity of the first generation product. In some cases the first medicine was withdrawn from the market some months after the launch of the second generation medicine.

2.7. Cumulative Use of Practices Against Generic Companies

(1050) As described earlier in this report (see Chapter C.2.1.), practically all originator companies have developed a tool-box of measures/instruments that can be used throughout the product life cycles to maximise the revenue stream from existing pharmaceutical products by delaying or dampening the effect of generic entry. It needs to be underlined that, as shown in the present chapter, the use of various instruments varies from company to company and from product to product. While the set of instruments available to originator companies (tool-box) is open-ended and thus not defined, the present section focuses on all practices described in Chapters C.2.1.-C.2.5.

(1051) While the preceding chapter concentrated on the various aspects of a specific life cycle strategy concerning follow-on product, this chapter presents a global picture of the overall occurrence of various instruments that originator companies may use in their strategies to hold rivals at bay. It will focus on possible cumulative use of these tools for a given INN, which will normally render generic entry more difficult than if only a single tool is used. Typically, such effects would take the form of delays in or disincentives for such entry. As already explained, delays of generic entry result from a number of factors including the regulatory environment and could not only be ascribed to practices of originators. Moreover, the present analysis does not claim that conduct geared against generic entry, be it on a stand alone or a combined basis, is invariably or often anti-competitive, since it is not the purpose of this report to classify any behaviour as anti-competitive. As mentioned, the Commission will further investigate whether individual company behaviour may have fallen foul of the competition rules.

(1052) First, this chapter will briefly analyse the main instruments/tools that originator companies may use against generic companies. Then some empirical data will be presented and, finally, the effects of possible cumulative use of several practices will be described.

2.7.1. Impact of Instruments on Generic Entry

(1053) Originator companies respond in several ways to the changing competitive environment and may use one or more instruments to diminish the entry incentive for generic companies. Their strategies⁵⁶⁹ are often labelled "generics defence strategies" or "brand protection strategies", but also "late life cycle management" since, as shown in previous chapters, these instruments are most often deployed in the period surrounding loss of exclusivity.

⁵⁶⁹ Originator companies may deploy a life cycle strategy, as outlined in Chapter B.1.2., by making combined use of the various tools, an example of which was presented in Chapter C.2.6. which deals with follow-on life cycle strategies.

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(1054) The evidence gathered during surprise inspections confirms that the companies indeed combine legal actions and other activities in an attempt to prevent generic entry, as exemplified by the following quote:

"We wish to exhaust all possible options and legal means to keep the [specific] generics of [compound] in [Member State] off the market."

(1055) The instruments most used by originator companies considered in this context are i) creation of a broad patent portfolio (Chapters C.1.2. and C.2.1.); ii) patent disputes and contacts (Chapter C.2.2.); iii) patent litigation (Chapter C.2.2.), iv) patent settlements (Chapter C.2.4.); and v) interventions before regulatory authorities and other interventions (chapter C.2.6.).

(1056) The panoply of instruments available to originator companies may be used to confront generic entry in two main ways. Firstly, by relying on a broad patent portfolio, i.e. by a combination of patenting activity and enforcement of patents by way of litigation and settlements, the originator may attempt to postpone the loss of exclusivity for its product. Secondly, the originator company can also try to defer generic entry after the loss of statutory exclusivity, most notably by intervening before regulatory bodies.

(1057) During the public consultation, originator companies, associations of originator companies and certain law firms have argued that the causal link between the practices and the delay of generic entry has not been established in the report. While this comment is addressed in a general way in the chapter on public consultation, the following analysis will summarise the relation between instruments and delay as already elaborated in the topical chapters above.

(1058) It is important to bear in mind that establishing causal links by using statistical methods is a very complex task. In fact, causality can only be established on a case by case basis. In this respect, case studies and certain quotations in the preceding chapters eloquently demonstrate that sometimes these instruments are in fact used – intentionally – to cause undue delays of generic entry. Chapter C.2.1. on patenting strategies gives an account of the intentions behind patenting, whereby the impact on generic entry – in addition to creating a platform for other patent-based practices – can be immediate in discouraging entry due to legal uncertainty. Chapter C.2.2. on patent litigations shows how judicial enforcement of patents that have made their way through the "coarse filter"⁵⁷⁰ of the patent offices, but were eventually annulled, can significantly delay generic entry. Similarly, Chapter C.2.4. shows that certain patent settlements can further protract the delay of generic entry as compared to situations where patent litigation would be duly completed. In cases where settlements or other agreements led to controlled generic entry, the empirical analysis in Chapter B.1.3. showed a reduced degree of generic penetration. Finally, Chapter C.2.5. on

⁵⁷⁰ This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying intentions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

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interventions mentions examples where high extra sales were recorded due to delayed generic entry owing to originator companies' interventions.

(1059) Whenever possible, each of the above-mentioned chapters provides an average duration of relevant administrative and legal procedures. While this encompasses all procedures, including those where the originator company prevailed at the end of the procedure, average durations may serve as a rough first indication of the delay of legitimate generic entry that may be at stake, bearing in mind that the use of such instruments is generally legitimate and that instances of undue delay of generic entry can only be established in specific cases. The period of delay may last – on average – from 1.5 years, in the case where the sale of a generic product is suspended by an interim injunction and under the conservative assumption that a generic company will (re-)enter immediately after the interim injunction is lifted. An average of 2.8 years is seen where a generic company is involved in litigation and chooses not to enter until the matter is resolved through all court instances. An originator company's intervention before a marketing authorisation body may have similar effects. Such an intervention may influence the timing of marketing authorisation, which is required for a commercial launch of any medicine; on average, this takes place approximately four months later than in the cases of non-intervention.⁵⁷¹

2.7.2. Empirical Data

(1060) In order to gain a picture of cumulative use of the above-mentioned practices by originator companies concerning specific INNs, the occurrence of these practices in the E75 group was quantified. The E75 group comprises 128 INNs, which correspond to the 75 top-selling INNs that faced loss of exclusivity in three Member States (France, Germany and the United Kingdom) over the period from 2000 – 2007 and are thus best suited for examination of use of the tool-box throughout the entire product life cycle. The same analysis was conducted on a narrower sample of the top 30 best selling E75 INNs during the period 2000-2007 (hereinafter referred to as the "top 30").

(1061) For the purposes of this exercise, the practices employed by originator companies have been classified into the following five blocks: 1) acquisition of secondary patents⁵⁷². As filing for secondary patents is common to all originators, this was considered as a separate practice for the purpose of the following analysis only in cases where its use was more frequent. More specifically, this tool was considered to be used whenever the number of secondary patents per INN exceeded the median number of secondary patents per INN within the E75 group. Moreover, this selection very often coincided with opposition proceedings lodged by generic companies against originator

⁵⁷¹ One should not attempt to compare different administrative and legal procedures in terms of expediency. They are being carried out for different purposes and under specific rules.

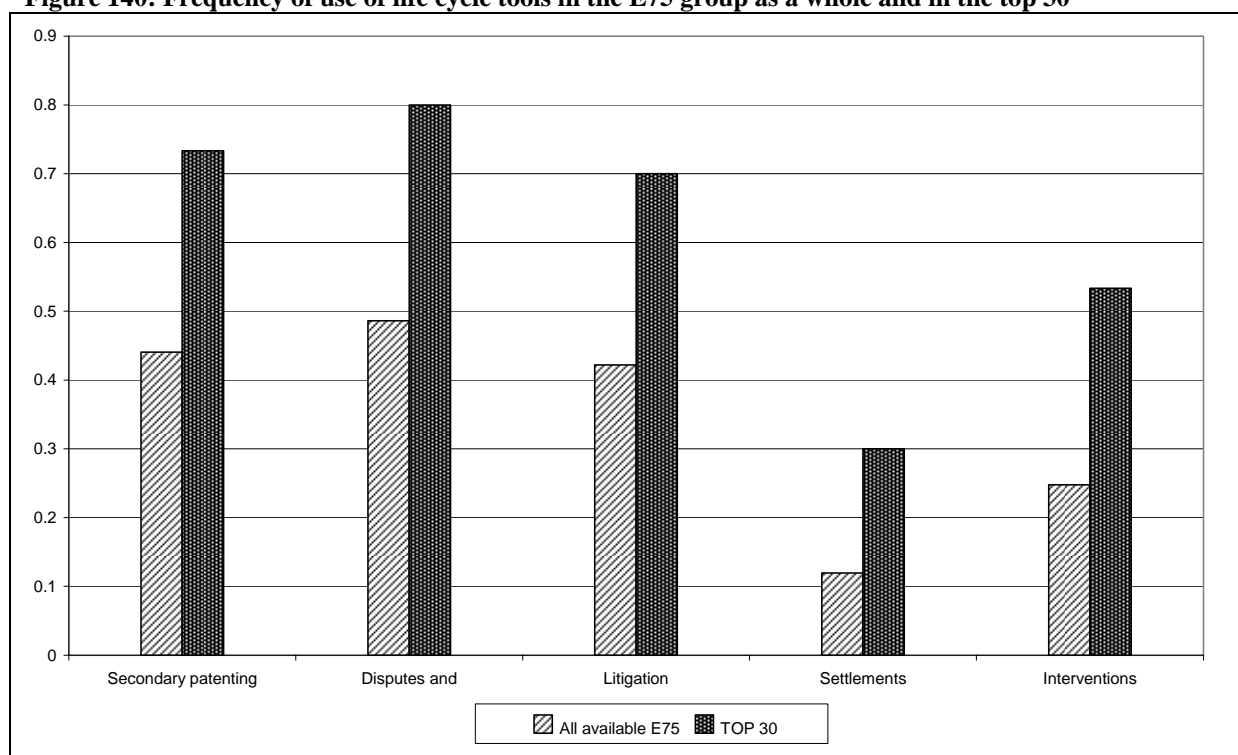
⁵⁷² This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying intentions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

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companies' patents; 2) patent-related disputes and contacts; 3) patent litigation; 4) patent settlements, where the selection was limited to value transfers from an originator to a generic company or other circumstances that may have an influence on generic entry; and 5) interventions before or against the national health authorities (marketing authorisation authorities and pricing and reimbursement bodies) and wholesalers. These four were deemed to be used whenever at least one occurrence per block has been recorded.

(1062) Taking into account the E75 list and measuring the use of life cycle tools per INN, Figure 140 demonstrates that for 53, or almost half, of the INNs analysed the originator companies were involved in patent-related disputes and contacts with generic companies, whereas secondary patenting and patent litigation were employed in connection with more than 40% of the INNs. Actions were brought on 25% of the INNs and settlements reached on 12%. Comparison of use of the corresponding tools on the top 30 and E75 INNs shows a strong increase in the frequency of use of all five categories. Use of secondary patenting, disputes and litigation almost doubled for the top 30. Even more importantly, use of settlements increased by 18 percentage points and use of actions by 28 percentage points, in both cases more than double the E75 average.

Figure 140: Frequency of use of life cycle tools in the E75 group as a whole and in the top 30



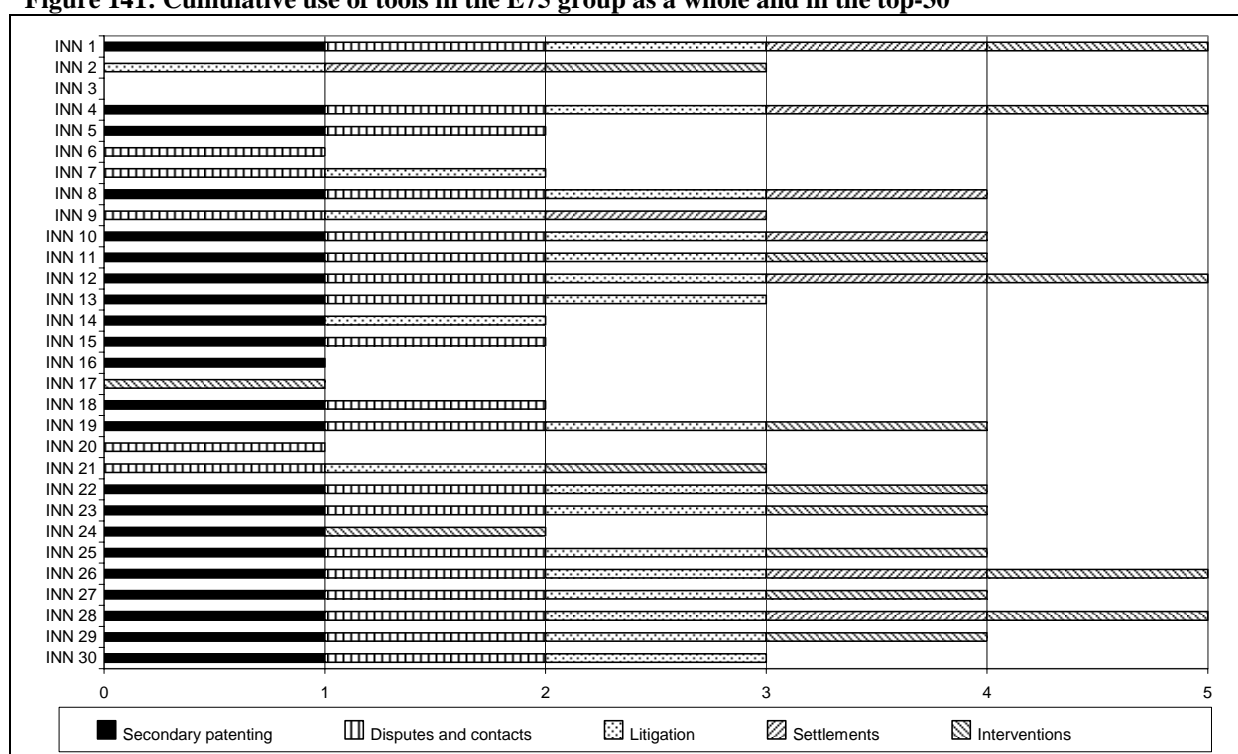
Source: Pharmaceutical Sector Inquiry

(1063) Figure 141 shows the cumulative use by originator companies of the different tools which could possibly delay generic entry on the top 30 INNs (in random order). There was only one of the top 30 INNs for which none of the life cycle tools was used. On the other hand, 25 INNs (or 83%) gave rise to use of at least two instruments. For more than half of the INNs, originator companies used a combination of at least three tools, whereas for five of the 30 INNs (or 16%) combined use was made of all five life cycle instruments against generic companies.

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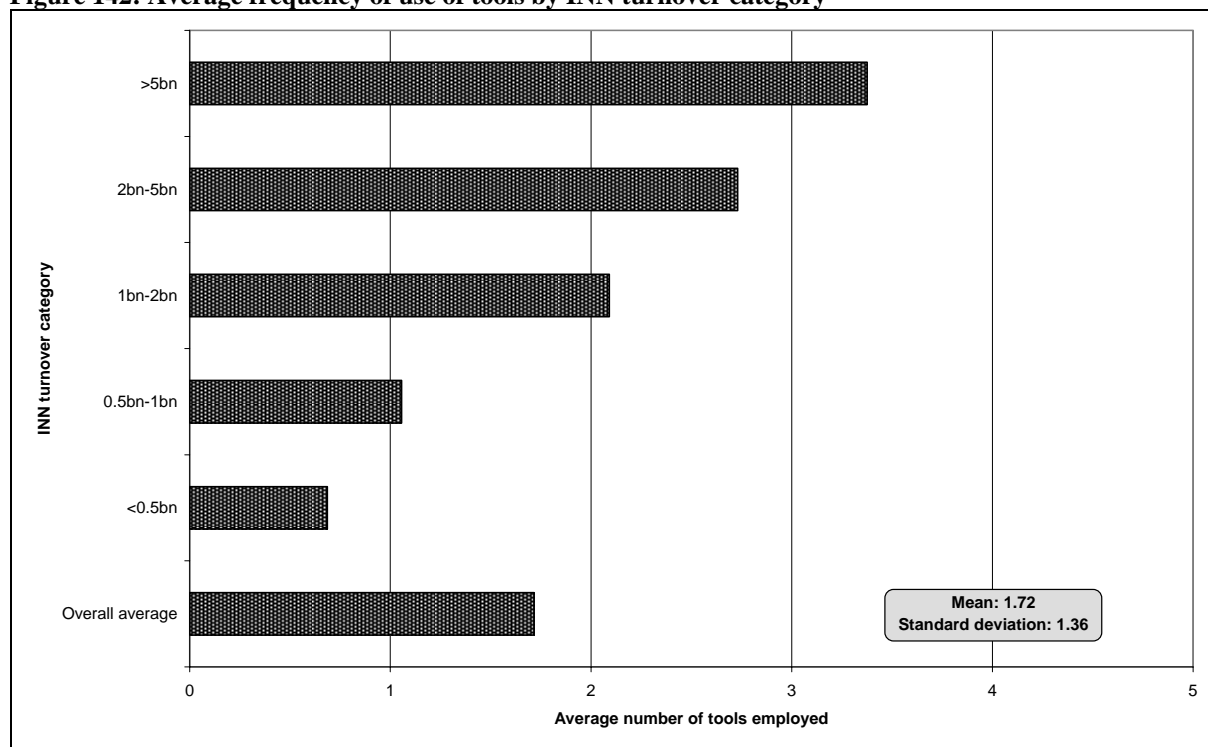
(1064) Figure 142 shows that originator companies resort to broader and more intensive use of life cycle tools for INNs generating higher revenue. Based on their aggregate 2000-2007 turnover, the INNs were ranked in five categories: > € 5 billion, € 2 billion-€ 5 billion, € 1 billion-€ 2 billion, € 0.5 billion-€ 1 billion and < € 0.5 billion. The average frequency of use of life cycle tools was then calculated by category. The analysis shows a consistent and linear increase in use of the five life cycle tools as the turnover category increases. In the lowest turnover categories (< € 0.5 billion), reports of use of life cycle tools are rare, with around 0.7 occurrences per INN. In the next category (€ 0.5 billion-€ 1 billion), the utilisation rate stands at one tool per INN and is still well below the average of 1.7 tools per E75 INN. This rate effectively doubles in the next turnover category (€ 1 billion-€ 2 billion). It then continues to progress significantly in the highest turnover categories too, with 2.7 tools per INN in the € 2 billion-€ 5 billion category, and peaks at approximately 3.4 tools per INN for the top INNs with turnover above € 5 billion.

Figure 141: Cumulative use of tools in the E75 group as a whole and in the top-30



Source: Pharmaceutical Sector Inquiry

Figure 142: Average frequency of use of tools by INN turnover category



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

2.7.3. Effects of the Combined Use of Practices

(1065) So far, the assessment of the possible effects of use of the life cycle tool-box on generic entry has been limited to an instrument-by-instrument analysis. However, the previous subsection shows that, very often, originators combine life cycle tools, be it simultaneously or successively. Moreover, the intensity of their use increases with the commercial importance of the product, which in turn goes hand in hand with the pressure, or potential, for generic entry. This does not purport to imply that if legitimate uses of several instruments are combined, such a combination would not be legitimate.

(1066) As the vast majority of the top-30 E75 INNs in Figure 141 show, an extensive patent position lays the foundation for using other patent tools, i.e. contacts/disputes, litigations and settlements. The patent position, in particular secondary patents, together with the originator company's overall enforcement strategy, typically decide the extent to which these tools are used upon loss of exclusivity of the base patent.

(1067) A broad patent portfolio may possibly deter certain attempts at generic entry. In other cases, generic companies may opt for opposition proceedings, lodge a non-infringement declaratory action or enter at risk. As demonstrated in Chapter C.2.3., opposition rates for pharmaceutical patents are above average, and generic companies succeed in 60% oppositions. However, as the same chapter shows, even such a favourable result for a generic company may come at a price – a delay compared to the situation without the originator company's ex post revoked patent.

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- (1068) An expected effect of multiple actions can however be that entry will tend to occur later and, more generally, the overall uncertainty will tend to be higher than in situations where only one instrument, or none, is used.
- (1069) In some scenarios, the delays due to simultaneous use of two or more life cycle tools could add up, for example in the case of settlements. As can be seen from the foregoing, settlements are usually preceded by securing a broad patent portfolio, disputes/contacts, litigation and interventions (alone or in combination). If the outcome of the settlement delays generic competition, this is added to the delays due to previous steps, such as litigation.
- (1070) Whilst exercise of originators' statutory and other rights, be it on a stand-alone basis or by combining several instruments, can generally be deemed legitimate, in certain cases of undue use delays in generic entry may be harmful for consumers, as discussed below. This is the case in circumstances where generic entry could be legitimately advanced in time absent the use of one or more life cycle instruments from the tool-box.

2.7.4. Possible Economic Effects of Life Cycle Tools

- (1071) It is generally accepted that a generic entry leads to lower prices⁵⁷³ for the consumers⁵⁷⁴. This is also a key assumption that has to be made in order to unravel the possible economic effects of delays of generic entry resulting from the use of one or more life cycle tools as already described.
- (1072) In particular, the focus is on the situations in which generic entry has been delayed as compared to the possible time of legitimate generic entry absent the use of various life cycle tools. The analysis in this section will be developed on an example of patent litigation, whereby the subsequent outcome of litigation suggests that an earlier entry would not have breached the patent rights of an originator company. While the example is instrument specific, the main consequence, i.e. delay of legitimate generic entry, is a common element of all other life cycle tools, whether used in combination or on a stand alone basis. The concluding part of the analysis presented in this section should be understood as extending to other situations in which a generic entry is suspended for other reasons than patent litigation.
- (1073) To begin with, it is worth recalling the different contexts in which a generic entry is delayed in patent litigation. A generic entry can be delayed by either (a) an interim injunction, which specifically prohibits a generic product from sales or (b) a generic entrant's own decision not to enter at risk after the originator started litigation and is threatening damages. The latter is a matter of subjective judgement, which may be

⁵⁷³ As regards the precise quantitative impact of generic entry on prices, the reference is made to Chapter B.1.3., which, in the context of this section, can also provide a useful indication as to the likely scale of the economic effects of patent litigation.

⁵⁷⁴ For the purpose of this section, the 'consumer' term encompasses both patients, in Member States where the co-payment system exists, and the reimbursement bodies.

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influenced by several factors, including a generic company's risk-averseness, perceived likelihood of damages, a generic company's current financial situation as well as other market opportunities on which a generic company may embark.

- (1074) It should be noted that such a subjective judgement may also lead to a decision to enter the market on a reduced scale. Among the generic respondents to the sector inquiry, almost a half of companies confirmed that they take an entry on a reduced-scale into consideration as one of the viable market options. In such a case, any potential damages are limited to what can be perceived as an acceptable amount that does not threaten the overall continuity of business activities. In exchange for taking the risk, a generic company is then able to establish its presence on the market. This may, in turn, put that company in a privileged position to further increase its sales, should the litigation proceedings subsequently end with a favourable outcome allowing it to remain on the market.
- (1075) As the sector inquiry shows, the above-mentioned limitations (related to both the court order prohibiting an entry or ordering a temporary exit, and the unwillingness to enter at risk) can be judged *ex-post* to be unfounded. This takes place whenever patent litigation proceedings end with: (a) a judgement allowing a generic entry, (b) a settlement according to which an originator company agrees to an earlier generic entry and/or transfers a net value to a generic competitor in order to compensate for the delayed entry of the latter or (c) a withdrawal of a case by an originator company before patent's expiry date, while other circumstances, e.g. a judgement in other jurisdiction, may lead to the supposition that the patent was invalid or non-infringed.
- (1076) In practical terms, a delay in generic entry also means a delay in (a) the price reductions on the originator product, (b) the savings due to a transfer of market shares from an originator company to its generic competitors, (c) possible substitution effects (where a cheaper product substitutes more expensive treatments within the same therapeutic group) as well as (d) other possible demand expansion effects (increases in the demand for the product concerned due to income effects or further substitution effects).
- (1077) Any undue delay obviously benefits an originator company that can continue charging its original price and does not lose its market shares, and harms a generic competitor that cannot enter the market. However, on top of that, the delay also harms the consumers who are being deprived of cheaper medicines.
- (1078) Figure 143 presents a simplified diagram showing the welfare effects of delayed generic entry.⁵⁷⁵ The vertical axis represents the average price for the product in the

⁵⁷⁵ For the purpose of the welfare effects analysis, two general assumptions relating to the system protecting the intellectual property rights are made: (a) the protection period provided for in the law is optimal from an economic welfare perspective, i.e. the applicable protection period induces the optimal level of R&D activities, (b) the originators cannot expect to be able systematically to extend the protection period over the period prescribed in the law and hence their level of R&D activities is strictly based on the anticipation of "super-normal" profit to be gained during the standard protection period and of normal profit after that protection period ends.

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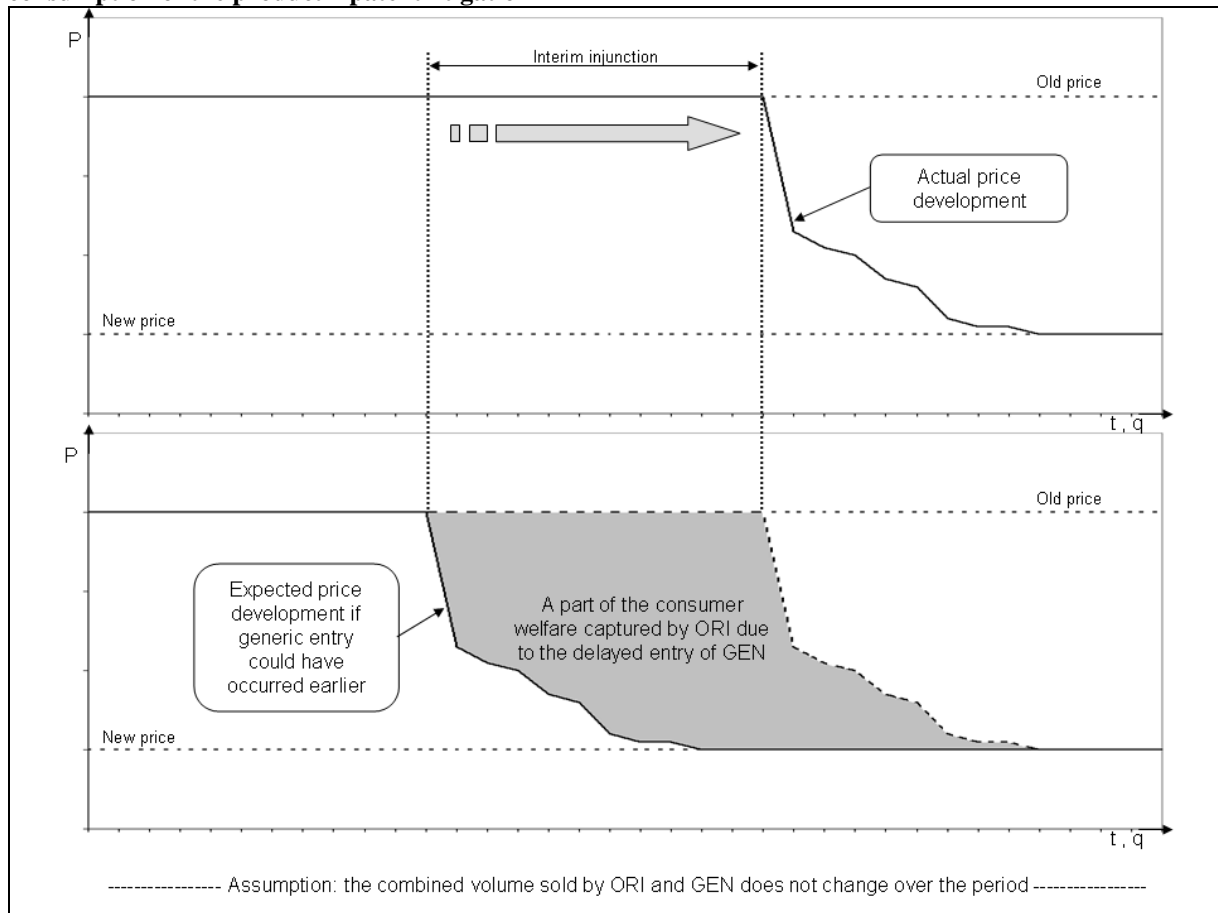
market, the horizontal axis sets out the time dimension. The diagram is based on a number of observations stemming from real life examples collected in the sector inquiry. The grey area in the lower part illustrates a part of the consumers' welfare captured by an originator company that succeeded in obtaining an interim injunction preventing the entry of a generic competitor. Because of that interim injunction, prices had stayed at the original level for a longer period and started decreasing only when the interim injunction ended. The delay is illustrated by the grey arrow between the two vertical dotted lines in the upper part of the diagram.

- (1079) A proxy for the overall damage suffered by consumers can, at constant consumption volumes, be calculated by multiplying (a) the difference between the actual and the expected price and (b) the quantities traded during the period of delay. Such a calculation provides only a conservative estimate, since it does not take into account the fact that the consumers could have also benefited from the substitution effect related to a generic entry, as well as from an income effect as described above.
- (1080) The damage at constant consumption volumes calculated in this manner is also the exact part of consumer welfare that is captured by an originator company, for which the appropriated value, after the deduction of costs incurred in litigation, represents a net benefit. Such litigation costs are usually a small fraction, e.g. 10%, of gains. It also means that originator companies will see a strong incentive to become involved in litigation unless there is a strong likelihood of them having to pay damages to a generic competitor for wrongful interim relief.
- (1081) One can observe that the above analysis can be applied by analogy also to circumstances where the delay of legitimate generic entry is due to other practices, most notably settlements and interventions at marketing authorisation offices as well as pricing and reimbursement bodies.

In addition, for illustration purposes, two working assumptions relating to prices and volumes are made: (a) the expected price developments if generic entry could have occurred earlier take the shape of the actual price developments, (b) the combined volume of sales of both the originator company and its generic competitors does not change over the analysed period, which, in turn, allows to plot both quantities and time intervals on the same axis.

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Figure 143: Possible effects of delayed generic entry in terms of welfare distribution, for given levels of consumption of the product – patent litigation



Source: Pharmaceutical Sector Inquiry

Summary

Patent and other strategies/instruments described above may sometimes be used cumulatively with a view to prolonging the life cycle of medicines. The extent to which these instruments are used depends on the commercial importance of the medicines. The sector inquiry shows that more life cycle instruments are used for best-selling medicines.

The combined use of life-cycle instruments may increase the likelihood of delays to generic entry. Delays due to the use of several instruments may sometimes be cumulative. More generally, it may significantly increase legal uncertainty to the detriment of generic entry. In this respect it is recalled that any unwarranted delay is not only detrimental to individual companies, but can cause harm to public health budgets and ultimately consumers.

It should be clarified, however, that the use of several instruments that are in themselves legitimate does not necessarily render their combination contrary to competition rules.

A case-specific analysis would be required to establish the precise effects of company behaviour on generic entry. Whilst such an analysis must be left to individual enforcement action where needed, the technical annex to the Final Report provides a number of examples and evidence based on concrete cases pointing towards such effects without specifying that the behaviour in question is contrary to EC competition law.

3. Competition between Originator Companies – The Issues

- (1082) The inquiry also sought to examine whether the behaviour of originator companies might be among the reasons for the difficulties to bring new medicines to the market.
- (1083) Other factors quoted by the industry for the decline in innovation as evidenced by a decline of novel medicines reaching the market may include increased scientific complexities, high attrition rates in late stage development due to regulatory risk aversion and uncertainty about the financial rewards. These factors were not subject of the inquiry, but will be further analysed in the ongoing market monitoring exercise.⁵⁷⁶
- (1084) In the pharmaceutical sector there are a number of therapeutic areas which are viewed by originator companies as being commercially particularly interesting, as the demand for treatments is high or is expected to be high in the future.⁵⁷⁷
- (1085) Originator companies compete with each other for this demand. This means that they are often engaged in competing R&D activities with the aim of being the first to market a treatment for a given disease. Moreover, even where treatments already exist, originator companies may compete against each other by, for example, marketing alternative treatments. This increases the consumer's choice.
- (1086) As explained previously, before being able to bring a product to the market, each originator company has to overcome a number of obstacles (e.g. failure during the R&D process, problems with authorisation), including obstacles which might be created by other originator companies.
- (1087) The purpose of this chapter is therefore to examine to what extent originator companies interact and, more specifically, to what extent they might find themselves in situations where one company blocks another.
- (1088) This chapter does not question the value of (incremental) innovation. Neither does this chapter aim to provide guidance on whether certain types of practices could be considered compatible or incompatible with the EC competition law. Such an assessment would require in-depth analysis of the individual practice taking into account the factual, economic and legal background. The Commission will further investigate whether individual company behaviour may have fallen foul of the competition rules.
- (1089) The following issues will be analysed:

⁵⁷⁶ Commission Staff Working Paper Document on 'The Single Market Review: one year on', at http://ec.europa.eu/internal_market/strategy/docs/smr_oneyear_en.pdf (see in particular p. 11 par. 3 and the following box on market monitoring as part of the follow-up to the 2007 Single Market Review).

⁵⁷⁷ For further details see Chapter B.1.1.

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Patent Strategies: an overview of patent strategies adopted by originator companies is provided. The purpose of these patent strategies is described, with a particular focus on so-called "defensive patents" against competing originator companies and their activities.

Potential patent infringement issues, patent-related exchanges and litigation: this section first analyses the potential for originator companies to find themselves blocked by another originator company. Subsequently, patent-related exchanges between originator companies which have not (yet) led to litigation, such as contacts and disputes, are examined. Finally, litigation between originator companies is analysed.

Opposition procedures: in this section, opposition procedures and any subsequent appeal procedures in which an originator company's patent is opposed by another originator company are considered.

Agreements: the different types of agreements between originator companies common in the pharmaceutical sector are outlined. This section first analyses settlement agreements and then looks at other agreements in more detail.

3.1. Patent Strategies

- (1090) The definition of the term "patent strategies" for the purpose of this section encompasses all company strategies concerning the use of the patent system for the benefit of the company, as can be seen in the section on patent strategies concerning the relationship between originator and generic companies.⁵⁷⁸
- (1091) This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying interventions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.
- (1092) The purpose of this section is to analyse whether a patent strategy within a more general strategy of an originator company is intended to block the development of a new competing product rather than to protect an invention of its own.
- (1093) Patents can fulfil many functions. Originally intended to entice an innovator to disclose his or her invention to the public — thereby benefiting society (information function), by offering him or her in return a fixed period of exclusive commercial exploitation of the innovation (exclusive and protective function) — they may serve additional purposes, e.g. to maintain freedom to operate, or serve bargaining, financing or other purposes.⁵⁷⁹ While patents generally fulfil the function of protecting innovation and

⁵⁷⁸ For further details, see Chapter B.2.1. and C.2.1.

⁵⁷⁹ For further details see Chapter B.2.1.1.

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thereby play a fundamental role in fostering innovation, there may be cases that suggest the use of patents with the main purpose of limiting competitor's R&D activities.

- (1094) This section will first look at the way in which originator companies preserve their freedom to operate, by patent clearance studies, identification of overlaps, resolution of dispute potential and ways of patenting. Then it will examine the extent to which patent strategies are used to prevent companies from developing a competing pharmaceutical product. In particular, this section sets out the role that so-called "defensive patents" play in this context. It will close with a short description of patent interference of R&D projects as perceived by some originator companies and the detection mechanisms for patent infringements employed by originator companies.
- (1095) Quotations from internal documents are used to illustrate the purpose of some of the companies' patenting strategies. They represent only a part of those obtained in the course of the sector inquiry. Again, it has to be pointed out that the majority of these quotes have been taken from documents obtained during the inspections in January 2008.
- (1096) It is not the purpose of this sector inquiry to provide guidance as to the compatibility of certain practices with EC competition law. The Commission will further investigate whether individual company behaviour may have fallen foul of the competition rules.

3.1.1. Strategies to Preserve Freedom to Operate

- (1097) It is essential for an originator company to ensure that its alleys of research remain as wide open as possible, in particular with regard to further development of its own inventions. This was confirmed by the vast majority of originator companies interviewed and is illustrated by the following quote from an originator company:

"Objectives of patenting activities [...] include: providing appropriate levels of protection for significant areas of R&D activity, preventing unauthorised competition and providing the necessary freedom to operate."

- (1098) Consequently, the companies' strategies usually include the initial filing of a patent for a family of molecules defined by a certain structure with similar (expected) properties, including molecules that are the actual development candidates. In fact, patents for several different molecule families might be filed in order to secure back-up candidates in case those of the first group do not get to and through the development stages.
- (1099) In order to maintain their freedom to operate, companies will usually, once the candidate compound has taken the first development hurdles, file for a number of patents applications on innovations around it (e.g. modifications and improvements, combinations with other molecules). This allows them to carry out further research in order to improve their own pharmaceutical product by further development and without interference from competitors.

3.1.1.1. Originator Company's Patent Clearance Studies

(1100) Before developing a new product, it is an established practice amongst the largest respondent companies to conduct patent clearance studies of all aspects of the product to determine whether any third party patent could present potential patent issues with regard to the development of the new medicine. In fact, one originator company, explaining that it did not have any patent litigation with other originator companies, claimed that it believed:

"[...] this is because originator companies tend to search and analyse potentially relevant third party patent property before commencing research activities in a particular area. This is to develop truly innovative products which seek to meet unmet patient needs, while avoiding dependency upon third party patents and licenses. The third party patent checks are repeated as the project progresses, with the same aim as before."

(1101) Another originator company described its policy as follows:

"Like most companies, [our company] runs regularly so-called 'freedom-to-operate' searches, i.e. it reviews publicly available patent information in order to establish to which extent third-party patents exist in a given area of its R&D poles. Where such patents are identified, a decision to continue with the activity in the R&D pole concerned is taken on a case-by-case basis after assessing the relative strength of the patents identified, including the number of patents, their validity and the breadth of their scope."

(1102) Such patent clearance studies concern a variety of patent-related topics. One originator company specified that it can include:

"targets and assays used, the active ingredient, the pharmaceutical formulation and its excipients, chemical processes and intermediates used, pharmaceutical manufacturing, etc. Such studies are performed throughout the development phase of the product as well as, if necessary, during its lifecycle as a commercial product."

(1103) Another company stated in this context that when it:

"believes [it] has discovered a new compound that may be useful in providing therapeutic effect in humans, the first task performed is to determine whether or not the compound is indeed new. A detailed, electronic literature search, therefore, is performed routinely on each compound. Usually this search is performed by a library service team within the research and development department of the company, but scientists often perform searches on their own."

(1104) Finally, a number of (smaller) originator companies did not indicate that they dedicate resources to tracking the existence of other originator companies' overlapping patents, even less by collecting records on such patents. Some of them simply stated that they are not aware of patents owned by any other originator companies which cover, if only in part, any of their INNs, R&D poles or patents.

3.1.1.2. Results of Clearance Study: Possible Overlaps

(1105) Given a certain concentration of the areas on which companies focus the risk of overlapping R&D poles increases and might lead to more disputes in the future. As one patent or patent application may cover hundreds of specific molecules, the likelihood of overlaps may be increased in certain cases. This is especially the case for patent applications which cover a new compound or combinations of compounds. According to one of the respondents, they:

"file new compounds patent applications which also cover combinations comprising (1) said "new compounds" and (2) a large number of combination partners. These combination partners can be other originator company's INNs or patented compounds."

(1106) To the extent that companies apply for a secondary patent⁵⁸⁰ regarding a product already marketed, such patents are reported to have less influence on the freedom to operate. In this context, one originator company explained:

"We are aware that numerous, typically hundreds of patent applications are filed by third parties, including generic companies, which disclose secondary aspects of a successfully marketed INN e.g. alternative formulations, processes of manufacture, salts, polymorphs, enantiomers, combinations etc. Most of these applications are filed after the launch of originator INN and hence do not represent a potential threat to our freedom to operate. In addition, many of these patent applications are abandoned before grant. They therefore represent no threat to existing products i.e. those launched prior to the filing date of any third party patent applications."

(1107) However, if further development of the marketed product goes in the direction of one of these "secondary" aspects and the patent applications covering them have not been abandoned, such patents could then influence the freedom to operate. An example of primary patents concerning a secondary aspect would be the development of a combination.

⁵⁸⁰ Patent law does not make a distinction between "primary" and "secondary" patents, and patents need to be evaluated on the basis of the statutory patentability criteria, not on the basis of the stage in which applications are made. The notion of "secondary patent" should not be understood to mean that these patents are of a lower quality or value, but merely that – from a time perspective - follow the primary patents. Yet this term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices, see also Chapter A of this report, explaining the use of terminology.

3.1.1.3. Solutions in Cases of Overlaps

- (1108) If at the end of clearance studies it is concluded that the activity does not infringe any third party patent, product development or commercialisation will likely continue.
- (1109) If, however, in the course of patent clearance studies it is determined that the compound developed is not new, companies may abandon R&D of the compound completely or take a different approach. If an overlap with a patent belonging to another originator is detected, a solution mentioned by some of the companies is to design around this patent, i.e. to develop alternatives to avoid falling within the scope of a patent which is considered to be valid, for example by generating an alternative process. If a company concludes that their intended activity infringes a third party patent, it seems to be a common practice to contact the patent owner in order to resolve the matter, possibly by concluding a licensing agreement.⁵⁸¹
- (1110) In some cases companies also decide to take the matter to the patent authority – they file Third Party Observations in connection with a patent application, if necessary, or launch opposition proceedings or annulment proceedings against the patent granted, as one company pointed out:

"Vice versa [our company] has made efforts to further opportunity to operate by challenging other's IP rights, in so far as these rights were granted wrongly in [our company's opinion] and hindered or would have been able to hinder our own development activities [...]."

3.1.1.4. Patenting

3.1.1.4.1. Scope of Patent

- (1111) Once the identification of drug development candidates has matured, an originator company will have to think about how best to protect them through patents.
- (1112) By filing patent applications with broad claims, a company will usually make sure that competitors do not identify the relevant candidate at an early stage and possibly block its development by patenting any further developments. This is illustrated by the following remark by an originator company:

"'Smoke screen' patenting is done by filing a number of patent applications relating to similar subject-matter in order to prevent third parties to find out which subject-matter is of primary importance to [our company]. Thus, e.g. in the field of the [class of compound] [our company] applied for patent protection for the specific development compound. In order to establish a "smoke screen" additional patent applications directed to specific other [class of] compounds were filed."

⁵⁸¹ For more detailed analysis of contacts between originator companies see in Chapter C.3.2., for analysis concerning licensing agreements between originators please see in Chapter C.3.4.

(1113) The patent applications will then usually claim a whole class of compounds that have a similar molecular structure and are believed to show similar effects. Later on the company may be able to split the application into divisional applications covering individual claims made in the first applications and/or file applications for secondary patents relating to, e.g. the formulation, dosage or new indications of the compound. In all of these cases the company will be able to support its applications with new experimental data gathered during its R&D phase in order to strengthen the application.

3.1.1.4.2. Time of Filing Patent Applications

(1114) For an originator company it is essential to get the timing right when filing patent applications. If it files too early, the company will lose a valuable portion of the patent exclusivity period, as development and approval of the pharmaceutical will take several years before product launch. If it files too late, the company runs the risk of its competitors discovering the same compound and filing their patent application first. All in all, originator companies tend to file early rather than late to secure their freedom to operate, as the following quote from one company illustrates:

"An early patent filing date is often critical for obtaining patent protection for a drug product. Delay in filing until identification of a lead compound may allow a competitor to obtain earlier patent coverage on the encompassing genus, potentially foreclosing development of the compound by [our company]. Priority of invention may sometimes be a matter of months. [...]"

(1115) Thus filing may take place even during the early phases of research.⁵⁸²

3.1.1.4.3. Geographical Scope of Patent Filing

(1116) As mentioned elsewhere,⁵⁸³ filing patent applications can become costly once the process reaches the national or regional phase. This is the latest point in time at which a company will have to decide which countries it wants to obtain the patent for. Usually, the more important the invention is for a company, in particular with view to turning the invention into a commercial product, the more national patents it will seek. Geographic priorities of the 43 originator companies addressed in the sector inquiry have already been explained in Chapter C.1.2.

3.1.2. "Defensive Patenting Strategies"

(1117) By definition each patent restricts other parties' freedom to operate. However, this is generally accepted as it contributes to the competition in R&D and as it entices

⁵⁸² For further details see Chapters B.2.1. and C.1.2.

⁵⁸³ For further details see Chapter C.1.2.

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originator companies, continuously and without too much delay, to produce R&D results beneficial to their own businesses and to society. From society's viewpoint, however, restriction of another company's freedom to operate may be problematic where the originator company maintains and uses patents to block the development of a new, competing product rather than for protecting an invention of its own. This is sometimes referred to as "defensive patenting".

(1118) "Defensive patenting" is a term used by several companies in their patent strategy. On the basis of the definitions in these companies' documents, defensive patent applications usually refer to inventions which the applying company considers to have little or no prospect of being developed and/or commercialised and/or which, once granted, the company holds primarily to protect itself against actual or potential competition. During the public consultation the use of this term in the preliminary report has been criticised, in spite of the fact that it is a term used in internal documents of originator companies themselves.

(1119) Usually, "defensive patenting" activities will only cover the strategically most important countries, as is illustrated by the following quote taken from an originator company patenting strategy document:

"List 3 Defensive: minimal commercial value, Intended (sic!) for purely defensive situations where there is no prospect of the invention being commercialised by [our company] and where it is unlikely that a third party will work inside the scope. The territorial coverage is designed to provide rights in the major markets rather than to provide a minimum [company] position. USA, Japan, Europe [all Contracting States]"*

(1120) Similarly another company stated in one of its documents:

"Defensive patents ("Limited list" Patents) serve to protect compounds closely related to [our company's] candidates or products. They do not cover [our company's] candidates or products. They protect compounds that would be of interest to a direct competitor."

(1121) When asked how many of their patents and applications originator companies would regard as defensive, most originator companies claimed that none of their patents would fall under this definition.⁵⁸⁴ The sector inquiry unearthed evidence that 13 companies filed or considered filing defensive patents, the number of reported filed patents ranging from two to 1,350 within individual companies.

⁵⁸⁴ In the public consultation it has therefore been submitted that defensive patenting is not widespread in the industry.

3.1.2.1. Blocking Competitors as Main Purpose

(1122) At times, defensive patenting strategies might pursue the aim of patenting an invention that the patent holder has no interest in developing and bringing to the market,⁵⁸⁵ with the main purpose of keeping other originator companies from further developing a specific invention and bringing it to the market, as the general patent strategy statement of one originator company shows:

*"We identify options to obtain or acquire patents for the **sole** purpose of limiting the freedom of operation of our competitors. [...]"(emphasis added)*

(1123) This company then goes on to explain that:

"[...] Rights covering competitive alternatives are maintained in major markets until risk of competing products appearing is minimal."

(1124) A quote of a different company's internal document shows its intention to use patents to block a competitor rather than to protect its own development:

"Filing directed to combinations of potential interest to competitors

We are sometimes asked to file patent applications relating to combinations which [our company] has no interest in developing but which may be of interest to competitors. The main question relating to these applications is what is their value

Proposal

- File only on combinations which are likely to pose a genuine competitive threat."*

(1125) Another company categorised patent applications for inventions into a specific group in order to prevent competitors from developing a certain project rather than to protect its own invention for the purpose of further research and commercialisation, as becomes apparent from the following quote:

⁵⁸⁵ In the public consultation it was submitted that defensive patenting is necessary as it cannot be decided at the point of filing the patent whether the invention will be of commercial and development interest at a later stage. However, the abovementioned definition for defensive patenting which was used in the questionnaires addressed to the companies asked for those patents which at that time were not envisaged to be developed.

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"Limited level: Compounds, processes or uses which do not relate to a candidate or potential candidate, but either have a clearly-perceived defensive value. [...] The term "defensive value" refers to a case that covers subject matter that [...] would likely be of interest to a research-based competitor seeking to develop a product that would compete with a developmental candidate or product [of our company]. Included here are cases that cover a competitor's product. [...] If the case no longer qualifies as a Candidate case but it continues to have defensive value [...], the case should be cut to the Limited list rather than completely abandoned."

- (1126) Similarly another company explained in its strategy documents that even where it does not want to pursue an invention it still wants to keep it from being developed by others:

"Attached is the Proposed Global Patent Strategy [...]. There are many countries in the world and obviously we cannot and should not file patent applications in all of them. [...] List 4 is not a filing list at all but is for Defensive Maintenance. Patents that are no longer of interest but that [our company] does not want to dedicate to the public (and to the competition) are kept and their annuities/maintenance fees are paid in these selected, core countries."

- (1127) In such cases of defensive patents the patent confers on its holder an absolute and enforceable right preventing other companies from developing such an invention. Furthermore the publication of the patent application will create prior art. The information published in this manner serves the dissemination of technical information and thus could be used for further innovation, an important policy aspect underlined by the EPO in the public consultation, once the patent applications have been published and thereby become public knowledge, the subject matter of the application itself may not be of development interest to other companies any more. This will be the case even if the applications are subsequently withdrawn, as the companies would not be able to get patent protection for their development if it has already been anticipated by the first patent application. Thus companies may achieve the aim of preventing the development of a new competing product by gaining an enforceable right on the one hand and by creating prior art on the other.⁵⁸⁶

- (1128) The following quote from an originator company shows how, by having patent applications published, it expects to render inventions uninteresting for competitors where the patent might overlap with one of the competitors' R&D projects, thereby blocking the development of competing inventions:

⁵⁸⁶ In cases of defensive publication, a company developing a medicine without patent protection could still obtain data exclusivity provided it has carried out the necessary clinical trials. However, it would not be protected against competitors running similar trials during that time. Also, the data protection period is shorter than the patent protection period.

"Defensive Patenting: Defensive patenting is done by filing a patent application for an invention in the most important countries and to have it become published. In this way a prior right to the invention is generated, which may prevent a third party to become or remain active in a certain field of interest for [our company]. Once the patent application is published it becomes prior art which prevents the patenting of the same invention or the obvious derivations thereof. [...]"

- (1129) Similarly, another company emphasises the deterrent effect that publication can have on other companies, even if it is not interested in pursuing the patented invention itself, as this quote taken from an internal communication in one originator company shows:

"Even if it turns out later that the combination of [our company's molecule] with [other molecules] will not be of interest to [our company], the publication of the appropriate patent application 18 months after the priority date will at least prevent third parties from gaining patent protection therefore. In other words, filing of an application creates "burned earth" with respect to the subject matter disclosed therein. Such a filing traverses third parties efforts to gain any kind of benefit from our substance [...] with respect to the subject matter disclosed in the application."

- (1130) The communication goes on to summarise:

"B) Disturbance of competitors

Even if [our company] chose to not develop an appropriate combination the filing of an application would prevent third parties from putting on the market and/or getting patent protection on such a combination later on. Therefore the filing of the patent application would simply "disturb" our competitors. To my personal opinion, everything that disturbs our competitors is useful to [our company]!"

- (1131) In one of its strategy documents a third company similarly puts emphasis on the deterring effect of publication of the patent application when not intending to develop the patented invention:

" 1. "Proposal to abandon patents apps"[...]

The amount of technical work required to support [...] is not warranted in view of their defensive nature and the uncertain outcome. [...] None of the combinations covered are actively being pursued by [our company]. Thus, the patent applications are regarded as defensive. [...]

Reasons for abandonment[...] The cases were considered defensive at the time of filing, and little, if any work has been carried out on the [compounds]. Certainly there is no data available to meet the current objections.[...] As these applications have been published others cannot now seek to patent them; this may deter [=deter?] third parties from developing said combinations.

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(1132) In this context it is also noteworthy that in a third of litigation cases on patents between originator companies, initial indications are that an originator company entered into litigation against another originator company over patents which did not in fact protect any of its activity in the market.⁵⁸⁷

3.1.2.2. *Defensive Publication*⁵⁸⁸

(1133) In general, publication of scientific observations that create prior art is beneficial to society as it grants the latter access to additional information enhancing its knowledge.

(1134) The effect of creating prior art can, however, to a certain extent, be achieved by so-called defensive publishing, i.e. the publication of an invention in an article, where a company is focusing on keeping its own freedom to operate as in the case of the following quote from an originator company:

"Finally, defensive publications are particularly useful to prevent competitors from using the patent system in order to block [our company]."

(1135) Judging from the documents gathered during the sector inquiry it seems also that publication is less used by companies for defensive purposes than defensive patenting. The reason may be that defensive publishing does not give the company an enforceable right. A company that decided to pursue an invention regardless of existing prior art, i.e. at the risk of not being able to obtain a patent but still with the aim of marketing a product, could not be prevented from doing so. For this an enforceable right such as a ("defensive") patent would be needed.

3.1.2.3. *Effect of Defensive Patenting on Other Companies' R&D Projects*

(1136) In a few cases originator companies expressed concern about the patent strategies of a competitor, in particular where they felt that their R&D projects were obstructed by the patent applications of competing originator companies. This is best illustrated by the following submission from an originator company:

⁵⁸⁷ See Chapter C.3.2.

⁵⁸⁸ This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices, see also Chapter A of this report on the use of terminology.

"[Another originator company] filed several "paper" patent applications related to [our company's molecule]. The only objective was to impede [our company] from developing [our company's molecule], as far as (i) no research laboratory data and/or work exists related to this paper patent applications, and (ii) [the other company] has no right on [our compound] compound, protected by patents owned by [our company] A letter [...] was received by [our company] from [the other company], [...] stating that [the other company] is not ready to achieve any settlement at all regarding the blocking patents."

3.1.2.4. Effect of Divisionals

(1137) Six (of 43) companies stated furthermore, that divisional applications⁵⁸⁹ by competing originator companies had interfered with some of their R&D projects. Thus one company stated:

"Issues, such as the filing of a divisional patent application by another company, may arise and impact on the business case for a R&D project [of our company]."

(1138) In several cases this has led companies to challenge these divisional applications, once granted in opposition procedures. One originator company, however, pointed out that:

"The filing of divisionals before EPO can extend uncertainty for several years."

(1139) In opposition procedures, in particular, unduly broad claims were challenged. Originator companies felt in general that they should not be accepted.⁵⁹⁰

3.1.2.5. Licensing

(1140) It was submitted during the public consultation that in cases of defensive patenting there still exists a possibility to request a licence where a company feels a patent to be an obstacle to its own development projects.

(1141) In fact, in some cases a company might attempt to patent certain inventions for just this purpose, i.e. to use them in negotiations with other companies without intending to develop them. Thus, one company claimed that it obtained patents:

"in order to create bargaining tools in cases of vital importance to [our company]"

(1142) During the public consultation some companies also maintained that they engage in patenting mainly to obtain legitimate business opportunities, e.g. through licensing.

⁵⁸⁹ For a general overview on divisional applications see Chapter in C.2.1.

⁵⁹⁰ For further details see Chapter D.1.

"Limited level: Compounds, processes or uses which do not relate to a candidate or potential candidate, but [...] could represent a licensing opportunity."

(1143) Thus it would seem that licences are possible where a company filed patent applications for that purpose. However whether a company would grant such licences where the applications were made with the intention to block competing products, such as indicated in some of the quotes mentioned above, would seem questionable. In fact, the sector inquiry confirmed that a number of requests for licences have been rejected.⁵⁹¹

3.1.2.6. Detecting Potential Infringement Issues by Patent Owners

(1144) Mirroring patent clearance studies, once a patent has been granted, the patent holder will in many cases ensure that his patents are not infringed. The analysis of material submitted indicates that many originator companies are concerned to defend their intellectual property rights and that many carry out a continuous and thorough review of their own patent portfolio with the intention of detecting potential infringements by other originator companies. As, for example, one company stated:

"Our company is continually reviewing its patent portfolio to ensure that our IP is properly respected [...]."

⁵⁹¹ For further details see Chapter C.3.2.

Summary

Originator companies continuously identify the most promising patent strategies in order to protect their assets. This is key for their innovative efforts. In certain cases, however, companies apply patent strategies which may interfere with the development of a competing medicine. When such strategies mainly focus on excluding competitors without pursuing innovative efforts, they are called by some originator companies "defensive patent strategies".

Such "defensive patent strategies" can serve several purposes. First, they create an enforceable right, which may prevent competitors from developing the subject matter of that patent. Secondly, they create prior art as soon as the patent application is published. Thus the development of the published invention may cease to be of commercial interest to other companies as they would not be able to get patent protection for their development.

At the same time some companies disputed these findings and maintained that they engage in patenting activities to obtain legitimate business opportunities, e.g. through licensing. Furthermore, EPO recalled the policy aspect of dissemination of technical information, as third parties remain free to build on the information disclosed in such patent applications.

Originator companies also mentioned the possibilities of competitors to introduce voluntary divisional patent applications as an obstacle to their innovative efforts.

3.2. Patent-Related Exchanges and Litigations

(1145) In this section, the prospect of originator companies finding themselves blocking one another is briefly assessed in order to illustrate the potential for conflicts between originator companies in the pharmaceutical sector. Next, patent-related exchanges between originator companies which have not (yet) led to litigation, i.e. contacts and disputes, are described, and then litigation between originator companies is analysed in detail.

(1146) From a methodological point of view, it must be emphasised that this section is based upon information received from originator companies relating to the whole universe of 219 INNs. As described in the Annex Methodology,⁵⁹² a good number of the 219 INNs are those for which generic product entry to the market may have taken place (e.g. the E-75 list). In order to analyse litigation and related issues between originator companies, such INNs are probably less helpful, since originator companies may lose interest in INNs which have lost patent protection and can be produced and sold by generic companies. That being said, the 219 INNs also include INNs which are not yet available for generic companies for copying. It is in this "mixed" universe that the sector inquiry investigated the issues dealt with in this section. In some instances, therefore, the analysis is based on lower sample sizes. However, where appropriate, the statistical robustness and significance of the results was verified, in order to evaluate the relevance of the results presented in this section.

(1147) It is not the purpose of this sector inquiry to provide guidance as to the compatibility of certain practices with EC competition law. The Commission will further investigate whether individual company behaviour may have fallen foul of the competition rules.

3.2.1. Potential Patent Infringement Issues

(1148) Where an originator company is prevented from launching a new medicine on the market because of existing broad patent protection granted to another originator company, the former may have a disincentive to carry out research and development into new medicines or be forced to find an arrangement with the other originator company owning the patent rights (e.g. licensing).

(1149) In order to ascertain what, if any, infringement issues exist, the sector inquiry looked into the extent to which overlaps exist between the patents of one originator company and the INNs, R&D programmes and/or patents of another originator company.

(1150) In the pharmaceutical sector, originator companies tend to focus on the most promising therapeutic areas, which necessarily increases the density of companies active in these areas. The R&D activity of an originator company leads to the filing of patent applications in many instances. This increases the probability of patents belonging to one originator company being infringed by the activity of another originator company.

⁵⁹² For further details see Annexes to Chapter A.

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Moreover, certain categories of patents, such as process patents, may potentially be infringed as soon as the process is used in any area, which may also increase the risk of originator companies ending up in conflict with other originator companies.

(1151) An originator company underlined the potential for infringement issues by explaining:

"In the field of prescription medicines for human use, there are a significant number of originator companies engaging in R&D activities with the objective of developing new and innovative products, uses and processes which are subject to patent protection. Moreover, there are also many originator companies active in the same therapeutic areas, seeking to discover and develop products to satisfy unmet clinical needs. Accordingly, there may often be a substantial volume of patents with similar or sometimes overlapping protection."

(1152) From data provided by respondent companies, the sector inquiry identified a total of more than 1,100 instances⁵⁹³, across the 27 EU Member States, where patents of one originator company may be infringed by the INNs, R&D programmes and/or patents of another originator company.⁵⁹⁴ It should be noted, however, that this figure is based on 40% of respondent companies providing detailed information on the issue, indicating that such overlaps are very common.

3.2.2. Patent-Related Exchanges between Originator Companies out of Courts

(1153) In the sector inquiry companies were asked to report disputes⁵⁹⁵ and other forms of patent-related contacts⁵⁹⁶ with other originator companies.⁵⁹⁷

(1154) Classifying a given patent-related exchange as a contact or as a dispute is not always straightforward and can be subject to interpretation. The difficulty of distinguishing disputes from contacts is illustrated by a reply submitted by one of the respondent companies, which claims that they do not "maintain systematic records of all contacts

⁵⁹³ These overlaps are based on information provided by responding originator companies identifying such cases.

⁵⁹⁴ During the public consultation it has been submitted that such overlaps are more common in some areas due to the fact that most companies direct their R&D efforts to unmet needs. It has also been submitted that in such situations granting a licence, including cross-licence, is the solution to the problem. For detailed findings on licences see further below.

⁵⁹⁵ As mentioned before in footnote 384, for the purpose of the sector inquiry, disputes were defined as any exchange of views between companies which had not (yet) resulted in litigation, where, in particular, issues were raised concerning alleged infringement, or counter-claims for non-infringement or invalidity of one or several patents concerning a specific INN or R&D programmes has been raised. For the sake of clarity, patent opposition procedures were excluded from the scope of the term.

⁵⁹⁶ For a definition of "contact", please refer to footnote 384.

⁵⁹⁷ The question concerned all INNs cited in the Annex on INNs, and any R&D programmes and patents which were subject to contacts in the period 2000-2007 in any of the EU Member States.

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with other industry players where either [they] or the other party assert claims against the other unless these rise to the level of a serious dispute that has significant potential to lead to litigation." Moreover, as stated above, the 219 INNs to which this information relates contain a good number of INNs of lesser importance to originator companies, because they have ceased to enjoy patent protection. In view of the difficulties of classifying exchanges as disputes or contacts and the generic focus of the 219 INNs, this section presents the combined findings on disputes and contacts.

3.2.2.1. Number of Patent-Related Exchanges

(1155) Respondent companies reported approximately 200 patent-related contacts that had not (yet) led to litigation between different originator companies in the period 2000-2007 across the EU. During the public consultation it has been submitted that this is a very low number, but it should be noted that the figure is in all likelihood a conservative estimate. Only 40% of respondent companies were able to provide useful information and many of the companies that did provide the requested information explained that they were not able to provide exact figures.⁵⁹⁸ As one of the companies puts it:

"For a multinational company on the scale of [ours], an interpretation of "contacts" that extended to contacts "related" to any product covered by a patent would necessitate the disclosure of an enormous volume of day-to-day communications with other originators.[...] Not only would such a wide disclosure be extremely burdensome for [our company], it would also be practically impossible given the limitations of internal records."

(1156) This is also confirmed by another originator company:

"In order to provide a meaningful answer [our company] has collected contacts on patent issues which went beyond the informal level of a mere telephone call or a spontaneous conversation but where proper meetings were held and/or where written communication was exchanged.

Please note that [our company] does not have a formal process neither on corporate nor on a national level for recording contacts similar to the way it has a standard operating procedure regarding archiving of executed agreements."

Respondent originator companies reported a lower figure for exchanges that they qualified as disputes. For the period 2000 – 2007, four companies reported eleven disputes concerning four INNs that did not end in litigation.

⁵⁹⁸ In addition, the sample of 219 INNs focuses on the relation between originator and generic products, and therefore is less helpful in analysing both number of disputes and litigation cases between originator companies.

3.2.2.2. Context and Initiation of Patent-Related Exchanges

3.2.2.2.1. Exchanges Initiated by the Originator Company Holding the Patent

(1157) As stated previously,⁵⁹⁹ a number of originator companies monitor possible infringements of their patent rights and attempt to ascertain whether, for example, the INNs and R&D programmes of other originator companies have potential to infringe their rights. Where a possible infringement is detected, the originator company owning the patent right may take up contact with the other originator company in question.⁶⁰⁰ As an originator company explained, this could be done to seek – in a first step – an amicable solution:

[If the company reaches the conclusion] "that a court of competent jurisdiction would find that the intended activity infringes one or more of [their] patents, the affected [...] company will contact the infringer and attempt to resolve the matter amicably (e.g. by granting an enabling licence). In the event the matter is not amicably resolved, patent enforcement proceedings may be pursued."

(1158) The statement of another company confirms that it is not unusual for an originator company holding a patent to contact another originator developing an R&D programme in the same field as the patent in order to offer the latter company a licensing agreement on one or more of its patents:

⁵⁹⁹ For further details see Chapter C.3.1.

⁶⁰⁰ One of the respondent companies provides a categorisation of their patent-related contacts with other originators, which are patent-related to various degrees. The first of the categories covers “*specific contacts relating to a defined project involving [the company’s] patent department.*” It includes “*approaches to and from other originator companies in contemplation of a specific project and potential proposals to license-in or out a patent for the project. Depending on the circumstances, such an approach may then develop into a discussion and even a series of negotiations.*” The second category concerns contacts encountered by local member state organisations of the company and the local organisations of other originator companies relating “[...] *to proposals to enter into licensing, supply, co-promotion, co-packaging and co-marketing arrangements. The focus of these contacts is on specific products that are on, or about to enter, the market. While these products are generally patent protected, the discussions and contacts are focused on the collaborative aspects of manufacturing or marketing the products. Thus, generally these contacts do not involve or relate to patents of the other companies that concern [the company’s] INNs, R&D programmes or patents.*” The third category of contacts as defined by the same company relates to contacts between its global or regional office and the global or regional offices of other originator companies. “*The focus of the discussions range from in-licensing of development-phase compounds, to out-licensing or divestment of mature brands, and everything in between (e.g., regional co-promotion deals, supply agreements, regional co-marketing, distribution, etc.). As above, the focus of these contacts is on the specific product or compound in development as opposed to any of the patents. Generally speaking, the products are patent protected, but the discussions do not involve or relate to patents of the other companies that concern [its] INNs, R&D programmes or patents. Typically, the discussion would involve another company’s product or compound (covered by its own IP) or [the company’s] product or compound (cove[re]d by [its] own IP). [...] To further amplify this point, at any given time, [the company] is in discussions with multiple companies about potential in licensing opportunities. The extent of these discussions varies considerably from a short meeting, to a due diligence review of the prospective compound or product, to full-blown negotiations at the global level.*”

[The company was contacted by another originator company owning a patent] "with an offer to license their [...] patent. [Our company] replied that it did not desire a licence at this time, but might speak with them about a licence in the future."

(1159) In some instances, originator companies owning the patent rights may send letters which could be of similar intention as warning letters addressed to generic companies.⁶⁰¹ They usually inform the addressee of the alleged infringement and, in some cases, outline the potential legal consequences. Although not directly adversarial from the outset, such letters indicate that the sending company has no intention to tolerate the alleged infringement of its patents.

Example warning letter:

"[Our company] has compiled a patent portfolio composed of four patent estates. [...] These patents may be of interest to you in connection with your [...] programs.

Specifically, absent a licence from [our company], you would be practising inventions claimed in these estates by your manufacture, use, sale, offering for sale, and/or importation of [a product]. [...]

For your reference, we have provided herewith:

1) four tables listing the issues patents and pending patent applications constituting the portfolio [...]; and

2) a bound copy of documents containing the title page and claims of certain issued patents and published applications included in the portfolio, [...] which are practiced (absent a licence) by the activities described above.

If you have any questions regarding the patent portfolio, please do not hesitate to contact me."

3.2.2.2.2. Exchanges Initiated by the other Originator Company

(1160) Originator companies, which for example develop a new R&D programme, carry out patent clearance studies or, as they may also be called, "freedom-to-operate" searches, verifying whether their R&D programme might violate the patent rights of another originator company.⁶⁰² The sector inquiry established that when an originator company engaged in R&D detects a possibly relevant patent right held by another originator company, it may contact the patent-holding originator company:

⁶⁰¹ For further details see Chapter C.2.2.

⁶⁰² For further details see Chapter C.3.1.

"[our company] has had contacts with other originator companies regarding patents of those other originator companies which concerned [our company's own] R&D poles."

- (1161) The sector inquiry also examined separately situations, in which an originator company requested a licence from another originator company. In addition to reporting exchanges with other originator companies, respondents were asked to report all cases in which they approached another originator with such a request.
- (1162) Half (22) of the respondent companies confirmed that they had asked other originator companies for licences in the framework of exchanges. In total, they reported 99 instances for the period 2000-2007. The requests concerned a total of 84 INNs and R&D poles.

3.2.2.3. Licences and Refusals to Grant a Licence

- (1163) Out of the 99 reported cases of licence requests mentioned above, in 77 cases a licence was granted. In four cases discussions between the patent owner and the company interested in receiving a licence were still ongoing⁶⁰³ at the time of the inquiry and it is not yet possible to foresee their outcome. As for the remaining cases – where a licence was not granted – in a significant majority of such situations the licence had been requested by a company who needed it to bring a novel product on the market. That was the case of 16 out of the total of 18 cases where the applicants did not receive a licence.
- (1164) In cases where no licence agreement was concluded, respondent companies were asked to give reasons for the failure of negotiations. According to the replies received, in seven cases this was because parties failed to agree on the contract terms. In seven other cases companies explained that they did not continue the negotiations because they decided to abandon the project or because obtaining a licence was not essential for the project. In one case the respondent company was outbid by a third party and in three cases a licence was refused without any reasons being provided.
- (1165) The sector inquiry also examined the effect of the failure to obtain a licence on the activity of the requesting company. In five cases respondent companies explained that they managed to design around the patent to develop a different but similar product and managed to launch (or were preparing to launch) that product on the market. Obviously this meant additional costs to bring the product to market.
- (1166) In half of all refusal cases (nine) companies decided to discontinue their projects, while in two of those cases the impossibility to obtain the licence was the sole reason for abandoning the project. In the remaining cases the companies are still trying to find a solution to the situation. While the refusal already created an additional burden on the companies concerned in the latter type of cases, especially in terms of expenditure on R&D, the final impact of the refusal is not yet clear, as it is not yet certain whether the

⁶⁰³ Such licences may be part of an (out of court) settlement, see Chapter C.3.4.

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companies will manage to overcome the difficulties related to the IP situation and successfully launch a product.

3.2.3. Litigation between Originator Companies

(1167) Another form of direct interaction on patents between originator companies that falls within the scope of the inquiry is patent-related litigation.

(1168) The term "litigation" refers in this context to any type of court proceedings or other form of adversarial proceedings, excluding opposition notified to any patent office. It includes litigation before all courts in any given proceedings.

(1169) Litigation is a factor to take into consideration when analysing market conditions. For originator companies, litigation may be a tool to enforce their patents and therefore defend and preserve their rights. It may at the same time affect the research activities and market entry of potential competitors. As shown in Section C.3.2.1., there may be overlaps between the patents of one originator company with, for example, an INN or an R&D programme belonging to another originator company, which in some cases can lead to legal proceedings.

(1170) The sector inquiry analysed data on litigation between originator companies submitted by the respondents in order to measure the extent of litigation in the sector. Respondent companies were asked to provide information on litigation with other originator companies in the period 2000-2007 in relation to any of 219 selected INNs, as listed in an annex to the questionnaire. As stated above, a good number of the 219 INNs are of more limited interest for this section, as they concern INNs which had lost patent protection and became eligible for generic copying.

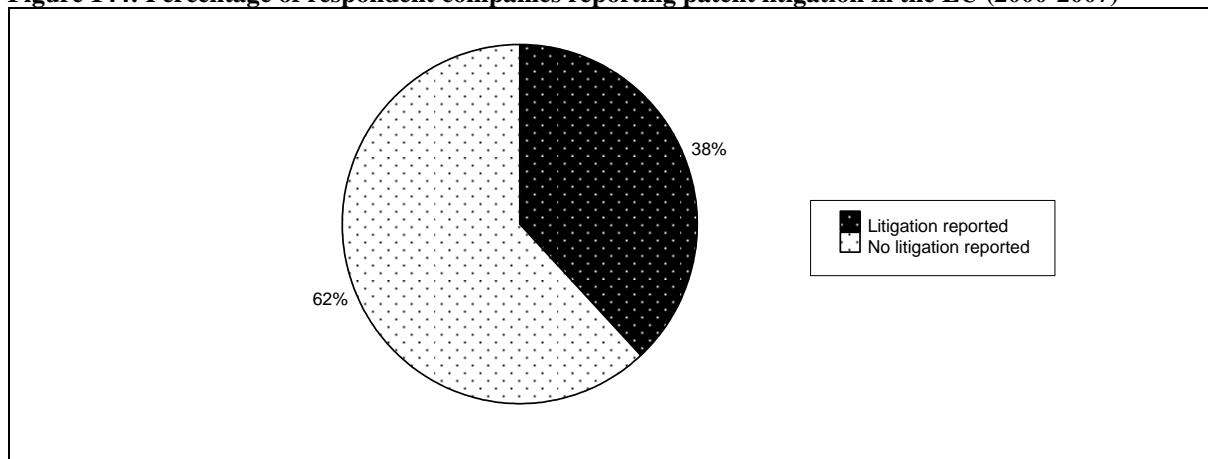
(1171) This section first presents general data on litigation, including the number of companies involved, the INNs concerned and the number of litigation cases between originator companies. Subsequently, the types of legal actions and the patents concerned by litigation are examined. The section also analyses the outcomes of litigation and discusses interim injunctions. Finally, the overlap of patents, INNs and R&D poles of originator companies involved in litigation is analysed.

3.2.3.1. Number of Companies Involved, INNs Concerned and Number of Litigations between Originator Companies

(1172) It is informative to analyse the proportion of respondent companies which were concerned by litigation on any of their INNs and to give a general overview on the total number of litigation cases reported.

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Figure 144: Percentage of respondent companies reporting patent litigation in the EU (2000-2007)

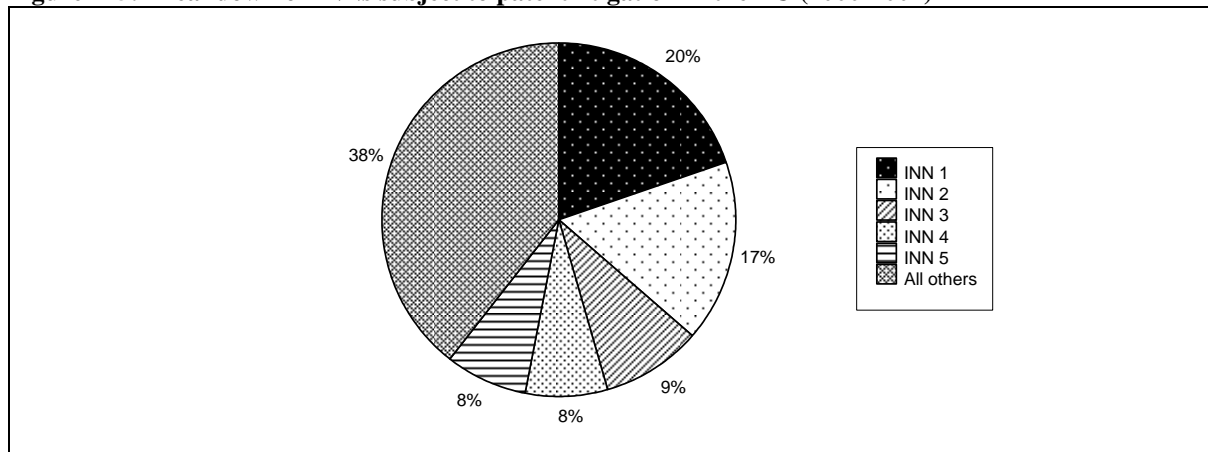


Source: Pharmaceutical Sector Inquiry

(1173) Figure 144 illustrates that 16 of the respondent companies (38%) reported that they were or had been involved in at least one separate case of litigation⁶⁰⁴ in the EU which related to another originator company's patents in the period 2000 – 2007.

(1174) Respondent companies reported a total of 66 separate litigation cases taking place between 2000 and 2007 in an EU Member State. This includes separate litigation cases where final judgments were reached ("*res iudicata*"), but also litigation which was pending at the time of the survey or that was ended before the final judgment was handed down, for example by means of a settlement between the parties. Together, the five companies most involved in litigation accounted for 68% of all litigation reported.

Figure 145: Breakdown of INNs subject to patent litigation in the EU (2000-2007)



Source: Pharmaceutical Sector Inquiry

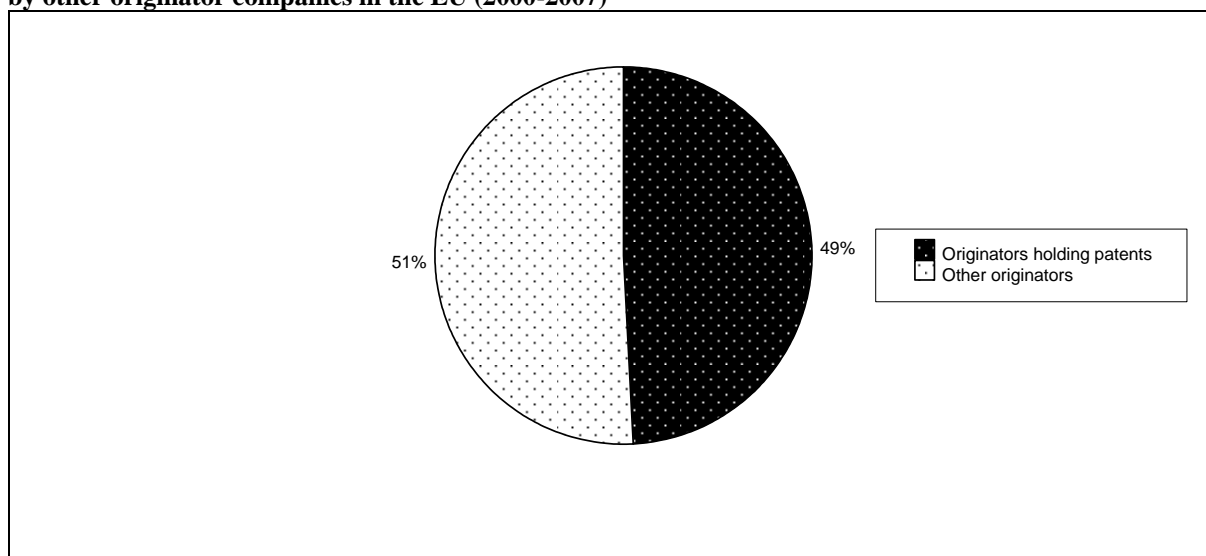
⁶⁰⁴ As in the section concerning litigation between originator and generic companies, the term 'separate litigation' is also used in the present section to refer to patent litigation cases in one Member State identified by a single court reference number irrespective of the number of patents concerned or parties and instances involved.

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(1175) Figure 145 above presents a breakdown of INNs subject to litigation between originator companies in the period 2000 – 2007. Out of 219 INNs, 18 INNs (8.2%) were subject to litigation between originator companies.

(1176) The five INNs subject to the most cases of litigation together accounted for more than 60% of all litigation, namely 40 of the 66 cases. It should be noted that four of these five INNs belong to the top-selling INNs (T50 list). What is more, only six out of 18 litigated INNs are not qualified as top-selling INNs. The single INN concerned by the highest number of separate litigation cases accounted for approximately 20% of all cases.

Figure 146: Percentage of litigation initiated by originator companies holding the patents concerned and by other originator companies in the EU (2000-2007)

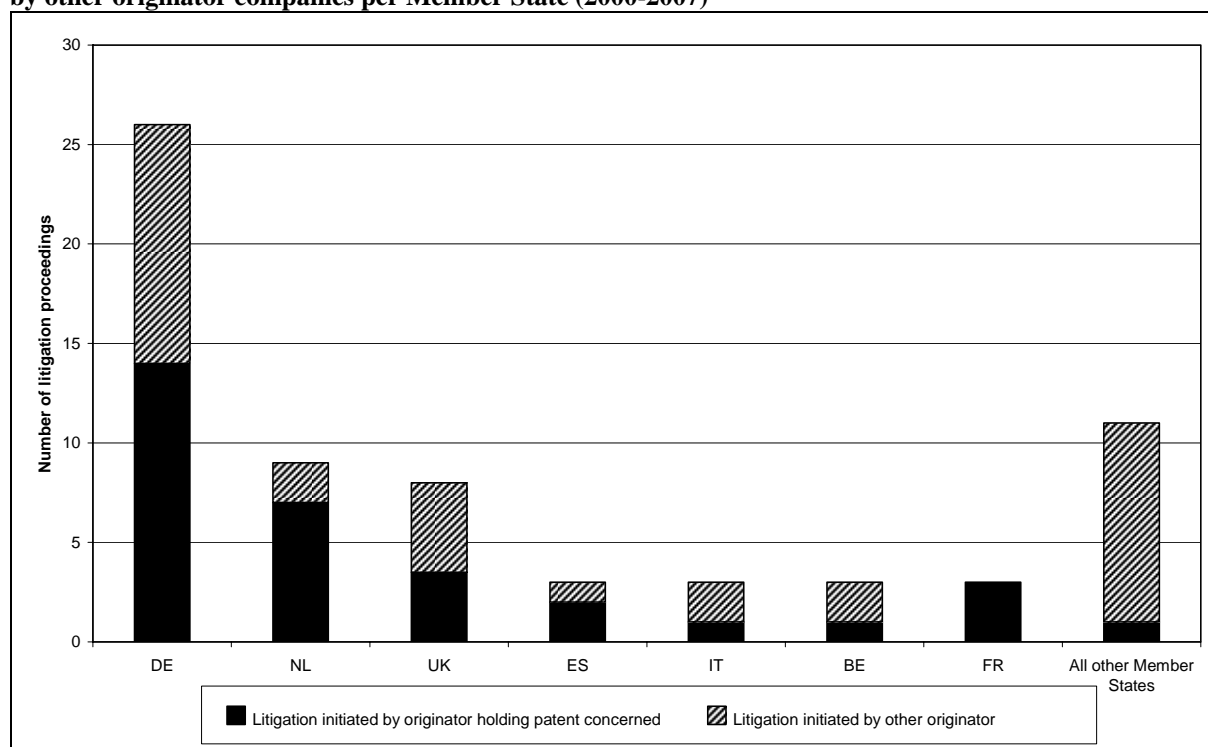


Source: Pharmaceutical Sector Inquiry

(1177) As shown in Figure 146 above, patent-related litigation was initiated to nearly the same extent by originator companies whose patents (including in-licensed patents) were concerned (49%) and by other originator companies (51%).

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Figure 147: Number of patent litigations initiated by originator companies holding patents concerned and by other originator companies per Member State (2000-2007)



Source: Pharmaceutical Sector Inquiry

(1178) Figure 147 above shows the number of patent litigations per Member State that were initiated by originator companies holding the patents concerned by litigation (including in-licensed patents) against other originator companies. The figure also shows the number of patent litigations initiated by the other originator companies. Member States concerned by two or less litigation cases are not presented individually, but grouped together in the last column ("all other Member States").

(1179) The litigation reported concerned 17 Member States; the five Member States in which most litigation cases took place accounted for approximately 74% of all litigation reported.

(1180) It should be noted that the highest number of litigation cases, 26 out of 66, took place in Germany, accounting for 39% of all litigation reported. Second ranked was the Netherlands with nine reported cases. These countries were followed by the United Kingdom with eight litigation cases and Spain, Italy, Belgium and France, with three cases each. Together, the remaining ten Member States in which patent litigation was reported by respondents accounted for 11 cases.

(1181) In Germany, the Netherlands, Spain and France, the majority of litigation cases were initiated by originator companies with the purpose of enforcing their patent rights. In the United Kingdom, Italy, Belgium and in the combined group of "all other Member States" the majority of patent litigation was brought against originator companies holding the patent(s) concerned by other originator companies.

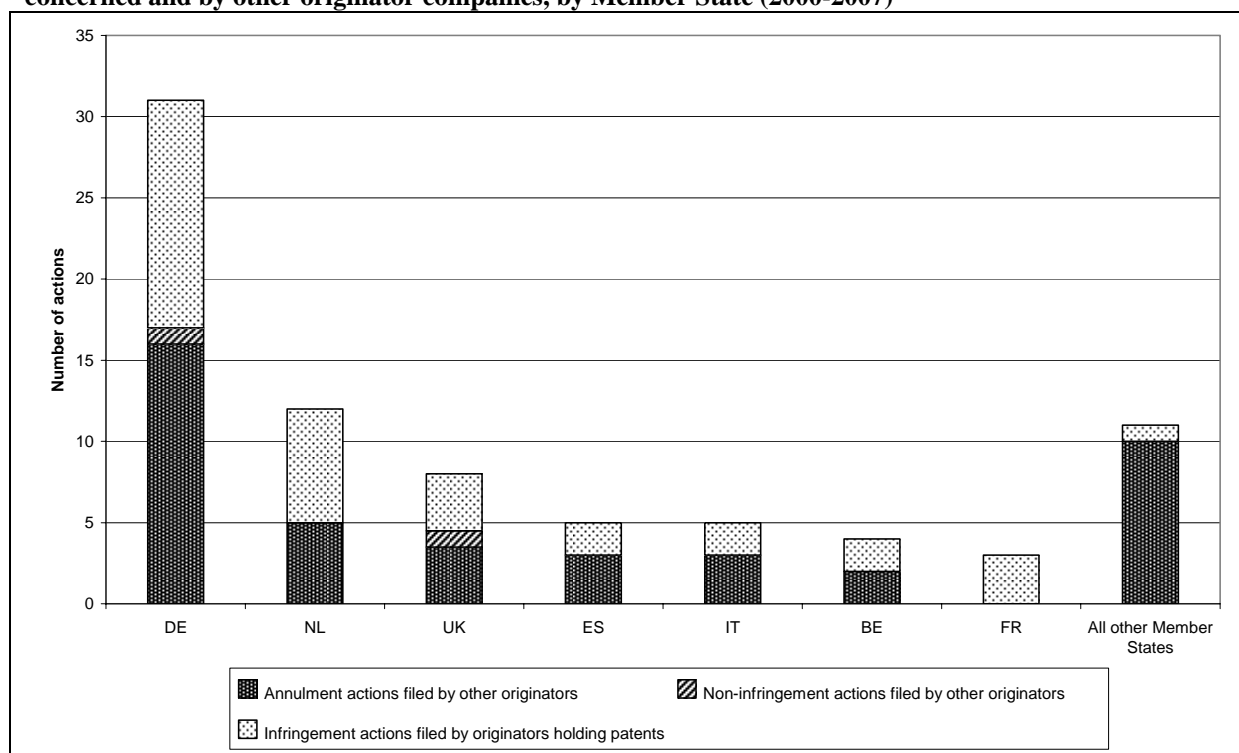
3.2.3.2. Types of Legal Actions Brought and Patents Concerned

(1182) In order to better understand the possible scenarios for litigation between originator companies, it is useful to look further at the types of legal action brought and at the types of patents concerned by litigation.

(1183) Figure 148 illustrates in detail the number of specific types of action initiated in each Member State. Member States with only one or two litigation cases are not presented individually but grouped together in the last column ("all other Member States").

(1184) Figure 148 distinguishes between annulment⁶⁰⁵ and non-infringement actions brought by originator companies facing the patents of other originator companies and infringement actions filed by originator companies with the purpose of enforcing their patents (including in-licensed patents).

Figure 148: Number of actions (per type of action) brought by originator companies holding patents concerned and by other originator companies, by Member State (2000-2007)



Source: Pharmaceutical Sector Inquiry

(1185) In 52% of litigation cases, originator companies aimed at enforcing their patents through infringement actions. In 68% of patent litigation cases, other originator companies challenged the validity of patents (65% annulment actions) or claimed that they did not infringe the patents in question (3% non-infringement actions). The sum of these figures exceeds 100% because some litigation cases concern more than one

⁶⁰⁵ Also sometimes referred to by the respondent companies as "invalidity". Please refer to footnote 207 concerning clarification on terminology.

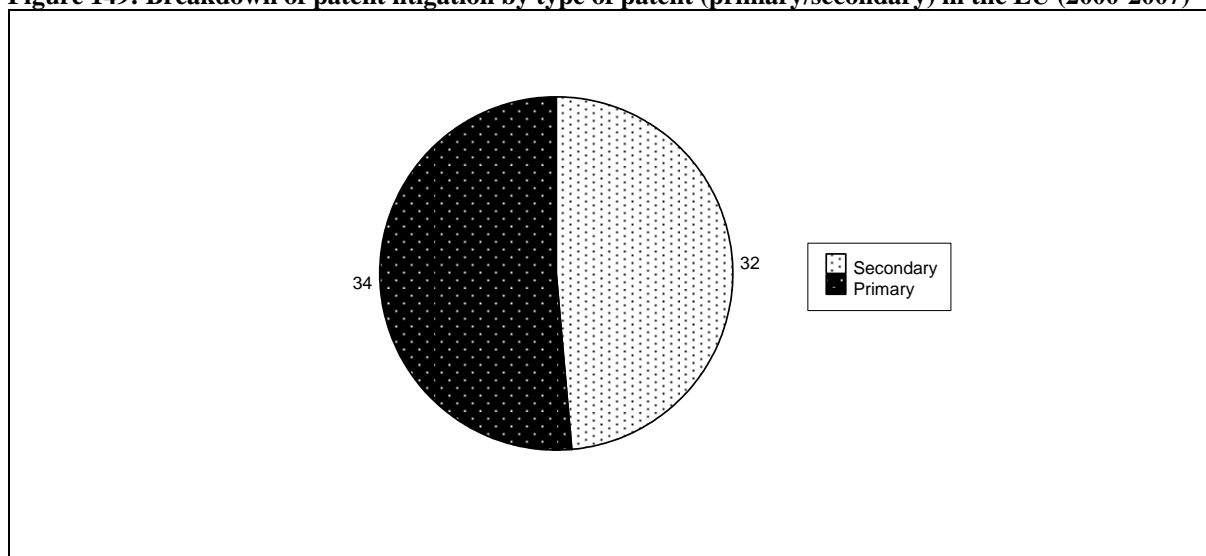
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action, whether infringement, non-infringement or annulment, at the same time (e.g. as actions and counter-actions).

(1186) In Germany, the United Kingdom, Spain and Italy non-infringement and annulment actions accounted for a slight majority of litigation cases. Infringement actions filed by originators seeking to enforce their patents were predominant in the Netherlands and in France litigation concerned exclusively infringement actions. In Belgium the number of annulment and infringement actions was equal. In the combined group "all other Member States", patent annulment actions clearly predominated.

(1187) Note that in ten litigation cases (approximately 15% of all cases) both parties to the litigation claimed infringement of their respective patents. Such cases took place in Germany, the Netherlands, the United Kingdom, Spain, Italy, Belgium and France.

Figure 149: Breakdown of patent litigation by type of patent (primary/secondary) in the EU (2000-2007)



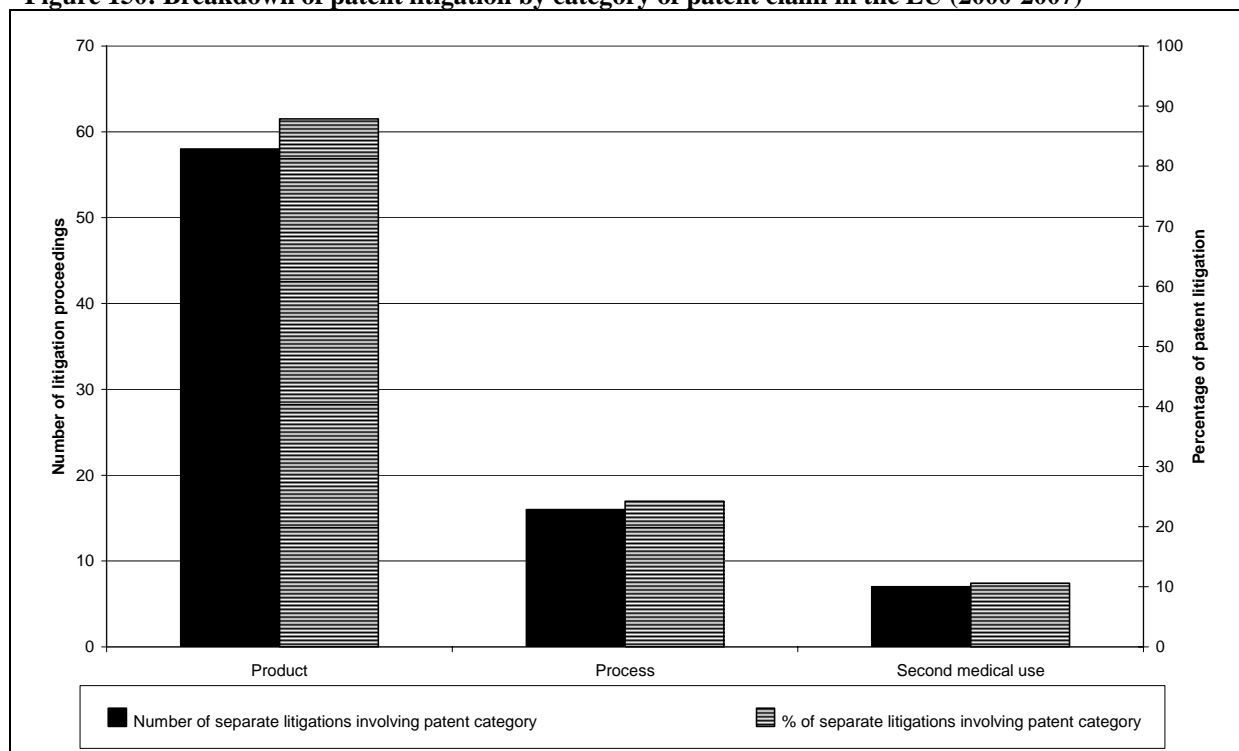
Source: Pharmaceutical Sector Inquiry

(1188) Figure 149 provides an overview of the types of patents concerned by litigation. Primary patents accounted for 34 of the 66 cases of litigation reported (51.5%), while secondary patents accounted for 32 cases (48.5%).⁶⁰⁶

⁶⁰⁶ The terms "primary patents" and "secondary patents" are being used by the report, as they constitute part of the terminology employed by stakeholders in this sector and thus are key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying interventions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

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Figure 150: Breakdown of patent litigation by category of patent claim in the EU (2000-2007)



Source: Pharmaceutical Sector Inquiry

(1189) Figure 150 above illustrates the number of litigation cases concerning a given category of patent claims and their proportion in the total number of litigation cases between originator companies. Since patents may comprise more than one patent claim at the same time, the number of cases provided exceeds the actual total number of litigation cases. Accordingly, percentages exceed 100%.

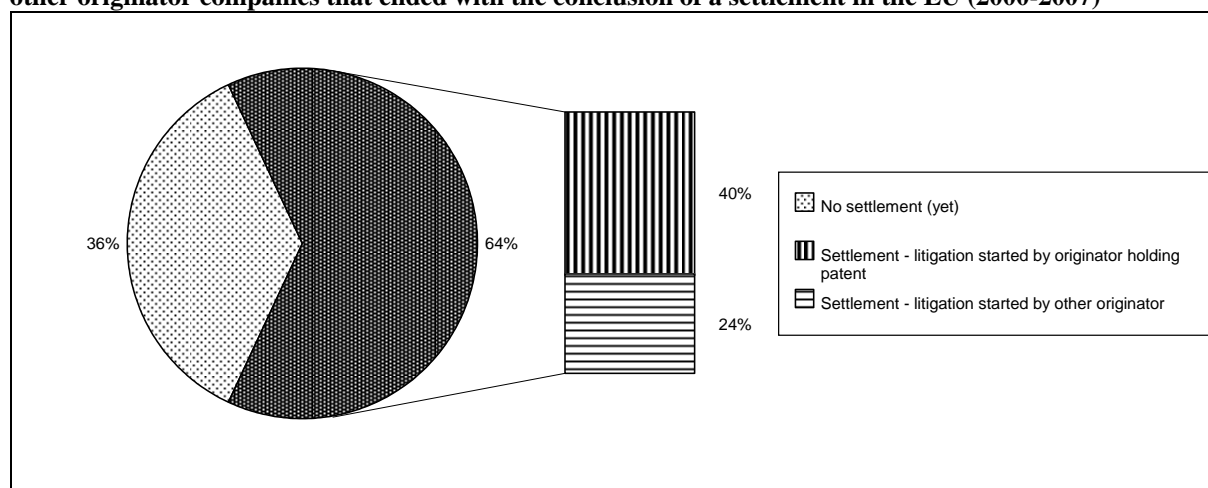
(1190) Figure 150 shows that in almost 88% of cases litigated patents included product claims. Process claims accounted for just over 24% of litigation cases and second medical use claims accounted for approximately 11% of litigation cases.

3.2.3.3. Outcome of Litigation

(1191) In this subsection the outcome of litigation reported by respondent companies is analysed, in terms of how many cases were settled or reached final judgments and, in the latter case, whether compensation was paid.

PHARMA SECTOR INQUIRY – MAIN ISSUES INVESTIGATED

Figure 151: Number of litigation cases started by originator companies holding patents concerned and other originator companies that ended with the conclusion of a settlement in the EU (2000-2007)

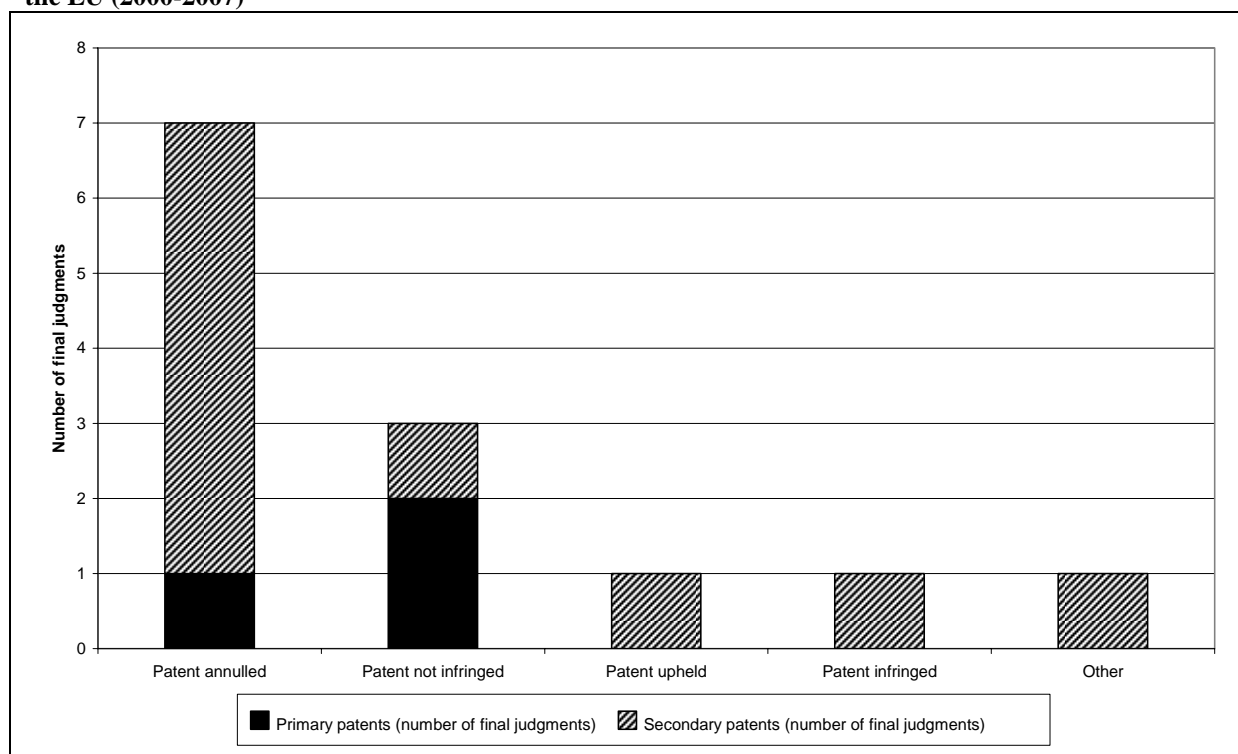


Source: Pharmaceutical Sector Inquiry

(1192) As can be seen in Figure 151, the majority of litigation cases between originator companies ended in a settlement agreement. Altogether, this happened in 42 of the 66 litigation cases, or 64% of cases. The majority of cases ending in settlement had been brought by originator companies holding the patents concerned (40% of all litigation cases, i.e. 82% of the cases brought by these originator companies). Cases brought by other originator companies ended in settlement in 24% of all litigation cases, i.e. 46% of cases brought by other originator companies.

PHARMA SECTOR INQUIRY – MAIN ISSUES INVESTIGATED

Figure 152: Outcome of litigation by primary and secondary patents and by number of final judgments in the EU (2000-2007)



Source: Pharmaceutical Sector Inquiry

(1193) Figure 152 illustrates the number of final judgments reached, broken down by outcome and by type of patent concerned.⁶⁰⁷ Final judgments were rendered in 13 of the 66 litigation cases reported and for primary patents in three cases and secondary patents in ten cases. Litigation had been brought in four of the cases reported by the originator company holding the patent concerned, and in nine cases by the other originator company.

(1194) As illustrated by Figure 152, in the majority of cases the patent concerned by the litigation was annulled, i.e. in seven of the 13 litigation cases (approximately 54%). In three cases (23%) the patent was found not to have been infringed. In one final judgment the litigated patent was upheld and in one case the patent was found to have been infringed. There was one other case, in which the patent was initially upheld in amended form; the judgment became final when litigation was abandoned due to the expiry of the patent in question.

⁶⁰⁷ The figures do not include judgments that became “final” pursuant to a settlement agreement between parties, e.g. by an agreement of the parties to renounce their right to appeal against a judgment or to withdraw a pending appeal.

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Table 36: Compensation paid by originator companies holding the patents concerned to other originator companies (number of final judgments)

Outcome of litigation by final judgment	Compensation paid by originator holding patent
Patent upheld	0
Patent infringed	0
Patent annulled	2
Patent not infringed	2
Other	0
Total	4

Source: Pharmaceutical Sector Inquiry

(1195) Table 36 shows for the 13 final judgments shown in Figure 152, the cases in which the originator company holding the patent concerned paid compensation to the other originator company. As can be seen, such compensation was paid in two cases pursuant to the annulment of a patent and in two cases pursuant to the finding that the patent had not been infringed. In all four of those cases, compensation was ordered by court.

3.2.3.4. Interim Injunctions

(1196) According to the data submitted by respondent companies, hardly any interim injunctions were issued in litigation between originator companies.⁶⁰⁸ This is in contrast to the findings on litigation between originator and generic companies, where interim injunctions are more regularly sought.

(1197) According to the explanations provided by respondent companies, some litigation cases concerned situations where the allegedly infringing product had not yet been marketed when litigation was begun. At that stage, for example, originator companies seeking to enforce their patents might not yet be able to seek interim injunctions, as no threat to their commercial position yet exists. The category of the patent alleged to have been infringed may also play a role. As one of the companies explains:

"the patent being asserted was a secondary patent on the process of making [a product]. Normally, it is difficult to obtain an interim injunction on a process claim and when many of the factual details relating to infringement were in dispute."

⁶⁰⁸ Out of 66 litigation cases only three procedures led to interim injunctions.

3.2.3.5. Cases of Litigation Concerning Potentially Overlapping Patents, INNs and R&D Poles of Originators with Patents of other Originators

(1198) In at least 75.8% of litigation cases between originator companies, the originator companies holding patents concerned by litigation had an INN or R&D programme in the same ATC3 class as the INNs and R&D programmes of the other originators, according to information obtained from the latter.⁶⁰⁹ In other words, in the vast majority of cases the activity of the originator company whose patent was in question was very similar activity to that of the other originator company, which can be taken as an initial indication that the two originator companies were actual or potential competitors.

(1199) According to the other originator companies, in 36% of all cases where the originator company holding the litigated patent had an INN or R&D in the same ATC 3 class as the other originator, that patent did not cover any of the patent-holding company's INNs or R&D programmes.⁶¹⁰ In other words, in more than one third of these cases, initial indications are that an originator company entered into litigation against another competing originator company over patents which did not in fact protect any of its activity in the market.

3.2.4. Use of Comparator Medicines for Clinical Trials

(1200) When testing new medicines on patients within clinical trials it is common and often necessary for originator companies to test them against existing products with similar therapeutic effects in order to compare the new medicines' efficacy to its potential future competitors. In fact, according to EU pharmaceutical legislation, marketing authorisation requires that the applicant company demonstrates quality, safety and efficacy of the product.⁶¹¹ Thus the general requirements for the demonstration of efficacy as set out in the EMEA guidelines include efficacy studies in relation to a comparator, in other words an established medicinal product of proven therapeutic values. For this purpose so-called comparator medicines need to be acquired from other originator companies. According to a major association of originator companies, in most cases comparator medicines are sourced from commercial supply chains. Where this is not feasible, they may be sourced directly from the manufacturer, e.g. where patient numbers are small and the product is not on the market or where the product is highly specialised and tests are to be carried out on comparator medicines from the same manufacturing batch.

⁶⁰⁹ In another 9% of cases the respondents to the market survey did not know whether or not this was the case.

⁶¹⁰ In another 16% of cases the respondents to the market survey did not know whether or not this was the case.

⁶¹¹ For details, see Chapter B.2.2.

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- (1201) During the course of the inquiry it was suggested that in some instances access to comparator medicines can be rendered difficult by originator companies which are claimed to use different means to create obstacles. Companies active in the sourcing of such comparator drugs for clinical trials pointed out that they had increasingly encountered cases where prices of the comparator medicines were raised between 50% to more than 100%. Furthermore several of these companies noticed delays in the delivery of comparator drugs of about three to four months. In some cases originator companies refused to supply comparator drugs to clinical trials for new medicines. It was also submitted that most originator companies that supply comparator medicines would only do so on the condition of obtaining trial details of their future potential rivals, in some cases full access to trial data.
- (1202) It was also pointed out that such practices can have an effect on the time schedule of clinical trials, possibly impacting the development schedule of new competing medicines.
- (1203) When asked about these submitted observations, an association of originator companies confirmed the increasing importance and use of comparator drugs in clinical trials. Furthermore it was stated that there may be objective reasons explaining delays in supply such as an insufficient production capacity due to a more rapid uptake of the medicine in the market than expected. Orders for comparator drugs that exceed planned production schedules would not necessarily get priority treatment. The association pointed out that to the best of its knowledge none of its members had ever identified the availability of comparator drugs as an issue of concern.

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Summary

In total, the inquiry reveals at least 1,100 instances where the patents held by an originator company potentially overlap with the medicines, R&D programmes and/or patents held by another originator company for their medicine. In these cases originator companies might find their research activities blocked, with detrimental effects on the innovation process.

In many cases originator companies managed to settle potential disputes, for instance through licensing arrangements. However, in approximately 20% of the 99 cases where a licence was requested, the requesting companies did not obtain a licence. Reportedly, in several cases this led to the discontinuation of the R&D project or required additional efforts to go around the obstacles.

Whilst the selection of the 219 molecules was largely based on patent expiries to capture the relationship between originator and generic companies, the inquiry still finds that originator companies engaged in 66 litigation cases against other originator companies. The patent-related litigation concerned 18 medicines. In 64% of the cases, litigation was concluded by means of settlement agreements. The number of cases where a final judgment was reported was relatively low (thirteen of the 66 cases), with patent holders losing ten of the thirteen cases (77%).

3.3. Oppositions and Appeals

(1204) This section analyses oppositions and appeals, in which originator companies opposed patents of other originator companies.⁶¹²

(1205) As explained in Chapter C.2.3., the report is based on information obtained concerning oppositions and appeals in respect of 219 INNs. For general information on opposition and appeal procedures, in particular, their average duration, we refer to Subsection C.2.3.1.4.

(1206) Opposition procedures are a quality control mechanism on which originator companies can rely to have the patents of other originator companies scrutinised. If, for example, an originator company faces a so-called "defensive patent"⁶¹³ belonging to another originator company, it can oppose that patent. In the opposition procedure the patent's validity and scope is verified. If the patent proves to be invalid, it is either revoked or restricted in scope.

(1207) This section only covers the opposition procedure before the EPO (including appeals).⁶¹⁴ It first presents the number of opposition procedures and opponents in the period 2000 – 2007. It then examines the types of patents opposed, before analysing the outcomes of the final opposition and appeal decisions. Finally, the section looks into cases where the originator companies involved in the opposition procedure entered into a settlement agreement with each other.

3.3.1. Number of Opposition Procedures, Opponents and Types of Patents Opposed

(1208) In the period 2000 – 2007, a total of 58 opposition procedures were reported in which 76 opponents were active (Figure 153). This means that on average 1.31⁶¹⁵ originator companies opposed the relevant patents of another originator company in each opposition procedure.⁶¹⁶

⁶¹² For oppositions and appeals concerning oppositions by generic companies against originator companies' patents, see Chapter C.2.3.

⁶¹³ This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying interventions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology. For further details on defensive patenting, see Chapter C.3.2.

⁶¹⁴ For information on opposition and appeal procedures, reference is made to Chapters C.2.3. and B. A general overview of oppositions before offices and bodies of the Member States is provided in Subsection C.2.3.1.5.

⁶¹⁵ $76/58 = 1.31$

⁶¹⁶ The same originator companies may be involved in a number of opposition procedures.

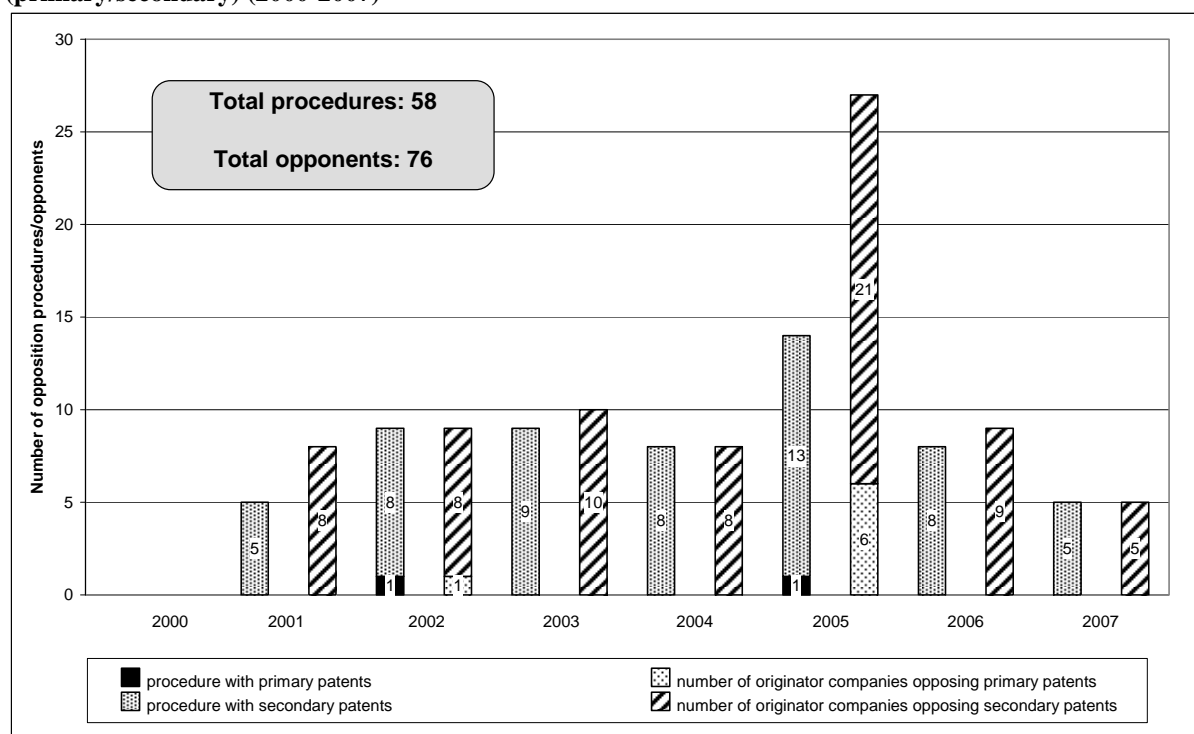
PHARMA SECTOR INQUIRY – MAIN ISSUES INVESTIGATED

(1209) Figure 153 presents the total number of opposition procedures and opponents (originator companies) by year for the period 2000 – 2007. For each year, two bars separately show the number of opposition procedures and the number of opponents (relating to these procedures). Furthermore, Figure 153 distinguishes between opposition procedures concerning primary and secondary patents.⁶¹⁷

(1210) Figure 153 shows that no opposition procedure was reported for the year 2000. For the remainder of the period under investigation, i.e. 2001 – 2007, the number of annual opposition procedures ranged from five (in 2001 and 2007) to a maximum of fourteen (in 2005).

(1211) Regarding the type of patents concerned, Figure 153 reveals that originator companies mainly opposed secondary patents (56 out of 58 opposition procedures). Only in the years 2002 and 2005 was a primary patent opposed.

Figure 153: Number of opposition procedures before the EPO initiated by originator companies by type (primary/secondary) (2000-2007)



Source: Pharmaceutical Sector Inquiry

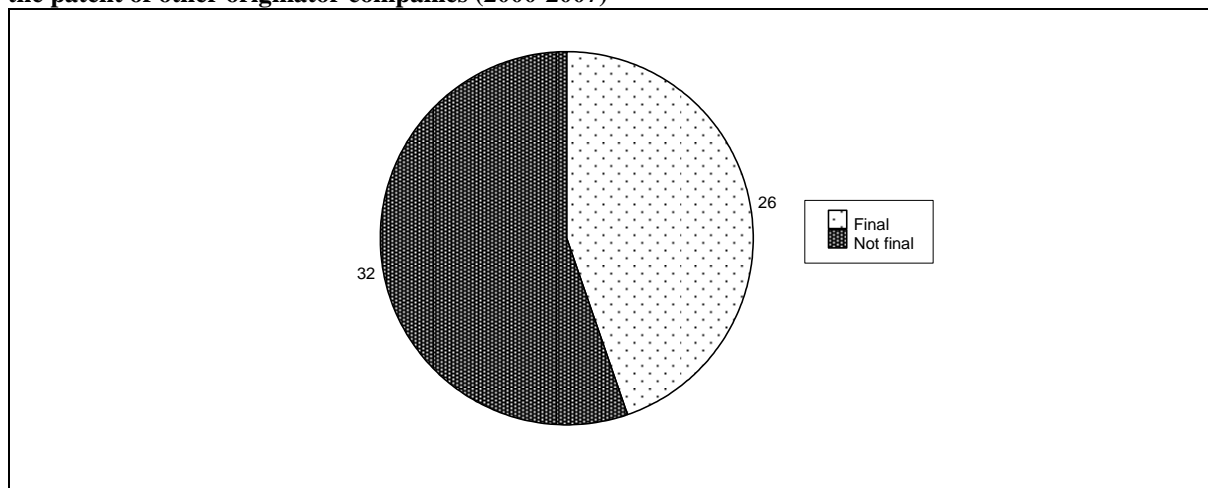
⁶¹⁷ This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying interventions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

3.3.2. Analysis of the Outcomes of Final Opposition and Appeal Decisions

(1212) This subsection analyses the final outcomes. Like the subsection on oppositions and appeals by generic companies,⁶¹⁸ it refers to final EPO decisions (including appeal decisions) (*res iudicata*).

(1213) Figure 154 below shows that in 26 of the 58 procedures (44.8%) begun in the period 2000 – 2007, a final decision was reached. For the other 55.2% (32 out of 58), the procedures were still pending.

Figure 154: Final and pending opposition and appeal procedures involving originator companies against the patent of other originator companies (2000-2007)



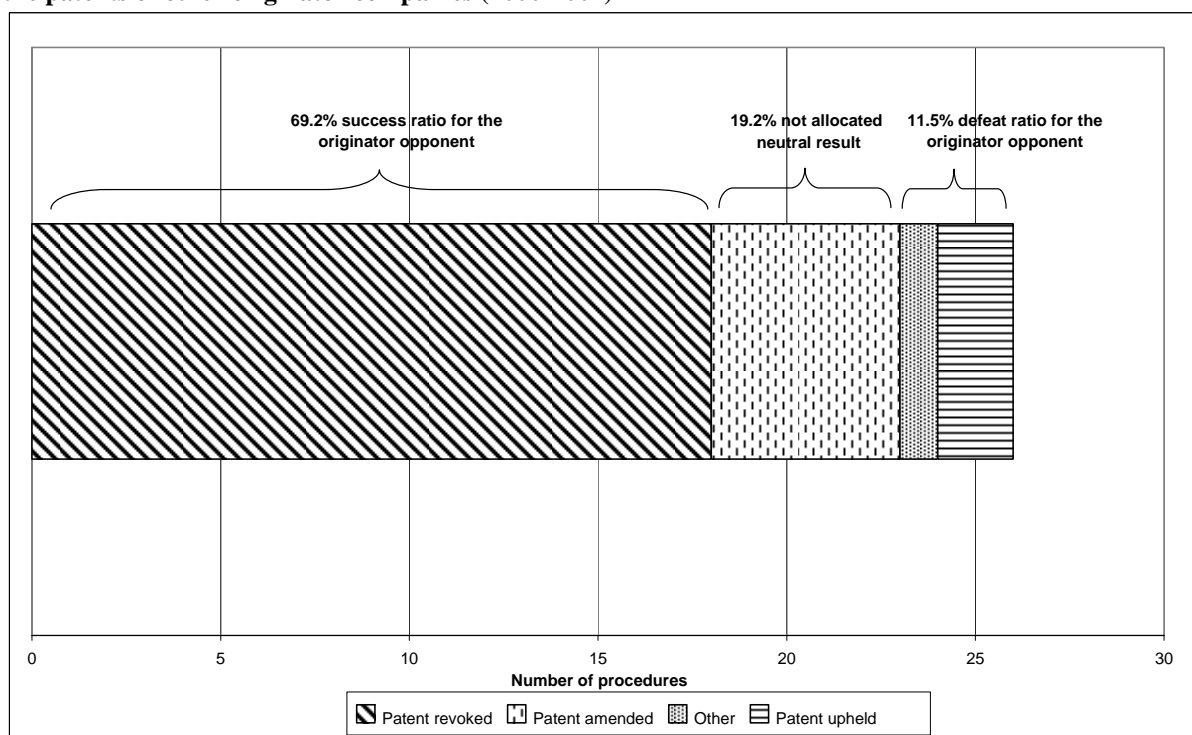
Source: Pharmaceutical Sector Inquiry

(1214) Figure 155 shows the number of cases in which originator companies' patents were revoked, amended or upheld by the final decision. The figure reveals that in 69.2% (18) of all final cases, the patent was revoked, whilst in 19.2% (5) of cases it was reduced in scope (i.e. the patent was amended). In only 7.7% (2) of the cases was the patent-in-suit upheld. One decision was reported as having the outcome "other", because the opposition was withdrawn by the opposing party. In the context of the public consultation, the EPO and other stakeholders pointed out that final outcomes resulting in amendments cannot clearly be identified as a success or defeat for either side involved in opposition and appeal procedures, therefore amendments are not allocated to either side.

⁶¹⁸ For further details see Subsection C.2.3.2.2.

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Figure 155: Final outcomes of opposition and appeal procedures involving originator companies against the patents of other originator companies (2000-2007)⁶¹⁹



Source: Pharmaceutical Sector Inquiry

(1215) From the above it is fair to conclude that, measured by final outcomes, opposing originator companies won the vast majority of opposition and appeal procedures. Even if the final outcome resulting in amendments would hypothetically be counted as defeat for the opposing originator company, the picture that opposing originator companies won the majority of cases would remain unaltered. Only one of the final decisions concerned (and amended) a primary patent, whilst the remaining ones related to secondary patents.

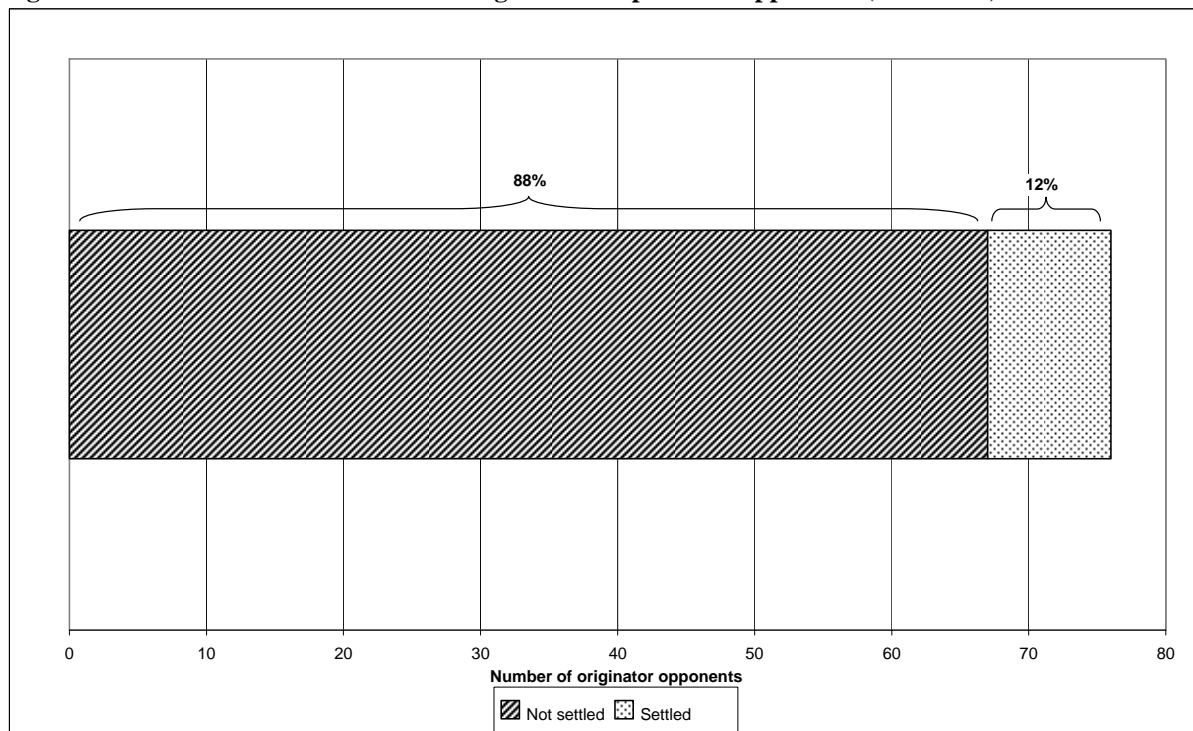
3.3.3. Settlements

(1216) The sector inquiry found that originator companies also enter into settlements with each other in opposition procedures. Figure 156 illustrates that the respondent opposed originator companies only settled with nine of the 76 opposing parties involved in the procedure. These settlements concerned eight different opposition procedures. The settlements are described in further details in Subsection C.2.4.1.

⁶¹⁹ Figure revised following update received from stakeholders.

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Figure 156: Number of settlements with originator companies as opponents (2000-2007)



Source: Pharmaceutical Sector Inquiry

Summary

Between 2000 and 2007, relating to the sample of medicines under investigation, originator companies mainly opposed each other's secondary patents.

The opposing originator companies were very successful when challenging the patents of other originator companies. They prevailed in approximately 70% of final decisions rendered by the EPO (including the Boards of Appeal). In addition, the scope of the patents was reduced in another 19% of the cases.

3.4. Settlements and other Agreements

(1217) As stated in the preceding sections, originator companies do in some instances reach settlements with one another as a result of specific disputes, litigation and/or patent opposition procedures. This chapter provides an overview of settlement practice between originator companies in the EU in the period 2000 – 2007.

(1218) In addition to settlements, originator companies enter into agreements with each other also outside the settlement scenario. This section provides an overview of agreements submitted for the purposes of this inquiry covering the entire value chain in the period 2000 – 2007.

(1219) Note that it is not the objective of this section to provide guidance on which type of agreements concluded between originator companies could be considered compatible or incompatible with EC competition rules.⁶²⁰ The Commission will further investigate whether individual company behaviour may have fallen foul of the competition rules.

3.4.1. Patent Settlement Agreements between Originator Companies

(1220) This subsection first gives an overview of patent settlement agreements between originator companies. Secondly, it sets out originator companies' general considerations with regard to entry into settlement agreements. Thirdly, it briefly describes patent settlement agreements concluded in the EU in the period 2000 – 2007.

3.4.1.1. Overview in the EU

(1221) For the purposes of the sector inquiry, originator companies were asked to submit all patent settlement agreements that they had concluded with other originator companies in the period 2000 – 2007 concerning disputes, litigation and/or opposition procedures with relevance to any of the EU27 Member States and any of the 219 INNs selected⁶²¹.

(1222) Overall, 50% of the originator companies that responded to the questionnaire had been party to settlement agreements with another originator company. Two of these companies had been party to five or more settlement agreements, whereas the majority of the companies that responded had been party to only one or two agreements. The proportion of settlement agreements to litigation between originator companies is 41%. Note that each settlement agreement usually covers several disputes and litigation cases.

⁶²⁰ For further details see Annexes: EC Competition Law (Annexes to Chapter A).

⁶²¹ For further details see Annexes: Methodology (Annexes to Chapter A).

3.4.1.2. Originator Companies' General Considerations and Decision Making Processes in Patent Settlements

Considerations when Entering into Patent Settlement Agreements

(1223) Originator companies that had concluded settlement agreements confirmed that they do not apply a specific or standard settlement policy. Accordingly, each patent litigation, dispute or opposition procedure is reviewed individually, with the overall goal of securing valuable patent rights and freedom to operate. On the other hand, originator companies view the option of settling with other originator companies as part of a bigger global patent position. Therefore, regardless of the eventual outcome of a specific opposition, dispute or litigation case, they might consider settling if they foresee issues of patent disagreement in other territories.

(1224) The key considerations of originator companies when settling are: the strength of their own position in the case (probability of winning or losing), market size and revenue of the originator company's product to be protected, expected/avoided cost of litigation and impact on personnel cost, the inherent uncertainty involved in patent litigation and the expected duration of litigation.

(1225) It has been submitted that in contrast to the originator-generic case, the stakes in disputes and litigation between two or more originator companies are often a question of avoiding or limiting litigation costs and possible damages rather than an attempt to gain market exclusivity. If the originator company which contests another originator company's patent right cannot successfully challenge the patent, it is likely to evaluate the feasibility of designing around the patent or examine the availability and cost of a licence agreement.

(1226) Most settlement agreements concluded between originator companies in fact involve the negotiation of a licence arrangement. One originator company summarised this as follows:

"Most litigation with an originator company involves disputes relating to secondary patents (such a process or other technology) which, if unlicensed, can be designed around. Originator companies generally do explore non-infringing alternatives. So, the issue in litigation between originator companies becomes an economic question—the costs to design around versus the cost to license versus the cost to litigate (if the patent appears invalid or if the question of infringement is a matter of dispute)."

(1227) Another originator company described the settlement situation as follows:

"We evaluate together with many other originator companies large numbers of third party patents and other assets prior to pursuing negotiations relating to licensing or collaboration. Typically such contacts or potential contacts between originator companies make it much more likely that both parties will be able to seek a mutually beneficial settlement of any areas of potential dispute. In contrast, generic companies are unlikely to have any innovative research assets protected by IP."

(1228) It has been submitted that settlements between originator companies occur at an early stage in the product life cycle, normally during the development phase of the product

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(i.e. before the product launch). Originator companies therefore consider litigation easier to settle. One originator company concluded:

"In matters involving originator companies, any litigation is initiated early to clear the way if necessary, or to design around the patented features while the product is in development."

Decision Making Processes

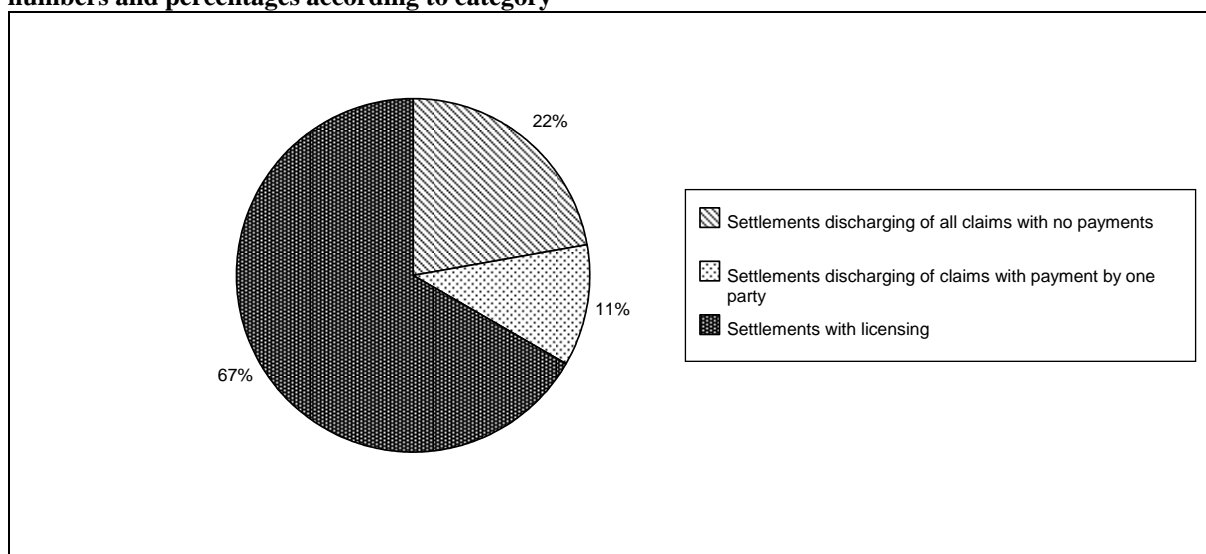
- (1229) Originator companies do not report applying a single or fixed process for deciding whether to enter into a patent settlement agreement with another originator company. Generally, one of the parties opens settlement negotiations through in-house patent attorneys, legal counsel or other departments. Occasionally the first contact is made at top management level.
- (1230) Typically, the in-house patent attorney and legal counsel, with the assistance of external legal advisers, assess the merits of the case and prepare a settlement proposal which is then presented to the executive management for review and approval. Some larger originator companies maintain a standing committee for intellectual property litigation which reviews all ongoing and potential IPR litigation. Important settlements with another originator company require prior approval by senior management.

3.4.1.3. Description of Patent Settlement Agreements between Originator Companies

- (1231) Settlement agreements generally cover all ongoing disputes, litigation and opposition procedures. Their geographic scope is typically determined by the territories covered by the patents.
- (1232) As stated above, settlement agreements concluded between originator companies are very closely linked to licensing. In fact, several originator companies submit that their settlements with other originator companies are licensing agreements rather than settlement agreements.
- (1233) The reported agreements can be categorised according to whether or not there was any value transfer between the companies involved in the agreement (Category 1 agreements do not involve any value transfer). If there was a value transfer (Category 2), one can further divide them into agreements where the value transfer only covers a specific payment (Category 2.I) and agreements where the main value transfer is the grant of a licence between the parties (Category 2.II). These main categories, which will be described in more detail below, are presented in Figure 157.

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Figure 157: Main categories of patent settlement agreements between originator companies, together with numbers and percentages according to category



Source: Pharmaceutical Sector Inquiry

1. Settlement Agreements with No Payments

(1234) This category covers settlements that were concluded on a "walk away" basis, where the parties mutually agree to grant immunity from suit and abandon all existing and future claims for patent infringement and withdraw all opposition. In these agreements both parties agree to respect each others' products and patents and there is no impact on either market presence or operating conditions. These agreements do not involve any value transfer between the parties.

(1235) Such agreements are likely in situations where both parties believe that the continuation of the litigation would be a waste of time and the case is brought to an end in order to save costs. As illustrated in the figure above, out of a total of 27 settlement agreements reported, six (22%) were concluded on this basis.

Example: Category 1 settlement with no value transfer

Originator A is the owner of specific patents. Originator B opposed the patents. Parties wished to save costs and eliminate uncertainty regarding the patents. Originator B withdrew its opposition. Originator A agreed not to bring any claim or suit alleging that the manufacture or sale of B's product infringed or had infringed A's patent in any geographic territory. A discharged B from any liability or claim that B infringed A's patent by its manufacture or sale of its product before the settlement agreement or during the agreement's validity. No payments were included in the settlement.

2.I Settlement Agreements with a Payment

- (1236) This category covers agreements whereby parties mutually agree to abandon all existing and future claims and grant each other immunity from suit, but where one of the parties agrees to pay a specific amount as cost compensation and/or damages, in full satisfaction of all existing and potential claims by the other party. As indicated in the figure above, three agreements out of 27 reported (11%) were concluded on this basis.

Example: Category 2.I settlement with a payment

Originator A and Originator B were engaged in various litigation actions in a variety of countries under their respective patents and licensed patents resulting in the expenditure on significant legal fees. Parties agreed to withdraw all related litigation and grant immunity from suit with regard to all past and ongoing actions for patent infringement. Originator A paid Originator B a specific amount in full satisfaction of all obligations.

2.II Settlement Agreements with Licensing

- (1237) This category covers settlements which, in addition to immunity from suit and claims, largely involve a licence agreement and respective payment. Eighteen out of the 27 settlement agreements reported belong to this category, making it by far the largest category of settlement agreements concluded between originator companies. Licence-related settlements accounted for 67% of settlements concluded between originator companies.
- (1238) A common situation for a settlement between originator companies involving a licence appears to be where one of the parties holds patent rights and the other is also developing a relevant product which it considers not to infringe the other originator company's patent rights. A difference in views arises, usually at the latest when the second originator company plans to launch the product. If the parties wish to settle, they typically grant each other such licences as necessary to allow each party to develop and commercialise their respective products free from the risk of infringement of the defined patent rights of the other party.
- (1239) Even though settlement agreement with licensing would not require the contesting party (the licensee) to exit the market, the company concerned may continue to operate in the market only under the specific conditions agreed with the licensor. Its presence in the market is controlled by the licensor. This may entail agreement on specific 'non-compete' clauses.
- (1240) The specific terms of settlement agreements with licensing vary in particular with regard to both the exclusivity of the licence and the level of the fixed payments and/or royalties. In addition to the specific issue of the patent opposition, dispute or litigation, the terms of a licence agreement contained in a settlement also reflect the parties' negotiated position.
- (1241) Fifty percent of the licences granted in the settlement agreements reported were exclusive licences whereby the licensor did not maintain the right to grant a licence to other companies within the same territory. Licences were granted under settlements either against fees or without any fee. The fees were either fixed or based on royalties.

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Two of the licence agreements reported were without any fixed payments and were royalty-free. In settlements which led to the termination of a licence agreement, one of the parties typically agreed to pay the other party a specific one-off payment in settlement of the alleged unpaid royalties. A non-competition clause with respect to products competing with the licensed product was in some cases included in the agreement.

(1242) Three of the reported settlement agreements contained a reciprocal cross-licence, whereby each party granted the other a licence.

(1243) One of the agreements submitted amended an existing licence agreement between the parties to allow the other originator company to launch a generic product, at the earliest when the patent in question loses exclusivity.

Box: Example: Category 2.II settlement with licensing

Two originator companies were parties to a licence agreement. The parties engaged in a dispute over the licensor's patent rights. The licensee consequently began proceedings at EPO seeking invalidation of the licensor's patent. At the same time, the parties opened negotiations to settle their dispute. Under the settlement agreement the licensor remained the sole owner of the patent and granted the licensee a non-exclusive licence in the patent for manufacture and sale of the product in the territories covered by the patent. The licensor agreed to discharge the licensee of all claims alleging infringement of the patent. The licensee withdrew its appeal to the EPO and agreed to make a lump-sum payment in consideration for all the products that the licensee had manufactured/would manufacture or sell.

3.4.2. Overview of other Existing Agreements between Originator Companies

(1244) This section will look at other agreements (beside patent settlements) that were concluded in the EU between originator companies during the period 2000 – 2007. It will provide a general overview of the extent to which such agreements exist and categorize the agreements to show to which extent cooperation between originator companies exists during the different phases of a life cycle of a pharmaceutical product. More in depth analysis has been done on a sample of agreements from six Member States (Germany, Spain, France, Italy, Poland and UK) and, in particular, on the agreements for which the contracting parties submitted a combined market share exceeding 20% in at least one Member State. The purpose of this chapter is to complete the picture of the competitive environment between originator companies during the life cycle of a pharmaceutical product.

(1245) It should be noted that it is not the aim of this chapter to provide guidance on whether certain types of agreements can be considered compatible or incompatible with EC competition law⁶²². Such an assessment would require in-depth analysis of the individual agreement, taking the factual, economic and legal background into account.

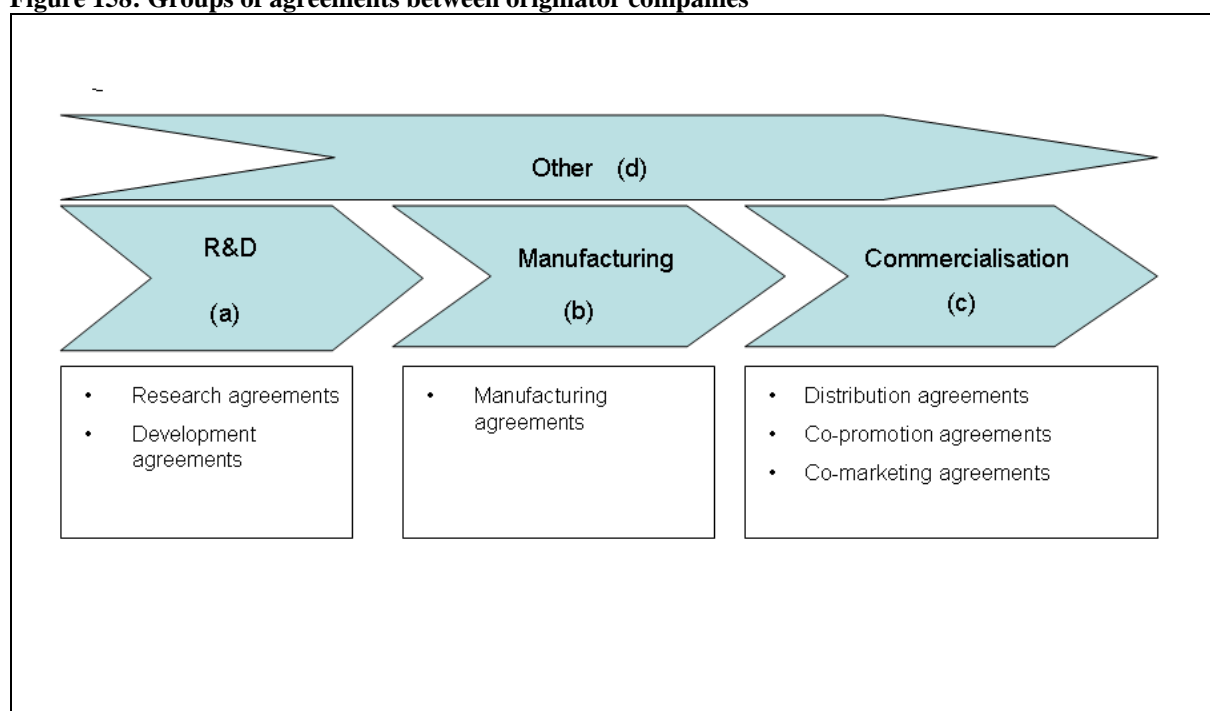
⁶²² See Annex: EC Competition Law (Annexes to Chapter A).

3.4.2.1. Categorization of the Agreements

(1246) In the course of the sector inquiry, the respondent originator companies were requested to submit information on all agreements that they had concluded with other originator companies not involving settlements. This information was requested for all 219 INNs selected for the inquiry and for the period 2000 – 2007.

(1247) For the purposes of the sector inquiry and given that companies could have concluded agreements on a whole range of activities, the reported agreements were grouped into four main categories. Figure 158 provides a schematic overview of how the agreements were categorised.

Figure 158: Groups of agreements between originator companies



Source: Pharmaceutical Sector Inquiry

(1248) The four main categories were: (a) Research & Development, (b) Manufacturing, (c) Commercialisation and (d) Other agreements. The agreements in the first three categories reflect the different phases that a pharmaceutical product undergoes during the normal product life cycle.

(1249) Agreements may focus solely or combine different stages of cooperation for example research and development, the production of its results, and finally its commercialisation. Agreements that did not fit into one of the first three categories or its subcategories were dealt with under "other agreements".

(a) Agreements Focusing on Research & Development

The first category of agreements contains both research agreements and development agreements between originator companies. Research and development agreements may vary in form and scope and range from the outsourcing of certain research and development activities to the joint improvement of existing products or technologies or to the cooperation concerning the research or development of completely new medical

products. Research cooperation agreements create a collaborative relationship between two originator companies in which the parties contribute to the overall discovery process by utilising the parties' combined expertise to deliver the desired outcomes. Development agreements could also bring significant advantages, including more efficient allocation of tasks and resources and the likelihood of earlier breakthroughs. Research and development agreements often contain a transfer of technology, i.e. they provide for the licensing or cross-licensing of certain intellectual property rights.

(b) Agreements Focusing on Manufacturing

The second category deals with agreements between originator companies that concern the manufacturing process. Manufacturing has been interpreted broadly and covers agreements providing for production of medical products, tolling agreements, quality and technical agreements as well as licence agreements that refer to the manufacturing process. Manufacturing services may relate, inter alia, to finished products, semi-finished products or packaging. Manufacturing agreements often contain provisions on licensing of intellectual property rights. The relationship between the contracting parties could be of a horizontal or a vertical nature. In general, one could distinguish three forms of production or manufacturing agreements:

- Joint production agreements: the parties agree to produce certain medical products, APIs or other semi-finished products jointly;
- Specialisation agreements: the parties agree unilaterally or reciprocally to cease production of a final medical product or a certain input product and to purchase it from the other party;
- Subcontracting agreements: one party entrusts to another party the production of a final medical product or a certain input product.

(c) Agreements Focusing on Commercialisation

Agreements focusing on the commercialisation of a final medical product concern a co-operation between originator companies in the selling, distribution and/or promotion of their products. Depending on the marketing functions which are being covered by the cooperation, the scope of commercialisation agreements ranges from limited agreements focusing on specific marketing functions such as distribution, advertising or promotion on the one side to the joint determination of various commercial aspects on the other side. Commercialisation agreements can be of a vertical (e.g. if one originator company supplies the other), a horizontal (e.g. if both parties market the product) or both a vertical and a horizontal nature at the same time (e.g. if one party supplies the other and both market the product). They may include licensing or other forms of transfer of technology. They are often combined with other stages of cooperation or are used when a company wishes to commercialise its product(s) in a given territory (e.g. an EU Member State) and lacks the infrastructure to support local marketing and/or sales. Common forms of commercialisation agreements between originator companies in the pharmaceutical sector are:

- Distribution agreements: a party appoints the other party to the agreement as a distributor for the sale of one of its medical products;

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- Co-promotion agreements: (joint) commercialisation of a specific medical product by both parties under one single trademark;
- Co-marketing agreements: commercialisation of a specific medical product by both parties under different trademarks.

(d) Other Agreements

This fourth category represents all agreements that were not covered under any of the previous three categories. The "other agreements" include, inter alia, pharmacovigilance agreements, safety agreements, consignment stock agreements, agreements focusing on the transfer of a market authorisation or the underlying documentation, confidentiality agreements, representative agreements, asset purchase agreements and agreements that provided for a warranty or covenant not to interfere with the launch and marketing of a product.

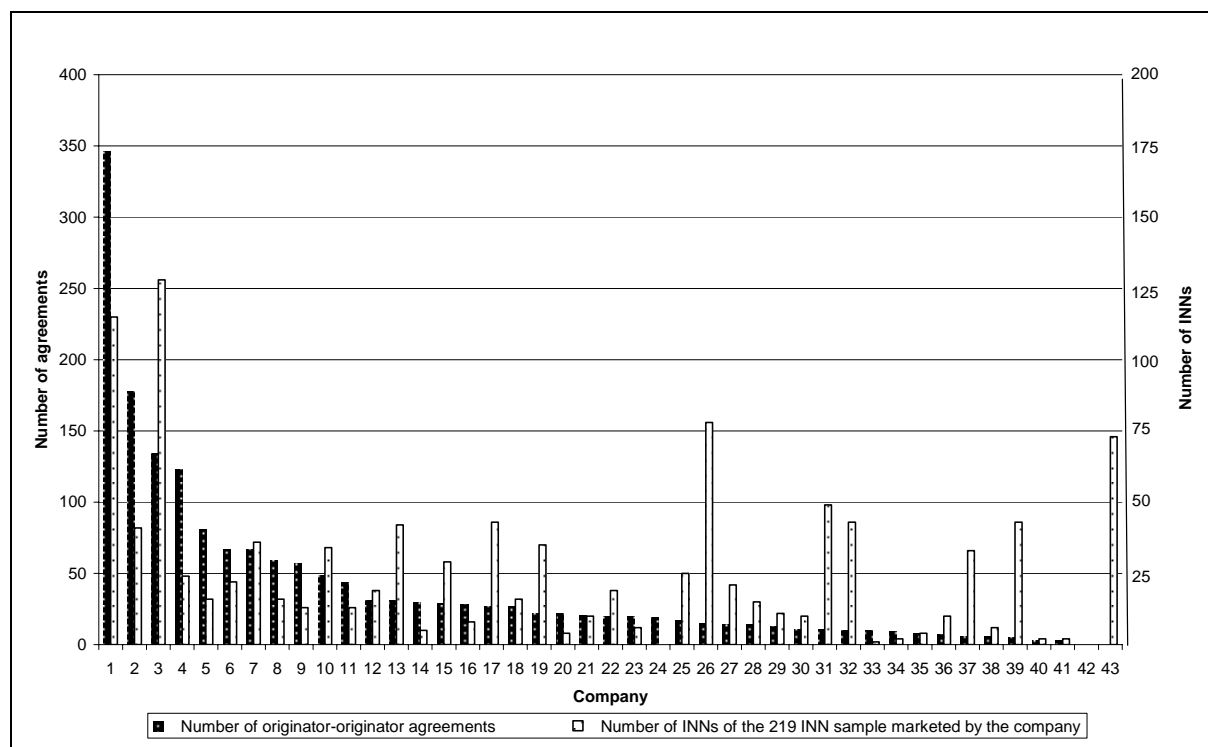
3.4.2.2. Extent of Cooperation between Originator Companies

(1250) Of the 43 originator companies that responded to the questionnaires during the sector inquiry, 41 confirmed that they had concluded agreements with other originator companies regarding the medicines under investigation. In total, some 1,453 agreements were reported in the sector inquiry.⁶²³ Figure 159 gives an overview of the number of originator-originator agreements per company as well as the total number of INNs out of the 219 INNs investigated in which the originator companies were active. One can observe the difference in the extent in which originator companies made use of agreements with other originators. Whereas ten originator companies reported less than ten agreements with other originator companies for the period 2000-2007, nine originator companies reported more than 50 agreements. Five of the nine originator companies with more than 50 agreements were among the ten largest originator companies in the EU by turnover in prescription medicines. The maximum number of agreements reported by one originator company was 346.

⁶²³ This figure is lower than the overall number of agreements reported to the Commission services as it had to be corrected for double counting and for INNs that were not in the Commission Annex.

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Figure 159: Number of originator-originator agreements and number of INNs in the portfolio per company



Source: Pharmaceutical Sector Inquiry

(1251) The agreements concerned some 177 of the 219 INNs selected for the sector inquiry. It is interesting to note that 77 INNs (or 85%) of the 90 INNs in the T50 list⁶²⁴ were covered by agreements between originator companies.

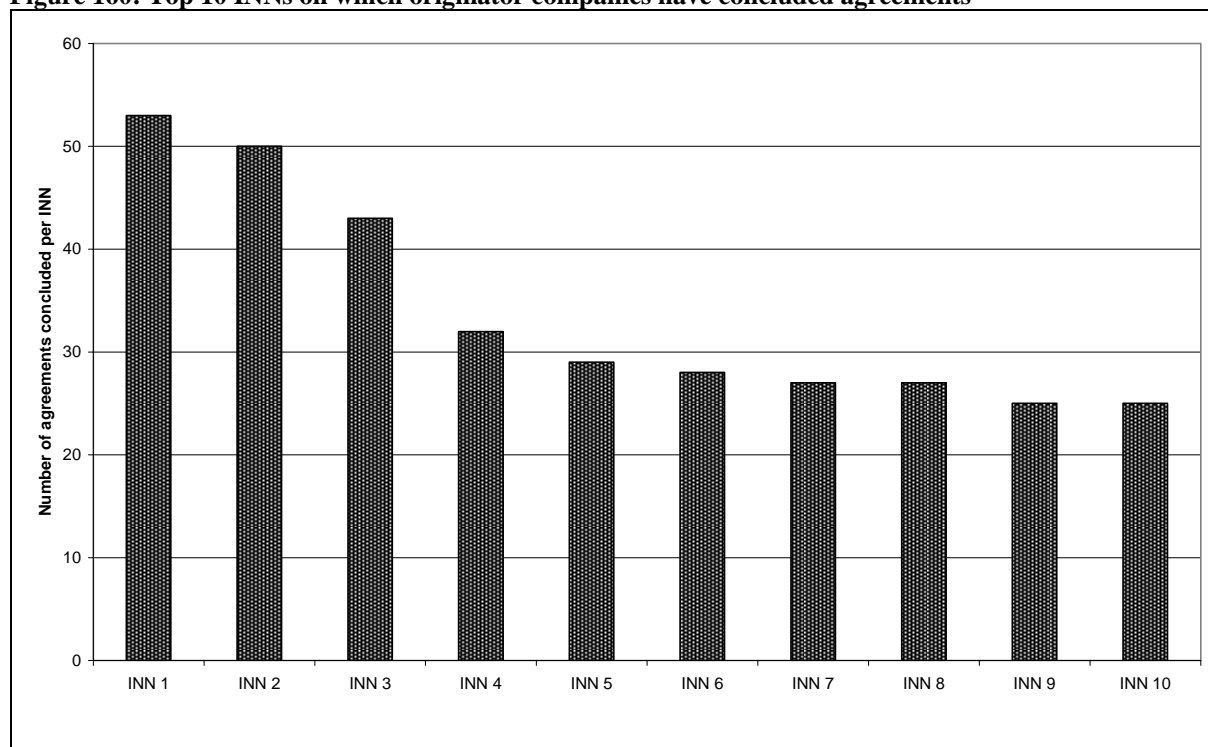
(1252) Figure 160 provides an overview of the ten INNs with the most agreements between originator companies.

(1253) The number of agreements for the top ten INNs varied between 25 and 53. Note that eight of the top ten INNs on which originator companies had concluded agreements appear in the T50 list. Half of the top ten INNs had many distribution agreements whereas the other half had many manufacturing or licence agreements.

⁶²⁴ The T50 list consists of the 50 top-selling INNs in three Member States over the same time period. For more details see the Annex Methodology (Annexes to Chapter A).

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Figure 160: Top 10 INNs on which originator companies have concluded agreements

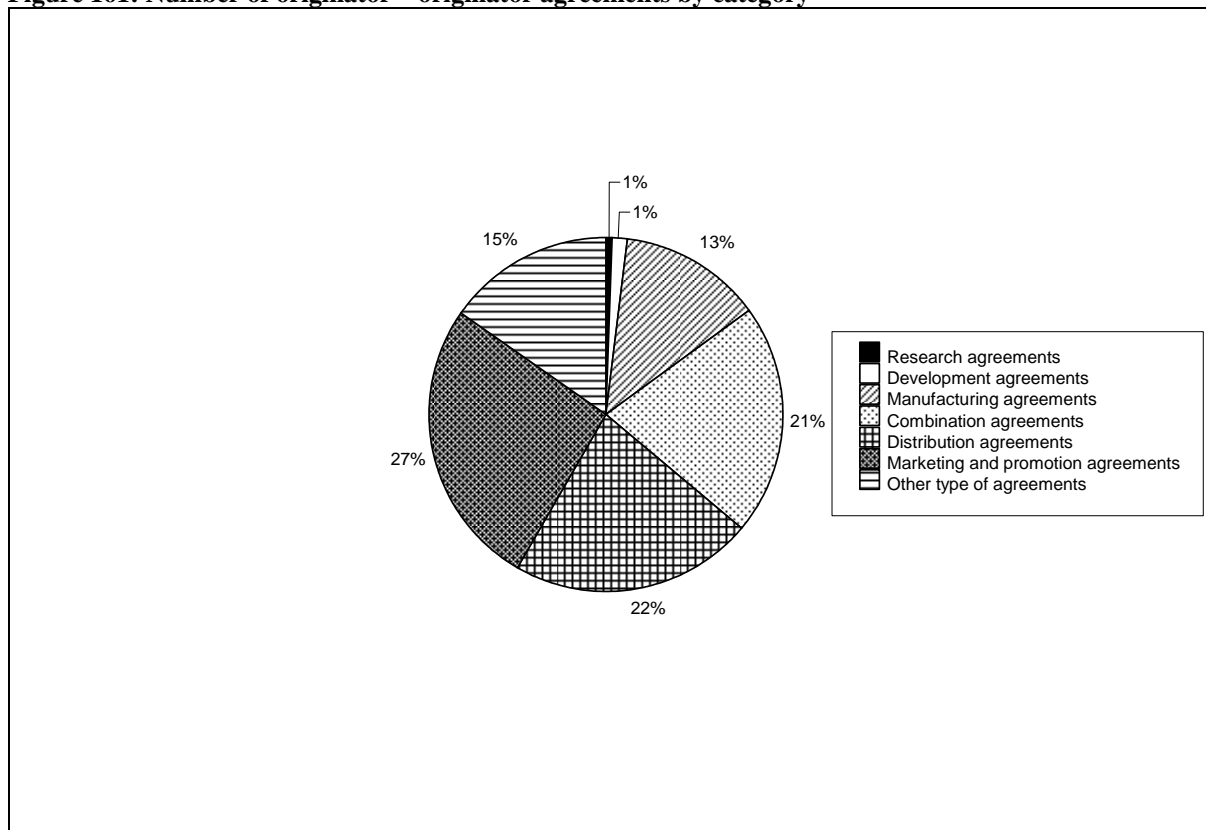


Source: Pharmaceutical Sector Inquiry

(1254) Figure 161 provides an overview of the number of originator company agreements with another originator company by category. It should be noted that 27% of the agreements (384) were marketing and promotion agreements, 22% were distribution agreements (325) and 13% were manufacturing agreements (189). Research and development agreements accounted for 1% each or respectively eight and 20 agreements. The category "other agreements" accounted for 15% (221 agreements). For 21% of the agreements (306 out of 1,453), a combination of agreements was reported between originator companies — hereafter called "combination agreements". In a combination agreement, research and development, manufacturing and/or commercialisation were combined with an agreement of the other categories.

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Figure 161: Number of originator – originator agreements by category

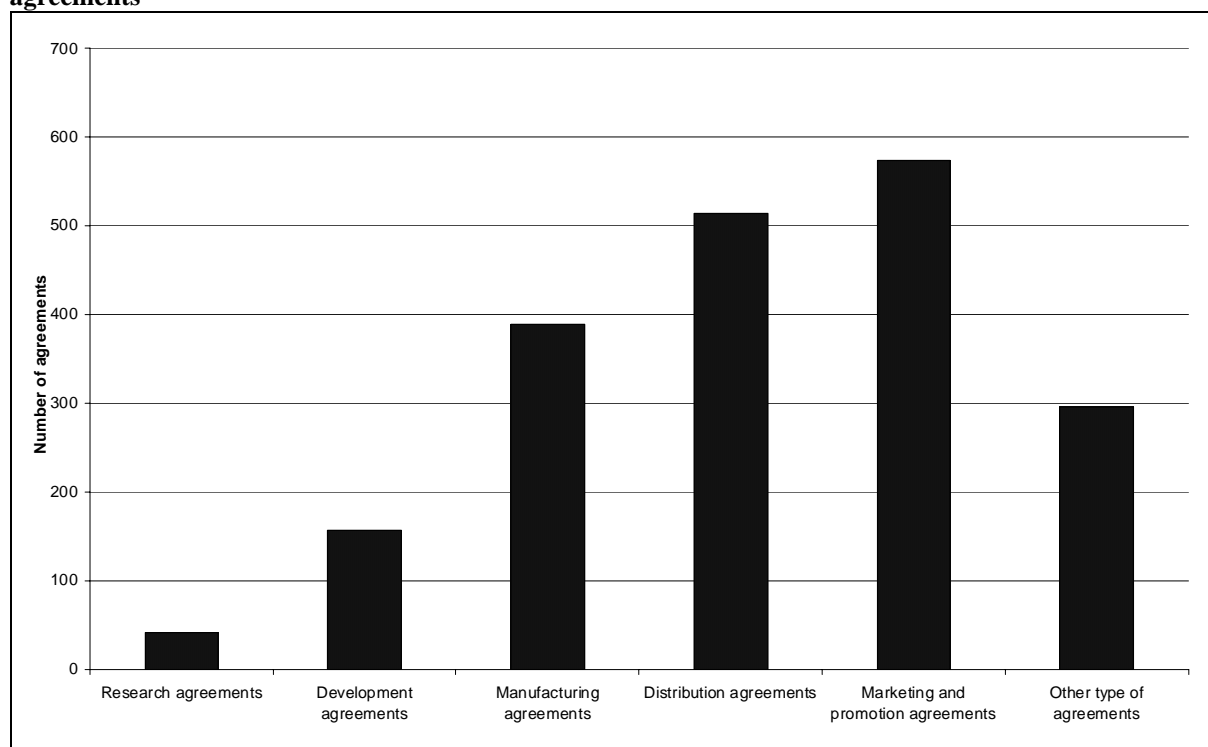


Source: Pharmaceutical Sector Inquiry

(1255) If the combination agreements were allocated amongst the specific categories agreements, it can be observed that in total 41 agreements dealt with research and 156 with development. The manufacturing stage was covered by 389 agreements. The largest groups are agreements focusing on distribution (514 agreements) and agreements focusing on marketing and promotion (574 agreements). 295 agreements were classified as other types of agreements. Figure 162 shows that there is an upward trend towards the end of the value chain regarding the number of agreements contracted between originator companies. In other words, more marketing, promotion, and distribution agreements were made, for instance, than research and development agreements. The sum of the figures exceeds 1,453 (agreements) as double counting occurs when a combination agreement is split up among all of the more specific agreements that it covers.

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Figure 162: Number of originator-originator agreements by category when splitting up combination agreements

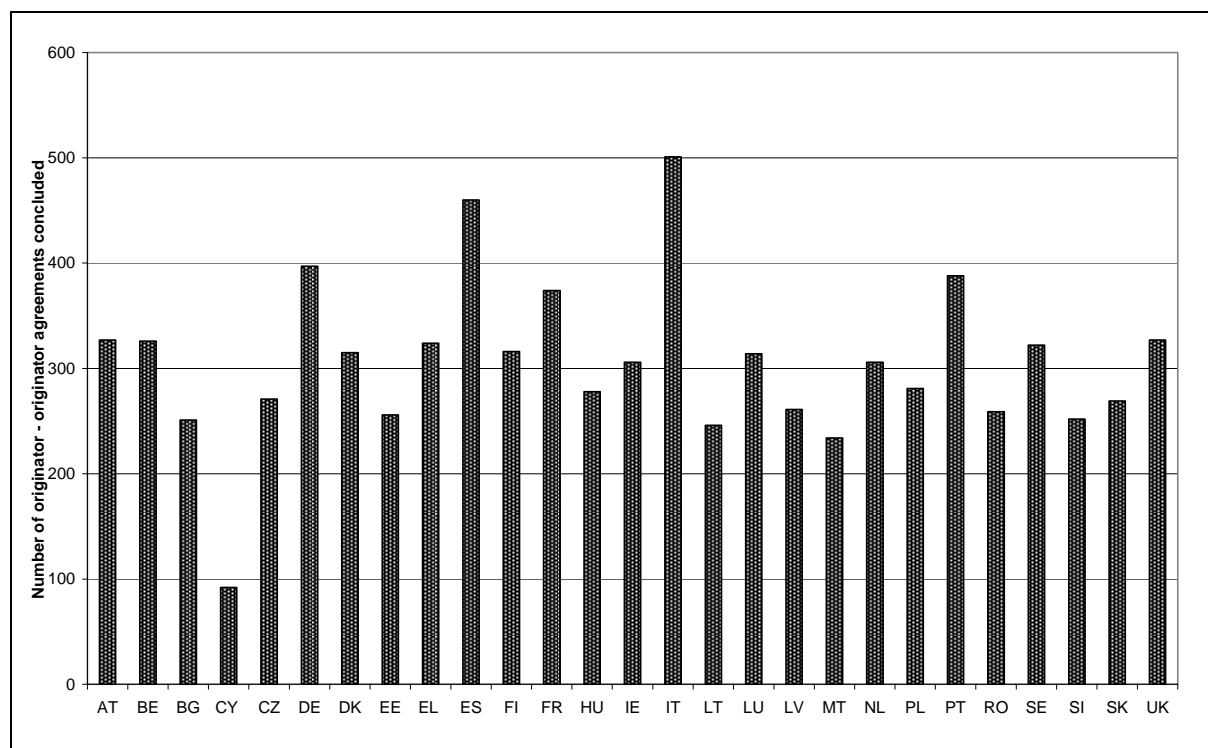


Source: Pharmaceutical Sector Inquiry

(1256) Figure 163 identifies the countries which were affected by the originator-originator agreements. It suggests that the highest number of agreements were found in Italy and Spain. It further shows that, with a few exceptions, almost all other Member States were covered by a comparable number of agreements between originator companies. For the majority (18 Member States), between 250 and 330 agreements were in place between 2000 and 2007. This is partly explained by the fact that originator companies often do not use a country-by-country approach but rather cover several Member States in the agreement or even use a EU27-wide or worldwide approach. In case originator companies entered into commercialisation agreements that were national in scope, the companies often had similar agreements for the same product with the same or with another partner in several Member States.

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Figure 163: The geographical coverage of originator-originator agreements by Member State



Source: Pharmaceutical Sector Inquiry

3.4.2.3. Sample Selected for Further Analysis

(1257) In the context of the Sector Inquiry, originator companies were asked to provide a copy of any agreement with other originator companies concerning 101 INNs selected from the 219 INNs list which are concluded between 2000 – 2007 and which are not purely research and development agreements and which covered one or several of the following Member States: Germany, Spain, France, Italy, Poland, and UK. The six Member States selected for analysis accounted for € 105 billion at ex-manufacturing level or € 164 billion at retail market level, i.e. respectively 76.4% and 76.9% of the overall turnover of prescription and non-prescription medicines in the EU in 2007.⁶²⁵

(1258) It has to be noted that not all originator companies submitted the full set of agreements.⁶²⁶ Further, originator companies often concluded several agreements (e.g. licensing, supply and distribution, pharmacovigilance, transfer of a marketing authorisation etc.) with another originator company concerning the same product or technology, whereas sometimes originator companies included different agreements in one single master agreement. For the purpose of the analysis, agreements relating to

⁶²⁵ For more details on the annual sales of prescription medicines (ex-factory and retail prices) per Member State see Figure 1 (Chapter B.1.).

⁶²⁶ Companies provided for various explanations, e.g. that the information was no longer available due to the fact that the subsidiary which entered into the agreement was sold in the past.

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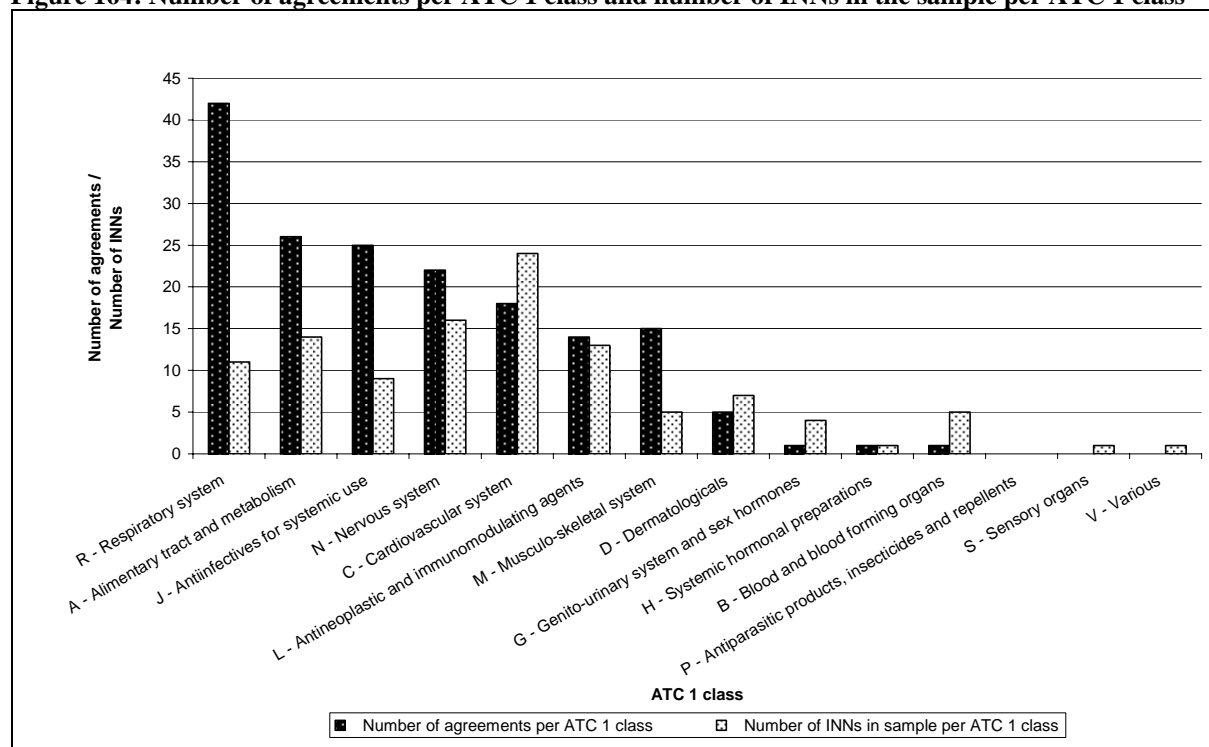
the same contractual relationship and the same product or technology were considered as one single agreement. As a consequence, the number of agreements analysed is considerably lower than the total number of agreements initially reported for the Member States and products concerned. In total, 165 originator-originator agreements that fulfilled the above mentioned requirements were submitted by 29 of the 43 originator companies.

- (1259) The companies were requested to submit information on how they have selected the other party to the agreement, to specify the efficiencies envisaged by the agreements, to describe the relevant product market for the products concerned by the agreements, and to submit market data for these agreements. It has to be noted that not all questions were applicable to all agreements and the companies did not/could not submit the full set of information for all agreements. Therefore, the analysis was not always based on the same number of responses.
- (1260) The sample of the 165 agreements covered 52 INNs of the 101 INNs selected for further analysis. Out of the 52 INNs, 48 were on the T50 list. Figure 155 gives an overview of the number of agreements per ATC 1 therapeutic class. It shows that the 165 agreements covered eleven of the fourteen ATC 1 therapeutic classes in the ATC classification system⁶²⁷. Figure 164 also shows the number of INNs in the sample selected for further analysis per ATC 1 therapeutic class. It indicates that cooperation between originator companies took place most often in the therapeutic class R (Respiratory system). The sample covered eleven INNs in this ATC class and 42 originator-originator agreements were submitted for these INNs.

⁶²⁷ For an explanation of the ATC system see the glossary.

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Figure 164: Number of agreements per ATC 1 class and number of INNs in the sample per ATC 1 class



Source: Pharmaceutical Sector Inquiry

Considerations of Originator Companies when Entering into Agreements with other Originator Companies

- (1261) To understand the considerations of originator companies when entering into agreements with other originator companies, the companies were asked how they have chosen the other party to the agreement.
- (1262) According to the submissions, the originator companies did not apply a general policy when entering into agreements with other originator companies but rather assessed a situation on a case-by-case basis. Different considerations were taken into account according to the different stages of the life cycle.
- (1263) Most companies submitted that the selection process included, inter alia, factors such as expertise in a specific medical field, pre-existing products or technologies owned by the other party, the reliability of the other party (e.g. financial security, ability to fulfil its obligations), and the compatibility with its own product portfolio and marketing strategy. Often the companies relied on established working relationships through other agreements. Most of the time, the potential partner was directly approached, however, sometimes the companies also used tender like processes to select the other party.
- (1264) Taking all submission of the companies into account, one can generally distinguish four main scenarios that lead to the conclusion of an agreement with another originator company. First, it might have been the case that the originator company already had an agreement with the other originator company for the same product or an earlier version in the past. The second scenario is that the company was already marketing products in a certain therapeutic area and wanted to expand or complete its product portfolio.

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Under the third scenario, an originator company lacked the necessary resources or know-how at some stages of the life cycle of a product and wanted to make use of the other company's resources or experience. And the fourth scenario describes the situation where patents prevented an originator company from developing or exploiting its own products.

(1265) Sometimes the companies already had a preceding agreement for a certain product. If the clinical and scientific development lead to a follow-on product, the originator companies submitted that they had an interest in continuing their contractual relationship for the successor product. New products or improved versions of existing products were either included into the existing agreements or were covered by new agreements.

(1266) The second scenario is well illustrated by the following quote:

"[The originator company's] approach is to identify potential targets of products which could synergize with its existing organisations (geographical approach) and/or its therapeutic domains. Potential originator companies are frequently small and mid-sized companies that have no or insufficient resources or expertise (in areas such as marketing and promotion, medical and regulatory, and development, when applicable) in a given country/territory."

(1267) Under the third scenario, it was submitted that, beside the resources and reliability of a potential partner, the companies often took account of whether the potential partner was distributing competing products. The general considerations when selecting a distributor are well summarized by the following quote:

"The distributors are chosen on the basis of having an established track record of successful commercialisation of specialty disease modifying therapies [...] in the relevant therapeutic area. Companies must satisfy a rigorous due diligence investigation prior to being appointed, to ensure that they are in a position to comply with [the originator company's] quality and ethical requirements."

(1268) Under the fourth scenario, the company usually considered the commercial importance of the exploitation of its own products on the one side, and the willingness of the counterparty to enter into an agreement and the terms of the agreement on the other side. The following was submitted by one originator company:

"[The originator company] had to get patent licenses to continue its existing business with an own developed and patent protected product in order to avoid disputes and indemnity claims due to infringement of [the other originator company's] patents."

(1269) The respondent companies were also asked whether they considered the other party to the agreement as a competitor and what were the efficiencies and benefits envisaged by the agreements. For about half of the agreements for which the companies replied to this question it was submitted that the respondent company considered the counterparty as an actual or potential competitor. However, the originator companies also submitted various explanations stating that they think that the agreements are pro-competitive, are not capable of having any appreciable effect on competition or on trade between Member States, are not covered by Article 81(1) EC, or are caught by a block exemption regulation or otherwise exempted.

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- (1270) As regards the efficiencies and benefits envisaged by the agreements, the companies considered in general terms that agreements with other originator companies would be an effective way to share risks and costs while reaching the maximum number of consumers, and, as a consequence, such agreements presumably allowed a greater number of consumers more quickly access to innovative products.
- (1271) With regard to the geographic scope of the agreements, originator companies generally distinguished between the different stages of a product life cycle. It was submitted that global arrangements are often made during the development phase and/or contemplate joint life-cycle management development programmes after the approval of a first indication.
- (1272) For agreements dealing only with the commercialisation of certain medical products, the companies tended to appoint the counterparty rather on a national basis in order to comply with the local specific requirements and to maximise efficiencies in the particular country. However, analysis showed that commercialisation agreements that were combined or linked with a research and development and/or manufacturing agreement often covered EU27 or were worldwide in scope. This may be motivated by the interest of the parties to exploit the results of a co-operation to the greatest extent possible.

Agreements for which a Combined Market Share Exceeding 20% Was Submitted

- (1273) Originator companies were also requested to describe the relevant product market for the products and/or technologies concerned in the agreements and to provide market data for these product markets. Most originator companies submitted that the market coincides with the ATC 3 therapeutic classes.⁶²⁸ For some agreements the companies used the ATC 4 therapeutic class or gave another market explanation.
- (1274) The companies were asked to submit estimates of their market shares for the products concerned by the agreement and estimates of the market shares of their main competitors for the last calendar year before the agreement ended or, if it was still effective in 2008, for the year 2007.
- (1275) Figure 165 gives an overview of the estimates of the combined market shares of the contracting parties (including affiliates).⁶²⁹ If the agreement covered more than one Member State, the Member State with the highest combined market share of the parties was taken into account. The companies submitted a combined market share exceeding 40% of the relevant market for the products concerned by the agreement for 31 of the 165 agreements. In 6 agreements the participating companies had a combined market share between 30% and 40%, and in 21 agreements the combined market share was

⁶²⁸ For an explanation of the ATC classification system see the glossary.

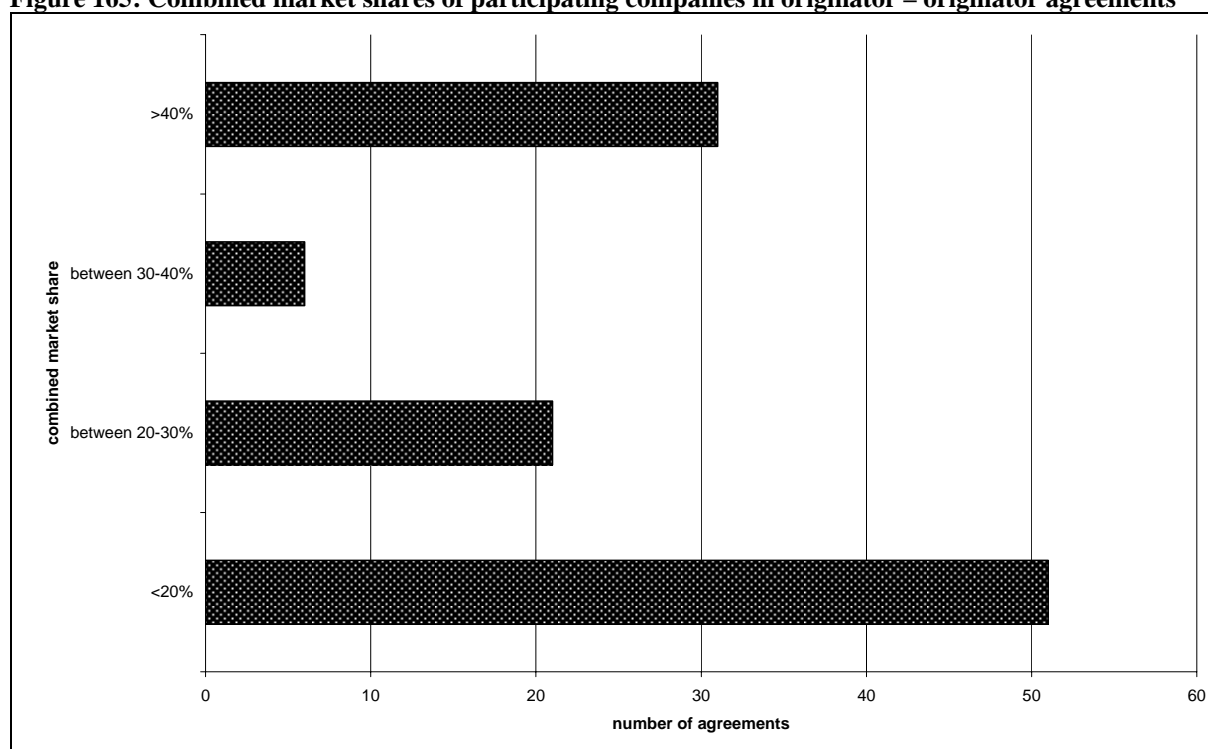
⁶²⁹ The Chapter is based on the submissions of the companies which might have used different sources to calculate the market shares.

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between 20% and 30%. For 51 agreements, the companies submitted a combined market share below 20%. For all other agreements, no data was provided.

(1276) If one takes the individual market shares of the parties to the agreements with a combined market share exceeding 40% into account, it shows that for the clear majority of agreements one party had a very high market share and the other party was not present on the market at all or had a market share below 5%. In most cases, the product concerned by the agreement was the only product marketed by the originator company with the smaller market share. Only in five agreements, the party with the smaller market share had a market share between 5% and 10%, and in six agreements both parties had a market share of at least around 20%.

Figure 165: Combined market shares of participating companies in originator – originator agreements



Source: Pharmaceutical Sector Inquiry

(1277) Further analysis has been done on the 58 agreements for which the originator companies submitted a combined market share exceeding 20% in at least one Member State. Agreements with a significant market share of the contracting parties are generally more likely to have a considerable impact on the competitive environment.⁶³⁰ However, this does in no way mean that agreements between originator companies that have a combined market share below 20% are considered to have no significant impact on competition on the relevant markets nor does it mean that agreements with a

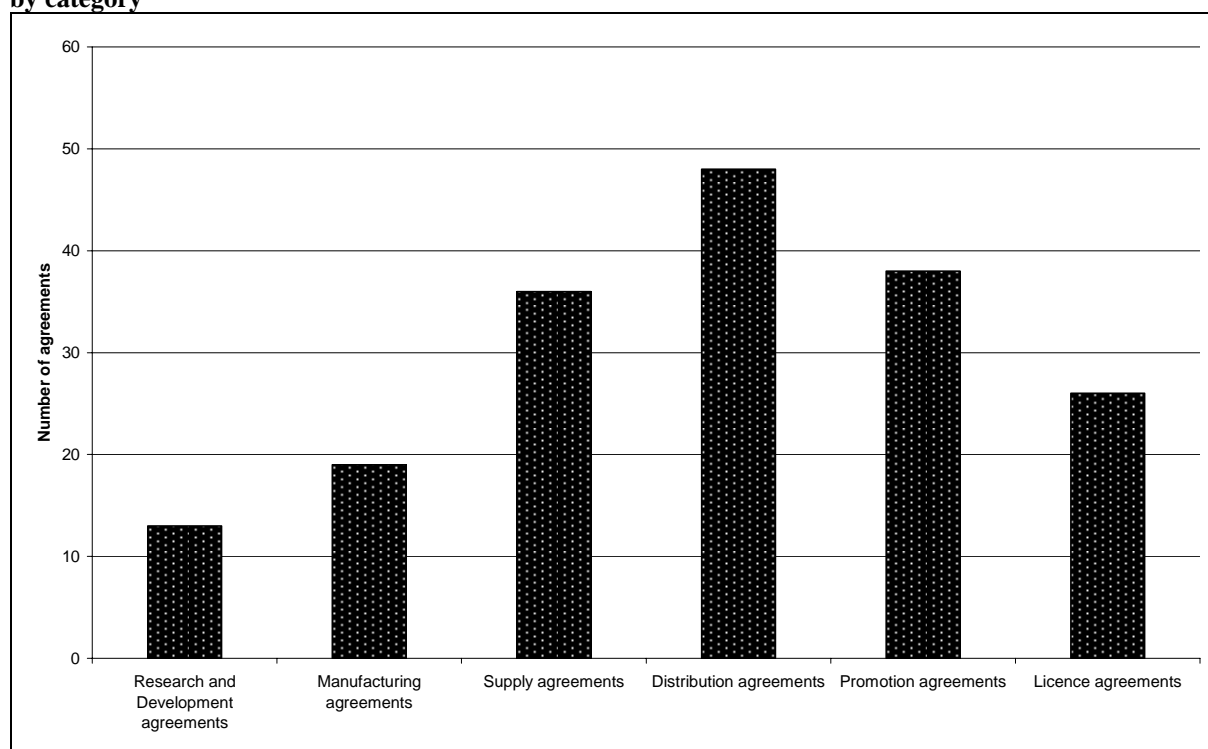
⁶³⁰ The threshold of a combined market share of the contracting parties of 20% is, amongst others, laid down in Article 3(1) of Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements, OJ L 123, 27.4.2004, p. 11, and in Article 4 of Regulation (EC) 2658/2000 of 29 November 2000 on the application of Article 81(3) of the Treaty to categories of specialisation agreements, OJ L 304, 5.12.2000, p. 3.

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combined market share exceeding 20% are particularly problematic from a competition perspective. The 58 agreements were categorised and analysed whether they contain clauses that provide for any restrictions on one or both parties.

(1278) Figure 166 sets out the number of the 58 agreements in the various categories. Combination agreements were counted in each category covered. The sample of the 58 agreements for which a combined market share exceeding 20% was submitted includes 13 combination agreements that also concerned research and development. 19 of the 58 agreements focused, amongst others, on the manufacturing stage. As all of the 58 agreements concerned, solely or inter alia, the commercialisation stage, the commercialisation agreements were further split up in subcategories. 36 of the 58 agreements provided for the supply of a product, 48 agreements focused on distribution, 38 agreements referred to the promotion of a product, and 26 agreements were licence agreements. The sum of the figures exceeds 58 agreements as double counting occurred if an agreement was split up among the specific subcategories.

Figure 166: Number of originator – originator agreements with a combined market share exceeding 20% by category



Source: Pharmaceutical Sector Inquiry

(1279) The duration of the agreements between originator companies for which the parties submitted a market share of above 20% in at least one Member States ranged from one year up to 15.7 years with an average of 7.9 years. In twelve of the 58 agreements the parties entered into a contractual relationship until the end of the expiry of the underlying patents and in two agreements for an indefinite period. For two agreements the information was not available.

(1280) The data on the duration shows that the originator companies considered agreements with other originator companies as a long-term strategy. As regards agreements covering also research and development, this may be explained by the interest to jointly exploit the results of an earlier cooperation. However, taking into account the

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large number of commercialisation agreements, the data suggests that after entering into a commercialisation agreement, once the parties continue this strategy to preserve the experience and know-how gained through cooperation in the long term or even throughout the whole life cycle of a product.

- (1281) The 58 agreements were analysed whether they contain an exclusivity and/or a non-compete clause. Both clauses should be understood as providing for some kind of exclusive relationship between the contracting parties, including exclusive supply obligations, exclusive sourcing, exclusive licensing or any other kind of exclusivity, and/or non-compete obligations, regardless of whether they are directed at one partner or both partners.⁶³¹
- (1282) About 81% of the agreements (47 of the 58 agreements) provided for some kind of exclusive relationship. 44 agreements contained an exclusive supply, an exclusive purchasing and/or an exclusive licensing provision. A non-compete clause was included in 27 agreements. Looking at the combination agreements one can observe that around half of the agreements that amongst other things focused on research and development (seven of the thirteen agreements) or manufacturing (nine of the 19 agreements) were entered into on a non-exclusive basis. This suggests that companies usually enter into exclusive relationships if they focus only on the commercialisation of products. However, if they also include research and development and/or manufacturing in the agreements, they more often reserve themselves the right to freely enter into agreements with other third parties.
- (1283) Sometimes the exclusivity and/or non-compete clauses were valid for only a fixed time period under the agreement, however for most agreements the clauses were in force throughout the whole period of the agreement. The duration of those agreements containing an exclusivity and/or non-compete clause ranged from one year up to 15.7 years with an average of 8.0 years. One agreement was entered into for an indefinite period and six agreements were in force until patent expiry. This shows that for about 81% of the agreements and on average for 8.0 years one or both originator companies were bound exclusively in some respect to another originator company under an agreement concerning products for which the originator companies had a combined market share exceeding 20%.
- (1284) As many agreements between originator companies involved patents or other intellectual property rights, the agreements were also analysed whether they contained any clauses that restricted the other party's ability to challenge the validity of the intellectual property rights concerned in the agreement. Such non-challenge clauses were found in twelve agreements (21%). Although this represents only the minority of the 58 agreements, it has to be noted that this number by far exceeded the extent of non-challenge clauses found in early entry agreements between originator and generic companies (5%).⁶³² From this one could conclude that the parties of an originator-originator agreement seem to have a greater interest to protect the intellectual property

⁶³¹ For further explanation of the terminology used see above Chapter C.2.4.2.

⁶³² See above Chapter C.2.4.2.2.

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rights concerned against challenges from the other party. This might be motivated, amongst other things, by the long duration of the agreements.

- (1285) Further, the 58 agreements were analysed whether the agreements contained any provisions on the parties' ability to carry out research and development. In the sample, 23 agreements (40%) with restrictions on one or both parties' ability to carry out research and development were found. The agreements usually contained a prohibition to develop competing or related products, to conduct studies or pre-clinical or clinical trials, or made this subject to the prior approval of the other party. Some agreements provided for a right to terminate the agreement if the other party would engage in the development of a competing product. Some of the combination agreements that, inter alia, covered research and development, contained an explicit restriction on one party's ability to conduct independent research and development.
- (1286) Almost half of the agreements (28 of the 58 agreements) contained a provision that provided for the other party's free access to any study performed on the products, for an obligation to offer improvements or new products to the other party, or for a (usually royalty-free) licence on improvements or new products for the other party. This kind of clause might be motivated by the parties' interest to share the know-how gained and the developments made under the agreement.
- (1287) Often the companies included provisions into the agreement to ensure that the other party has a sufficient focus on the commercialisation of the products concerned. 25 of the 58 agreements provided for minimum annual sales, target sales or minimum annual purchase amounts. If the distributor failed to purchase the fixed minimum annual quantities or did not reach the target sales, the supplying company was usually entitled to terminate the agreement. In some agreements focusing on promotion, minimum marketing investments were fixed. Some distribution agreements also provided for the coordination of the promotion, e.g. by a sales budget and/or a marketing plan that had to be agreed on by the supplying originator company.
- (1288) It has to be noted that originator companies rarely appointed another originator company as its sole distributor for a specific product in a territory (only eleven of the 58 agreements). Usually, the companies reserved itself the right to market and distribute the products in the territory as well (co-promotion or co-marketing agreements) or to appoint one (semi-exclusive distribution agreement) or various other distributors (non-exclusive distribution agreement). Some commercialisation agreements (16) contained a provision that prohibited active sales or the establishment of any branch or distribution depot outside the territory.

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Summary

The inquiry confirmed that originator companies concluded settlement agreements with other originator companies in the EU in order to resolve claims in patent disputes, oppositions or litigation. In the period 2000 – 2007, some 27 settlement agreements relating to the sample under investigation were reported. Approximately 67% of these settlement agreements concerned a licence agreement (including cross licensing).

Besides settlement agreements, the findings of the inquiry also reveal that originator companies concluded other types of agreements with each other. In total, some 1,450 originator-originator agreements were reported. The majority of agreements concerned the commercialisation phase rather than the R&D phase.

81% of the agreements for which the originator companies submitted a combined market share of the contracting parties exceeding 20% contained provisions that provided for some kind of exclusive relationship between the companies, i.e. the agreements provided for an exclusive supply obligation, exclusive sourcing, exclusive licensing or any other kind of exclusivity, and/or a non-compete obligation. The average duration of these agreements with an exclusivity and/or non-compete obligation was eight years.

PHARMA SECTOR INQUIRY – COMMENTS ON THE REGULATORY FRAMEWORK

D. COMMENTS ON THE REGULATORY FRAMEWORK

(1289) The Commission services received a significant number of comments on the regulatory framework, including during the public consultation on the preliminary report. As explained in Chapter B.2., the most relevant areas of legislation for the pharmaceutical industry seem to be a) patent law and the enforcement system, b) the marketing authorisation system and c) the pricing and reimbursement system. The comments on these three areas are described in this chapter. The chapters also contain observations from the Commission services on these proposals, which can be translated in policy options for the Commission.

1. Patents

(1290) With respect to the patent system, which is defined broadly so as to include patent litigation, substantive replies from 22 generic companies and 43 originator companies were received in reply to the Commission's requests for information. The Commission's services also received submissions from EGA and EFPIA.

(1291) In response to the public consultation on the preliminary report, many comments were received on the functioning of the patent system, including from originator and generic companies and their associations, general business associations, associations of health insurers and associations of intellectual property law practitioners. In general, these comments strongly supported the observations the Commission services had made on the patent system in the preliminary report.

(1292) The comments received are presented below by issue and by source of the comment, followed by the Commission's services observations on the issue. A short overall conclusion on possible reform of the regulatory framework for patents is given at the end of this section.

1.1. Community Patent

(1293) As explained in Chapter B.2.1. of this report, more than 50 years after the foundation of the European Economic Community, it is still not possible to obtain a patent that is valid and enforceable throughout the Community. At present, patents in the EU can be obtained by filing either applications at national patent offices or by filing a single patent application at the EPO. However, national validation and maintenance of the "European patent" granted by the EPO remains necessary in each Member State where the patent owner wishes the patent to exist and to be enforceable. The "European patent" – as it exists today – is thus merely a bundle of national patents. The current fragmented patent system is therefore seen as a major impediment to innovation in Europe and to the EU's global competitiveness.

Comments by Originator Companies

(1294) Most originator companies said that, despite the high costs of national validation and maintenance of a European patent, they did nowadays normally obtain patent protection for their new products in all EU Member States. There does, therefore, seem

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to be a general desire to obtain patent protection throughout the Community, even among the smaller originator companies. Almost all originator companies felt however, that currently the total cost of validating and maintaining a patent in all EU Member States is much too high when compared to other countries like the USA or Japan. These costs are estimated at around € 55,000 for validation of a single, relatively short patent of 30 pages in all EU Member States.⁶³³ They are estimated at € 8,000 per year on average⁶³⁴ for maintaining that same patent in all EU Member States. Although the London Agreement on translations has the potential for significant savings in this respect, most of the states whose language is not in common with one of the official languages of the EPO had maintained translation requirements to some degree.⁶³⁵ Nor does the London Agreement solve the problem at source of why it would be necessary in the first place to obtain validation for a European patent in 27 EU Member States. Introduction of a Community patent would greatly simplify companies' management of their patents in Europe, in particular to the benefit of SMEs.⁶³⁶

(1295) The cost of national validation and national renewal could be eliminated if a patent, once granted, automatically applied to the entire EU, by the introduction of a Community patent as proposed by the Commission. According to some originator

⁶³³ This calculation is based on a patent with 20 pages of application, 5 pages of claims and 5 pages of drawings. The amount includes the patent fees of the EU's 27 national patent offices, agents' fees and translation costs for each Member State. Internal costs of patent owners are not included. The cost of obtaining the same patent at the EPO is around € 10,000 (about half of which consists of official EPO fees and the other half of agents' fees). This fee is generally considered reasonable by originator companies, given the amount of work involved in examining the patent application. It is therefore the subsequent formality of validation at the national patent offices that makes the European patent system expensive. Source: originator companies' replies to the Commission's requests for information.

⁶³⁴ This calculation is based on the renewal fees for the ninth year of the EU's 27 national patent offices plus an agent fee of € 25 per Member State. Internal costs of patent owners are not included. Again, it is the formality of annual renewal fees to be paid at each of the national patent offices that makes the European patent system very expensive. Source: originator companies' replies to the Commission's requests for information.

⁶³⁵ EPO: National validation fact sheet at EPO website, at <http://www.epo.org/patents/Grant-procedure/Filing-an-application/European-applications/European-applications/national-validation.html>, 30 April 2008.

⁶³⁶ The latest draft text of the proposal for a Council Regulation on the Community patent foresees that applications for a Community patent can be filed either at the EPO in one of the EPO languages (French, German, English) or via a national patent office in the national language concerned. The costs related to translating the latter kind of application into one of the EPO languages shall be borne by the system, not the applicant. This provision has been inserted to facilitate access to the Community patent system, in particular for SMEs. The Community will also set up a machine translation programme enabling instant access to translated publications of patent applications in all official languages of the EU. This programme will provide instant translations at the request of any interested party via the internet upon publication of a patent application.

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companies, that should ultimately lead to lower prices of originator medicines for consumers.⁶³⁷

Comments by Generic Companies

(1296) For generic companies, the fact that European patents granted by the EPO are subsequently transformed into a bundle of national patents is seen as a major problem, as these national patents are then enforced (or have to be challenged) in each Member State separately. As products are often covered by multiple patents, trying to obtain market entry for a generic product can become very costly and time-consuming. In the words of the European Generic Medicines Association (EGA):

"There are very few pharmaceutical products covered by a single patent on the product. A generics company may have to work through literally hundreds of patents and patent applications from the originator and other companies who are developing forms of that product, steering a precarious course through all of the potential issues. Multiplying the number of patents by the number of countries in which they can be enforced provides astonishing numbers and gives a clear indication of the extremely complex 'minefield' in which generic companies are operating".⁶³⁸

Comments during the Public Consultation

(1297) Strong support for the urgent need to establish a Community patent system was received from many parties during the public consultation, including associations of the originator pharmaceutical industry, associations of the generic pharmaceutical industry, associations of industry in general, individual pharmaceutical companies (both generic and originator), an association of health insurers and a biotech industry association.

⁶³⁷ Several originator companies said that, partly because of the high costs involved, they might not go through the trouble and expense of obtaining a patent in all Member States. In that case, some of them said they would be reluctant to actively market their products in Member States where they did not enjoy patent protection (especially if they also did not enjoy marketing exclusivity protection). While overall commercial considerations undoubtedly played the most important role in the decision as to whether or not to actively market in smaller Member States, it is clear that the "national patent cost" disincentive to marketing in such Member States would disappear if a Community patent automatically valid and enforceable in the entire EU could be obtained. Originator companies emphasised that, even if a particular medicine is not actively marketed in a particular EU Member State, it would still normally be available upon specific request for a patient.

⁶³⁸ European Generic Medicines Association (EGA): Patent-related Barriers to Market Entry for Generic Medicines in the European Union, May 2008, page 18.

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Observations of the Commission Services

- (1298) The sector inquiry confirms that large originator companies nowadays validate and maintain their commercially important patents in all or most Member States.⁶³⁹ The Commission has already carried out considerable analysis on the costs of obtaining and maintaining patents in Europe. It has estimated that a European patent designating only 13 out of the 27 Member States is about nine times more expensive than a USA or a Japanese patent if total costs are considered.⁶⁴⁰ This fully confirms that national validation and maintenance of European patents, including processing and translations that are still necessary in many Member States, are costly and burdensome for the patent holder. High costs may also preclude certain originator companies – especially SMEs – from having their patents protected in all Member States.
- (1299) This situation would change with the adoption of the proposed Regulation on the Community patent. This patent, which would also be granted by the EPO, would be a unitary legal title valid and enforceable throughout the Community.⁶⁴¹ It would provide uniform protection throughout the Community, with unified post-grant law and procedure ensuring consistency, legal security and a level playing field for all stakeholders in the patent system. A declaration of invalidity would also apply throughout the Community. The commercial planning of both originator and generic companies would be considerably facilitated by the uniform effects produced by the patent in the Community. In all cases where a patent should apply in more than just a few Member States, the Community patent would also be considerably more cost-effective than the current system.⁶⁴² For these reasons, all stakeholders, including SMEs, would significantly benefit from the creation of a Community patent. The Community as a whole would benefit from the closing of one of the last remaining loopholes in the Internal Market. Innovation and effective competition within the Internal Market would be stimulated, in accordance with the Community's Lisbon objectives.

⁶³⁹ For the sample analysed in the sector inquiry the number of designated member States per EPO patent amounted to 14.8 on average (see Chapter C.1.2.).

⁶⁴⁰ See Communication from the Commission to the European Parliament and the Council - Enhancing the patent system in Europe (COM(2007) 0165 final).

⁶⁴¹ The latest draft text of the proposal for a Council Regulation on the Community patent can be found in Council Working Document 8588/09 of 7 April 2009, at <http://register.consilium.europa.eu/pdf/en/09/st08/st08588.en09.pdf>. See also http://ec.europa.eu/internal_market/indprop/patent/index_en.htm for the Commission's Recommendation to the Council to provide the Commission with negotiating directives for the conclusion of an agreement creating a Unified Patent Litigation System.

⁶⁴² Under current proposals, the option of applying for a national or a European patent would continue to co-exist with the possibility of obtaining a single Community patent.

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1.2. Unified Patent Litigation System

(1300) As mentioned in Chapter B.2.1., at present the national courts of each Member State are competent to determine the validity and/or infringement of a patent in their own territory. This means that any legal action in Europe needed to enforce or to invalidate a patent or any action for a ruling of non-infringement, has to be brought before the national courts of the Member States concerned. This forces both challengers and enforcers to multiply national court procedures, at considerable costs to all parties. Moreover, there is a considerable risk of diverging judgments in different Member States on the substantive question of whether the same patent granted by the EPO is infringed or invalid. The creation of a unified patent litigation system in Europe would ensure that not only Community patents but also existing European patents are uniformly interpreted through a single unified judiciary, with immediate legal effect throughout the Community (or, for European patents, those Contracting States for which the patents has taken effect).

Comments by Generic Companies

(1301) Almost all generic respondents observed that the courts of different Member States regularly take divergent, indeed opposing views on the validity or scope of the same European patent, leading to considerable legal uncertainty.⁶⁴³ There were also significant perceived disparities between Member States in the granting or denial of interim injunctions against alleged patent infringements. According to the EGA, some Member States granted interim injunctions too easily, especially in the case of secondary⁶⁴⁴ patents.⁶⁴⁵ Finally, there was a demand to see patent cases handled by specialised and technically qualified patent judges, which it was said was not currently the case in all Member States.

(1302) Generic respondents also noted that there could be conflicting conclusions on the validity of a patent resulting from the EPO's opposition and appeal procedures, on the one hand, and from national courts, on the other. To avoid such divergences, some national courts did not give any ruling on the validity of a patent until the EPO had taken a definitive position. However, this was potentially worse for the generic company as it could then lead to years of delay in the national court procedure. Such

⁶⁴³ According to the European Generic Medicines Association (EGA), sometimes this even happens within a single Member State, for instance where regional courts maintain equal jurisdiction over patent matters. See EGA: Patent-related Barriers to Market Entry for Generic Medicines in the European Union, May 2008, page 22 and annex D thereto.

⁶⁴⁴ This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying intentions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

⁶⁴⁵ European Generic Medicines Association (EGA): Patent-related Barriers to Market Entry for Generic Medicines in the European Union, May 2008, page 20.

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legal uncertainty often prevented generic producers from marketing new generic products, given that they could be held liable retroactively should the originator company's patent ultimately be considered valid. The multiplication of national court procedures and the absence of the possibility of a rapid uniform binding ruling on the validity of a patent throughout Europe were therefore seen as major weaknesses of the patent system in Europe.

- (1303) Many generic companies complained that they face high litigation costs brought about by originators' enforcement actions in each individual Member State in which generic companies tried to market new generic products. To counter or prevent such actions, generic companies also often felt obliged to bring non-infringement or invalidity procedures in individual Member States, increasing further their litigation costs. While originator companies could easily afford the legal expenses involved from the considerable income stream generated on the market by the product under challenge, generic producers, especially the smaller ones among them, were in a much weaker position as they did not derive any income yet from the new generic products they intended to market. As one generic company remarked:

"The financial burden and the financial risk incurred by the generic company puts [the generic company] in a disadvantageous position as compared to the originator. The originator can employ the revenues from his monopoly to finance the patent disputes, whilst generic companies have to make an investment (additional to R&D, marketing, etc.) in a product of which they cannot be sure when they will be able to bring [it] on the market."

Comments by Originator Companies

- (1304) Many originator companies agree with generic companies that a major weakness of the European system is the requirement to enforce European patents in different national courts, leading to high costs and potentially diverging decisions. Moreover, as EFPIA described:⁶⁴⁶

"Further, failure to enforce a patent in one country can have significant negative impact in others; for example, because of national pricing and reimbursement rules. For example, if a company were not to enforce a patent against a generic company in one Member State, this could force it to reduce its prices in that Member State. [...] this in turn can lead to a reduction of the prices in other Member States, which use international price referencing to fix prices, causing significant damage to commercial operations in those other Member States. That is the case even if the equivalent national patents in those other Member States are successfully defended."

- (1305) Many originator companies also prefer to see their cases handled by technically qualified, specialised patent judges. Some explicitly ask for a "single patent court with

⁶⁴⁶ EFPIA: Intellectual Property and Pharmaceuticals, June 2008, page 28.

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EU-wide jurisdiction". Generic and originator companies therefore appear to have a common interest in the creation of a more efficient patent litigation system in Europe.

- (1306) A number of individual originator companies and EFPIA submitted comments aimed at further strengthening intellectual property protection in the Member States. They considered, for instance, that it is too difficult and takes too long in some Member States to obtain interim injunctions against alleged patent infringements. Such injunctions are particularly important for originator companies in order to prevent rapid profit erosion due to the market entry of generic products and because the level of damages granted in the main proceeding was not always sufficient to completely compensate the patent holder for its commercial losses or to dissuade generic companies from entering the market. At present there were seen to be too many differences in the interim injunction regimes of Member States. The effectiveness of legal actions to seize evidence also varied between Member States.

Comments during the Public Consultation

- (1307) Associations of originator and generic companies, as well individual pharmaceutical companies, confirmed their strong support for the urgent creation of a unified patent judiciary in Europe. An association of health insurers said in the public consultation that it could be hoped that a Community patent combined with a unified specialised judiciary "will lead to increased transparency and faster access to (...) medicines for patients and that the savings will be translated into lower costs for healthcare systems". Several of the respondents mentioned the need for the unified judiciary to be capable of producing high-quality, cost-effective and timely judgments.

Observations of the Commission Services

- (1308) The findings of the sector inquiry fully support the need to create a unified and specialised patent litigation system for European and Community patents.⁶⁴⁷ Chapter C.2.2. of this report shows that the number of patent litigations between originator and generic companies increased very substantially between 2000 and 2007, that patent litigation was often initiated in many different EU Member States simultaneously and that the average duration of a patent litigation was 2.8 years. The costs of such litigation between 2000 and 2007 for the 219 INNs investigated amounted to € 420 million for the parties involved. Importantly, 11% of final judgments were conflicting between courts in different Member States, causing considerable legal uncertainty.
- (1309) Duplication of litigation in multiple Member States and conflicting rulings between Member States could be avoided by the creation of a unified patent litigation system. Direct costs savings for the parties concerned (originator and generic companies)

⁶⁴⁷ See Communication from the Commission to the European Parliament and the Council - Enhancing the patent system in Europe (COM(2007) 0165 final). The latest text of the Draft Agreement on the European and Community Patents Court and Draft Statute can be found in Council Working Document 7928/09 of 23 March 2009, at <http://register.consilium.europa.eu/pdf/en/09/st07/st07928.en09.pdf>.

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would be considerable.⁶⁴⁸ Perhaps even more important would be the increase in legal certainty for parties resulting from a unified patent litigation system in Europe.

(1310) The Commission services agree that the unified patent litigation system must be capable of producing high-quality, cost-effective and timely judgments. This is necessary not just to protect the legitimate interests of patent holders, but also the interest that challengers and society as a whole have in obtaining early clarity on the scope and validity of patents (including the annulment of patents that do not meet the criteria for patentability). An efficient, highly qualified and speedy mechanism of revoking patents as an alternative to opposition at the EPO is therefore an essential part of the unified judiciary. It will also require that there are sufficient incentives for companies to apply for European and/or Community patents rather than national patents in order to allow for the benefits of the unified patent judiciary to deploy fully.

1.3. Quality of Patents

(1311) As mentioned in Chapter B.2.1, a patent granting up to 20 years of legal exclusivity to the commercial exploitation of a product or process is an important reward from society to inventors, meant for genuine contributions to innovation. Patents that are subsequently revoked can impose a significant cost on society as they may have limited competition, including competition in research, that would have taken place in the absence of the patent and as they may have led to excessive prices for the product or process protected by the patent. On the other hand, if patents are granted too restrictively, innovation may be discouraged. It is therefore very important that the substantive criteria for patentability, in particular novelty and inventive step, are set at the right level and that they are strictly implemented in the examination process leading up to a decision on whether or not a patent should be granted.

(1312) With respect to the process of granting patents, most pharmaceutical companies said they had much more experience with the EPO than with national patent offices.⁶⁴⁹ The comments below therefore focus on the granting procedure at the EPO. It is important to note that these comments are relevant not just for European patents but also for the Community patents that will be granted by the EPO once the Regulation establishing the Community patent has been adopted. It is also important to realise that the creation

⁶⁴⁸ A recent study performed for DG Internal Market & Services concludes that avoidance of duplication alone would result in total private savings of between € 148 million and € 289 million per year, for all sectors combined. In this calculation, the pharmaceutical sector represents about a fourth of all duplicated cases. The same study estimates that the economic benefits of a unified patent judiciary would exceed the costs of establishing one by a multiple of between 5.4 and 10.5. See Professor Dietmar Harhoff: Economic Cost-Benefit Analysis of a Unified and Integrated European Patent Litigation System, 26 February 2009, pp. 40, 52-53. For the INNs under investigation the duplication rate of litigation cases between the same parties with respect to the same medicine is estimated to amount to 30%.

⁶⁴⁹ This includes both originator and generic companies. It should be noted that generic companies regularly participate in opposition procedures at the EPO. In particular, the larger generic companies also regularly file patent applications themselves at the EPO. A few originator companies remarked that, based on their limited experience, certain national patent offices did not make a detailed examination of novelty and/or inventive step.

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of a cost-effective, highly qualified and speedy mechanism of revoking patents at the unified patent judiciary will contribute significantly to ensuring a high quality of European and Community patents (see Section D.1.2. above). The same can be said about the acceleration of opposition and appeal procedures at the EPO (see Section D.1.4 below). These measures are therefore all inter-linked and aim at the same objective of creating a single European space of high quality patents that are granted in efficient procedures.

Comments by Generic Companies

- (1313) While generic companies considered the quality of the work of the EPO to be adequate or satisfactory overall, a number of examples were given of patents on pharmaceuticals which, in the view of many generic companies, were granted too lightly. These comments related in particular to patent applications that do not concern a new molecule or a new medical use of an existing molecule, but rather new forms, formulations, combinations, processes, particle sizes, devices or dosage regimes of already patented molecules (so-called secondary patents).⁶⁵⁰
- (1314) According to generic companies, the purpose of secondary patent applications was often to extend the market position of the originator company in respect of the existing treatment, for which they had enjoyed patent protection, with considerable commercial consequences.⁶⁵¹ If the EPO granted these new patents on minor modifications of a medicine too lightly, the marketing efforts of the originator could ensure that doctors and patients switched to the new version of the product even before generic companies were allowed to enter the market with a generic version of the previously marketed product. Market demand for the latter would then drop significantly.
- (1315) Generic companies felt that in this manner originator companies could succeed in "evergreening" their blockbuster medicines well beyond the protection period of the patent covering the active ingredient of the previously marketed product. As one company said:

"The European patent system allows the originator companies to keep adding patents (i.e. evergreening their products) to a product (whether legitimate or not), forcing the generic companies to choose between waiting for all the patents to expire and applying for marketing authorisation anyway, running the risks of litigation and the associated costs and delays."

Another remarked:

⁶⁵⁰ See Chapter B.2: Patents for a description of the different claim types found in pharmaceutical patents.

⁶⁵¹ See Chapter C.2.1. for a detailed description of patent filing strategies.

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"The entire point of the patenting strategy adopted by many originators is to remove legal certainty. The strategy is to file as many patents as possible on all areas of the drug and create a 'minefield' for the generic to navigate. All generics know that very few patents in that larger group will be valid and infringed by the product they propose to make, but it is impossible to be certain prior to launch that your product will not infringe and you will not be the subject of an interim injunction."

- (1316) Generic companies suggested that in particular in such situations of relatively minor modifications to already patented products, the EPO should examine the patent application very closely before granting it. At present, it was felt by many respondents that the novelty and the inventive step requirements for such patent applications were at times too easily considered as being met, partly because the EPO sometimes overlooked prior art⁶⁵² and partly because the EPO sometimes accepted, as part of their "problem-and-solution approach" to inventive step, claims from applicants regarding non-existent or obvious problems. One company considered that there was an "unwritten benefit of doubt principle" at the examination stage.⁶⁵³ While generic companies were, in principle, also free to apply for patents on (minor) modifications of products already patented by an originator company, it was clear that the latter, being the original inventor, had a natural advantage in this respect.⁶⁵⁴
- (1317) It was further observed that while under EPO rules a patent might always be challenged in the opposition procedure before the EPO, the commercial reality was that once the patent had been granted and had been validated at national level, it was enforceable before the national courts, even if an opposition procedure at the EPO was pending. Enforcement might, for instance, take the form of an interim injunction being granted when prima facie justified, blocking generic market entry. A granted patent therefore provided clear commercial benefits to the patent holder, even if the patent might later be revoked by the EPO or invalidated by a national court.

⁶⁵² There is no obligation under current EPO rules for the applicant to disclose the prior art known to it. Article 124 EPC merely allows the EPO to invite the applicant to provide information on prior art taken into account in national or regional patent proceedings concerning the same invention.

⁶⁵³ With respect to the opposition procedure, the Board of Appeal in case T 72/04 confirmed that each party normally carries the burden of proving the facts it alleges. But it also said that "in a case where the parties make contradictory but unsubstantiated assertions concerning facts relevant for establishing patentability and the EPO is not in a position to establish the facts of its own motion, the benefit of the doubt is given to the patent proprietor". See Special Edition No. 6, OJ EPO, 2007, page 35.

⁶⁵⁴ During the public consultation, one association of originator companies referred to this as a company "using its superior knowledge of its own products to devise and protect new and valuable improvements for the benefit of patients and prescribers".

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Comments by the BEUC

(1318) The European consumer organisation BEUC expressed the view that:

"patent strategies can constitute barriers to the entry of new generic medicines into the market. We are very much concerned by the phenomenon of so-called "evergreening", which describes a specific tactic used by originators to extend patents by seeking to obtain as many patents as possible during the development of the product and the marketing phase, and to obtain a patent extension for new manufacturing processes, new coating and new uses of established products...Originators can also slightly change an active ingredient and present an old medicine as a new product and register a new patent.

We consider that these practices are anticompetitive and prevent generics' entry into the market. They also incur higher health care expenditures and/or higher prices for consumers."

(1319) Moreover, the BEUC wrote:

"We also think that the list of medicine properties eligible for patent should be stricter."

Comments by Originator Companies

(1320) With respect to the functioning of the EPO, the general level of satisfaction among originator companies was high, considerably higher than among generic companies. The duration for granting or rejecting patents at the EPO were seen as reasonable and EPO searches were of a high standard. The examination of novelty and inventive step by the EPO was considered on the whole to be somewhat stricter than at the US Patent and Trademark Office (USPTO), with the degree of scrutiny at the EPO being considered satisfactory.⁶⁵⁵ One originator company acknowledged:

"This [high quality of EPO examinations] is important as it is in the best interest of both originator and generic companies that only good quality patents are granted as this reduces the number of potential court challenges and results in increased legal and business planning certainty".

(1321) Most originator companies did not share the comment by generic companies that the EPO tended to grant patents for modifications to existing products too lightly.

⁶⁵⁵ One originator company commented: "The European patent system provides a strong possibility for third parties to challenge the patentability assessments by filing oppositions, which certainly has an impact on examiners to provide a careful in-depth analysis before granting a patent. The possibility to file oppositions thus can be seen as a quality control of the examination procedure."

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Comments during the Public Consultation

(1322) Several commentators, including an association of originator companies, observed that secondary patents may contain very useful inventions.

Observations of the Commission Services

(1323) The Commission services fully recognise that following the grant of a patent for a new molecule, important improvements may subsequently be made. Such improvements may for instance enhance the effectiveness of the medicine, reduce its side effects, facilitate its administration or ease the dosage regime. Such significant inventive contributions merit patent protection.

(1324) However, from the internal strategy documents of originator companies analysed in this report it transpires that originator companies themselves consider some of their patent applications nowadays to be less solid.⁶⁵⁶ The EPO has drawn attention not only to the ever-increasing number of patent applications, but also to the deterioration in their quality, especially in terms of clarity and conciseness.⁶⁵⁷ In particular in those cases where such patent applications, if granted, could serve to prolong the income stream from a medicine well beyond the expiry of the original patent protection, it is crucial that such an application be scrutinised very carefully and that a patent be awarded only where a true inventive contribution is made.⁶⁵⁸

(1325) In this respect, the fact that third parties make observations on a patent application could, for instance, serve as a signal to the EPO examiners that the application is likely to be commercially important and potentially contested. It is therefore desirable that third parties are stimulated to make pertinent observations already during examination and not to wait until opposition. The Commission welcomes the fact that the EPO is currently reflecting on ways to make filings of third party observations easier and more attractive.

(1326) In order to limit to an inevitable minimum the costs imposed on society by patents that are subsequently revoked, it is important that the same strict standards are applied to all patent applications and that each patent application receives the close scrutiny it deserves.

(1327) The Commission services very much welcome the fact that the EPO has recently launched a major initiative to further increase its focus on quality and to implement

⁶⁵⁶ See Chapter C.2.1.

⁶⁵⁷ See EPO Annual Report 2007, In Focus: Raising the Bar on Patent Quality, available at Raising the bar on patent quality.

⁶⁵⁸ On the quality of patents, see also Section 3.1 of the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: An Industrial Property Rights Strategy for Europe, COM (2008) 0465 final.

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strictly its standards of novelty and inventive step. In the words of EPO President Alison Brimelow:

"What we need is not more patents, but more good patents. The EPO aims to make sure that the patents it grants are relevant. The lower number of patents published in 2007 reflects this priority and is a step in the right direction. Putting the emphasis on quality over quantity in the granting of European patents is a key strategy for safeguarding the proper functioning of the European patent system."⁶⁵⁹

(1328) These efforts should be continued and intensified in the months and years to come, not least with a view to the early introduction of the Community patent. A high quality patent system is not only what the European population deserves in exchange for the legal exclusivity society gives to patent holders, but is also crucial to stimulate competition and innovation in Europe.

1.4. Duration of Procedures at the EPO

(1329) From a competition perspective, the duration of procedures – also before at the EPO - is important in two respects: firstly, as mentioned in Chapter B.2.1. and further discussed in Chapter C.2.1., applicants may deliberately try to delay the EPO's decision on their patent application, in particular when they think the patent may not be granted, in order to maintain as long as possible legal uncertainty for their competitors, whether originator companies or generic companies.⁶⁶⁰ This legal uncertainty may deter generic market entry and block competitor research. Secondly, the basic balance at the EPO (as at other major patent offices in the world) is such that patent granting decisions are taken after an *ex parte* procedure with the applicant and that the *inter partes* opposition procedure serves to revoke patents that are ultimately found not to meet the criteria for patentability. Because patents, once granted and validated, can have important commercial consequences in the market, for instance through the issuing of interim injunctions, it is very important that unmerited patents can be quickly revoked through an efficient and speedy opposition procedure at the EPO (in addition to the possibility to revoke a patent through a court proceeding, see Section D.1.2. above). Each of these issues will be discussed below.

(a) Countering Delaying Tactics at the Granting Stage

⁶⁵⁹ EPO press release to the 2007 Annual Report, 19 June 2008.

⁶⁶⁰ For the period of provisional protection, between the moment of publication of the patent application and the moment of the publication of the patent grant, Article 67 EPC requires Contracting States to ensure that the applicant can claim compensation reasonable in the circumstances from any person who has used the invention in their territory. Following publication of the mention of the patent grant, full compensation of any losses suffered may be claimed, depending also on whether the infringer knew or should have known that he or she was infringing.

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Comments by Generic Companies

(1330) Several generic respondents observed that originator companies sometimes seem to have an interest in creating and maintaining for as long as possible a maximum degree of legal uncertainty for potential generic market entrants. This may lead originator companies to file, in particular towards the end of the life of a basic patent, multiple secondary patent applications, possibly with overlapping substance matter and then to delay or obfuscate the handling of those applications, for instance by launching voluntary divisional applications, by not immediately transmitting required information to the EPO or by making misleading representations.

(1331) These generic companies feel that the EPO should take stricter measures against such practices. As one of them said:

"Obviously, [originator company]'s strategy is to file numerous identical or practically identical divisional applications from one basic application – which has been found invalid [meant is: refused] by the EPO! – and keep them pending. Should the grant of one of them be denied, the other still pending applications are such a threat to the generic companies that many of them are extremely reluctant to enter the market. [...] The grant [meant is: EPO decision on the patent application] can be delayed for years by [originator company]"

Comments by Originator Companies

(1332) At least one originator company explicitly acknowledged:

"Pending applications filed with broad claims on commercially relevant subject matter often present a measure of uncertainty. [...] The filing of divisionals before the EPO can extend uncertainty for several years."

Most other originator companies decided not to comment on this issue.

Comments during the Public Consultation

(1333) Several commentators, including an association of generic companies, confirmed the problem of legal uncertainty caused in particular by repetitive, sometimes even identical, voluntary divisional applications. This issue was also reiterated by the EPO, which also pointed to the additional work load created by such applications.

Observations of the Commission Services

(1334) The sector inquiry has gathered information that originator companies consider secondary and voluntary divisional patent applications as a strategy to prevent or delay generic entry and to create uncertainty for generic competitors as to whether they may

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develop a generic product without infringing a potential patent.⁶⁶¹ During the period under investigation, the subject-matter contained in a patent application could in principle be kept pending indefinitely by constantly creating new voluntary divisional applications shortly before the previous application is decided upon. Under EPO jurisprudence, such divisional applications can even be identical to the parent application. The Commission services observed in the preliminary sector inquiry report that the adoption by the EPO of stricter rules against potential abuses of voluntary divisional applications would be desirable. The Commission services welcome the fact that in the meantime the EPO has, within the framework of its "raising the bar" initiative, adopted measures ensuring that voluntary divisional applications can only be made within a certain period after the original application was filed.⁶⁶² This measure will help to reduce legal uncertainty for competitors. Other procedural measures to tighten up time limits in the granting procedure and avoid deliberate delays by applicants, whether for voluntary divisional applications or normal applications, would also be welcome.

(b) Speeding up the Opposition Procedure

Comments by Generic Companies

(1335) While most generic companies welcomed the fact that an opposition procedure existed at the EPO, a majority of them felt that the procedure as a whole (the opposition itself and any possible appeal arising from it) takes quite a long time, causing continuing legal uncertainty in the market place.

Comments by Originator Companies

(1336) A significant point of agreement with generic companies was that many originator companies also felt that the opposition procedure and any appeal took too long. As one originator company expressed it:

"The duration of the examination phase can take many years; however this is not necessarily problematic, since the development of pharmaceuticals also takes many years. However, it is a concern that opposition and appeal proceedings also typically take several years."

(1337) Originators also had a common interest with generics in that they felt that unduly broad claims (of competitors) in patent applications should not be accepted. Originators used the opposition procedure to challenge such broad claims of

⁶⁶¹ For further details see Chapter C.2.1.

⁶⁶² This period shall not exceed 24 months after either the first communication of the Examining Division on the original application or any communication in which the Examining Division raises a specific objection of lack of unity with regard to the original application for the first time. See Decision of the Administrative Council of 25 March 2009 amending the Implementing Regulations to the European Patent Convention (CA/D 2/09). This measure will enter into force on 1 April 2010.

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competitors, but might also use national court procedures because in opposition procedures, in the words of one originator,

"(i)t will often take many years to determine an opposition, given the pace at which the EPO and its appeal procedures operate."

Comments during the Public Consultation

(1338) Several associations of generic and originator companies, business associations in general and associations of intellectual property law practitioners reiterated their support for a shortening of the time taken by the opposition and appeal procedures at the EPO. The EPO itself recognised that "dilatory tactics" are sometimes engaged in by parties and that "time delays can occur in the combined opposition and appeal procedures". The EPO said that "we are striving to improve our performance in this respect".

Observations of the Commission Services

(1339) The sector inquiry has confirmed that for the pharmaceuticals investigated, the opposition procedure lasted on average 3.6 years from initiation to final ruling (including an appeal where an appeal was made) and that 80% of all procedures take more than two years.⁶⁶³ This long average duration of the opposition procedure considerably limits companies' perspective to clarify the patent situation efficiently and speedily.

(1340) The Commission services observe that the EPO already offers parties the possibility to accelerate, on a voluntary basis, opposition and appeal procedures in cases where an infringement proceeding is pending before a national court. Apparently, however, parties make little use of this possibility. Stricter procedural rules and shorter time limits, not just on voluntary basis but obligatory and in all cases, could allow the EPO to considerably reduce the time taken by the opposition and appeal procedures

1.5. Patent Settlements

(1341) Chapter C.2.4. of this report provides an overview of the patent settlement agreements which have been concluded between originator and generic companies. In total, the report identifies 45 agreements in which there was a limitation on the generic company's ability to enter the market and a value transfer from the originator to the generic company. They lead to direct payments exceeding € 200 million, often in addition to other commercial benefits.

(1342) Patent settlements with a value transfers from the originator company to the generic company can be used to eliminate competition if the generic company agrees to delay its market entry beyond the point in time when it would have expected to be able to enter the market, for example following a judgment in the litigation, or agrees to enter

⁶⁶³ For further details see Chapter C.2.3.

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the market in a more limited fashion than it would have done in the absence of a settlement.⁶⁶⁴ Such an agreement could serve the purpose of sharing the consumer savings that would have resulted from the lower prices following the generic company's market entry. This may be optimal for both parties, but could harm national health schemes, and thereby consumers.⁶⁶⁵

- (1343) Because the content of patent settlements is often confidential, in particular when done outside the court room, there is also a risk that problematic settlements are not detected, neither by competition authorities nor by public or private health insurers.

Comments by Originator Companies

- (1344) During the public consultation, many originator companies, their associations and lawyers rightly observed that patent settlements can be an efficient way of ending patent disputes. They can lead to the avoidance of litigation costs and the resolution of uncertainty. Furthermore, settlements can reduce congestion in the court system which is also one of the reasons why many courts generally support settlements.
- (1345) Originator companies and their associations also submitted that a settlement negotiation is a dynamic process in which each company tries to get the most out of the agreement. It was argued that it may be difficult for parties to reach an agreement, for example because both parties are overly optimistic about the likelihood of success in litigation. In order to bridge the gap, it should be possible to conclude settlements with reverse payments.
- (1346) Finally, originator companies and their associations and lawyers requested guidance on the limits to what originator and generic companies could legally agree on between themselves in the context of patent settlements.

Comments by Generic Companies

- (1347) Generic companies and their associations also submitted that patent settlements can be a desirable way of ending patent litigation, especially given the high costs associated with litigation and the constraints litigation put on the courts. Companies should therefore be given flexibility in concluding such agreements. Generic companies argued that settlements are generally beneficial to consumers as it can allow generic entry before loss of exclusivity.
- (1348) Furthermore it has been submitted that due to the imbalance of interests of the parties in the outcome of the litigation, a payment to the generic company may be the only

⁶⁶⁴ Such an outcome is possible because of the special impact generic entry has on the sales of the originator product. Generic products usually enter the market at a considerably lower price than the originator product which leads to lost sales for the originator company.

⁶⁶⁵ It should be noted that the value transfer to the generic company can take other forms than pure payments. For example, the originator company can offer a side deal to the generic company or offer the generic company to become a distributor of the originator company's own authorised generic product.

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way that a settlement can be reached. It was also argued that settlement agreements should not be pursued under Article 81 EC (anti-competitive agreements) but, if at all, only under Article 82 EC (abuse of a dominant position).

Comments by Other Stakeholders

- (1349) The problem of lack of transparency was observed by stakeholders in the public consultation. In this connection it has been submitted that patent settlements should be supervised. As explained in Chapter C.2.4., since 2004, pharmaceutical companies are required to file US related patent settlement agreements with the Federal Trade Commission (FTC) and the Department of Justice (DoJ) within ten days of execution. The FTC has brought several patent settlement cases to the courts claiming that settlements involving a payment to the generic company in exchange for delayed market entry are anticompetitive. However, as evidenced by the Eleventh Circuit Court's decision in the Schering-Plough case, the US courts have not always agreed with the view of the FTC.
- (1350) As a response to the Courts' decisions, Senate Judiciary Antitrust Subcommittee Chairman Herbert H. Kohl and Senator Chuck Grassley recently proposed legislation (S. 369) that would prohibit brand name pharmaceutical manufacturers from paying off generic drug companies to delay entry of a generic drug into the market. The proposed legislation ("The Preserve Access to Affordable Generics Act") would make it unlawful for a company to be a party to a patent settlement agreement in which (i) the generic company receives anything of value and (ii) the generic company agrees not to research, develop, manufacture, market, or sell the product concerned for any period of time. The proposal specifically mentions that patent settlement agreements in which the only value to the generic company is the right to market the product prior to the expiration of the patent are lawful.⁶⁶⁶

Observations of the Commission Services

- (1351) The sector inquiry has confirmed that originator and generic companies conclude settlement agreements in the EU in order to resolve claims in patent disputes, oppositions or litigation. Furthermore, a significant number of patent settlements include a limitation on the generic company's ability to market its medicine combined with a value transfer from the originator to the generic company. At present, the Commission services are not in the position to make any policy recommendations whether and if so which settlements should be regulated in one way or another. It is therefore deemed appropriate – as set out in Chapter F.1. – to first gain further experience through a tailored monitoring exercise.

⁶⁶⁶ For the full text of the bill, please see: <http://thomas.loc.gov/cgi-bin/query/z?c111:S.369.IS>: A similar bill was introduced in the House. See H.R. 1706: Protecting Consumer Access to Generic Drugs Act of 2009, at <http://thomas.loc.gov/cgi-bin/query/z?c111:H.R.1706.IH>:. The enactment of this bill was formally recommended by the U.S. House Energy and Commerce Committee's Commerce, Trade and Consumer Protection Subcommittee on 3 June 2009.

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1.6. Clearing the Way

(1352) When a generic company launches a new generic product in the market and is faced with a legal proceeding by an originator company claiming patent infringement, costly consequences can arise for either side, depending on the outcome of the proceedings. If, for instance, the court refuses an interim injunction and the patent is later found to have been infringed, the price level for the originator product may in the meantime have considerably dropped under the price pressure from the generic product and it may be difficult for the originator company to restore prices for its product to their previous level. At the same time, it may be difficult for the originator company to obtain full damages for its losses from the generic company concerned. If, on the other hand, the court issues an interim injunction and the patent is later found not to have been infringed, the generic company loses, as it will have been prevented from entering the market and as it may be difficult to obtain compensation for the full damages suffered. Very often the generic company might therefore also be interested to enter into settlement agreements with the originator companies (for details see Chapter C.2.3.). In this second scenario, consumers lose too.

(1353) One way of avoiding these costs to either side would be to solve all possible patent issues before the generic product is launched on the market, thereby "clearing the way" for a generic market entry (if successful in the "clearing the way" procedure) without interim injunctions and damage suits.

Comments by Originator Companies

(1354) In the public consultation, EFPIA suggested that the Commission services should recommend a greater use in Europe of "clearing the way" mechanisms. The mechanism proposed by EFPIA would be based on the mandatory notification to the originator company of an application for marketing authorisation of a generic product combined with a right for the originator company to bring infringement proceedings based on the notice (i.e. before market launch). EFPIA also pointed out that Member States already offered possibilities for generic companies to challenge the validity of patents before national courts, as well as, in many cases, possibilities to obtain a declaratory judgment of non-infringement.

Comments by Generic Companies

(1355) Generic companies were generally not in favour of rendering obligatory any "clearing the way" mechanism. Nor did they want to be faced with any sanctions, such as a greater likelihood of interim injunctions, if they chose not to use such a mechanism. Generic companies especially disliked the mechanism proposed by EFPIA, regarding it as a back door measure to introduce patent linkage.⁶⁶⁷

(1356) Generic companies feared the delay in generic market entry that could arise if the "clearing the way" procedure were not finished before the generic company concerned

⁶⁶⁷ See Sections B.2.2.3., C.2.5., D.2. and D.2.3. of this report.

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was authorised and able to enter the market. This was because in most Member States the existing procedures for declaratory judgments of non-infringement could only be launched shortly before generic product launch. As such procedures could take (at least) several years in many Member States, significant delays in generic market entry would almost certainly occur. Generic companies were also concerned about the possible duplication of such procedures in 27 Member States and the considerable cost thereof. They further observed that the generic company that cleared the way for a particular product, would make market entry possible for all its generic competitors as well, thus losing partly or entirely the first mover advantage the company would have had if it had not bothered to "clear the way" before launching its product on the market..

Observations of the Commission Services

(1357) When a generic company considers its product is not likely to infringe any patent, it has little to gain from going through a "clearing the way" procedure before launching its product on the market. Gaining a first mover advantage by being the first to launch the generic product on the market would, in that case, appear more attractive. The possibility to obtain a first mover advantage is important from a competition policy perspective, because it stimulates companies to enter the market as quickly as possible, thereby creating competition and bringing down prices for consumers.

(1358) Using a "clearing the way" procedure could, on the other hand, be an attractive option for a generic company when it has a genuine doubt about whether it would be infringing a patent. Whether it would want to use a "clearing the way" mechanism in that case would depend on the mechanism's costs and benefits compared to directly entering the market. In this respect, several elements could be envisaged that would make it more attractive for generic companies to "clear the way", if they wished to do so, before entering the market:

- Normally, the procedure should result in a final ruling (i.e. including appeal) not later than the moment when the generic company obtains the necessary authorisations to enter the market (marketing authorisation, pricing and reimbursement decisions where applicable) and the loss of exclusivity of the product occurs in the assessment of the generic company. This means that it should be possible to initiate the procedure sufficiently early in time and that the procedure itself should be conducted as expeditiously as possible. Under the current legal regime in many Member States that does not seem to be the case, as patent litigation cases last on average 2.8 years with significant variations across Member States (for details see Chapter C.2.2.).
- If the court proceedings take longer, the generic company should not be "punished" if it decides to enter to market. In other words, the normal criteria for granting or refusing an interim injunction would apply. Any clearing the way mechanisms must not create incentives for either side to artificially delay the court proceedings.
- If requested by a generic company at the start of the procedure, the originator company concerned would have to indicate all patents that it intended to invoke against the generic product. Any patents not mentioned could no longer be invoked before the court. Also the patent holder should be obliged to react

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within a relatively short period of time. If it fails to do so, the originator company should be deemed to have accepted the legal position of the generic company.

- The unsuccessful party could be ordered to pay the costs of the proceedings, including a large part of the legal costs of the successful party. This would deter frivolous challenges to patents as well as frivolous infringement proceedings.

(1359) In conclusion, regarding the request by the originator industry to introduce so-called "clearing the way" mechanisms to solve patent issues before generic market entry, it is not clear that such new mechanisms would bring a positive added value at this stage when there are still significant discrepancies between national legal systems (e.g. on duration of court proceedings or the conditions/likelihood to obtain interim injunctions). In this light, generic companies should remain able to maintain the first mover advantage in relation to other generic competitors, unless an effective national system to clear the way exists. In any event the conditions, under which such a mechanism could be introduced, would need to be studied carefully.

Summary

All stakeholders expressed strong support for the urgent creation of a single Community patent and a unified and specialised patent litigation system in Europe which are currently under discussion. Rulings by the unified litigation system should be swift, of high quality and cost-effective. The results of the inquiry confirm that the Community patent and unified litigation system would create significant cost and efficiency improvements, in particular by reducing the costs associated with multiple filings, by eliminating essentially parallel court cases between the same parties in different Member States and by enhancing legal certainty through the avoidance of conflicting rulings. The Commission continues to make all efforts leading to the rapid adoption of these instruments.

Stakeholders agree on the importance that European – and in the future Community – patents granted by the EPO should respond to a high quality standard. Strong support was further received by all stakeholders that the EPO should be enabled to accelerate procedures whenever possible. Based on its findings of the sector inquiry, the Commission supports the recent initiatives by the EPO to "raise the bar". In this respect the Commission welcomes the recent decision to limit the time period during which the voluntary divisional patent applications can be filed. The Commission also supports the EPO in its efforts to shorten the opposition and appeal procedures.

Regarding the request by the originator industry to introduce so-called "clearing the way" mechanisms to solve patent issues before generic market entry, it is not clear that such new mechanisms would bring a positive added value at this stage when there are still significant discrepancies between national legal systems (e.g. on duration of court proceedings or the conditions/likelihood to obtain interim injunctions). In this light, generic companies should remain able to maintain the first mover advantage in relation to other generic competitors, unless an effective national system to clear the way exists. In any event the conditions, under which such a mechanism could be introduced, would need to be studied carefully.

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2. Marketing Authorisation

(1360) This section summarises the main comments received from companies and other stakeholders regarding the framework governing marketing authorisations for pharmaceuticals in Europe, including comments received during the public consultation of the Preliminary Report. It also provides the observations of the Commission services on the points raised.

(1361) It should, however, be noted that the sector inquiry does not include within its scope an in-depth analysis of the Community regulatory framework for pharmaceuticals and moreover, the Community rules on the authorisation of generic medicines and on data exclusivity were substantially reviewed in 2004. New provisions apply from 2005, although some will only show their full effects in some years' time.

(1362) Overall, most stakeholders took the view that the current regulatory framework on marketing authorisations, which was substantially reviewed in 2004⁶⁶⁸, provides a fair balance of interest⁶⁶⁹, but called for strict implementation and enforcement of both the old and new regulatory framework as well as for some additional adaptations. The comments of stakeholders received during the inquiry will constitute an additional valuable information basis to be taken into account by the Commission in the further implementation of its policies in the sector. The pharmaceutical industry reported concerns common to all companies but also specific issues faced by either originator or generic companies.

(1363) In their submissions, individual companies, associations and other organisations have identified delays in the assessment process due to shortcomings and backlogs in national approval systems (Chapter D.2.1.). Stakeholders also provided their point of view on perceived discrepancies with regard to the national implementation of the EU regulatory framework (Chapter D.2.2.). Mainly generic companies also raised concerns about the possibilities of originator companies to intervene⁶⁷⁰ in regulatory proceedings before marketing authorisation bodies and reported about diverging

⁶⁶⁸ For details see Chapter B.2.2. Most changes took effect in 2005, however some will only be effective as of 2013.

⁶⁶⁹ One generic company called, however, for a more radical change in the current system. The company suggested to introduce a period of exclusivity for the first generic product entering the market prior to patent expiry, similar to the provision existing in the United States under the Hatch-Waxman Act (see annex to Chapter C.2.4. The company argued that the first generic entrant has higher costs and risks and is followed by other generic entrants which may allegedly enter at diminished risk and costs. According to this company, establishing a period of marketing exclusivity in favour of generic companies which come first to the market would promote generic competition. It would also be beneficial for generic companies as it could help to recoup investments, fund additional development of medicines and stimulate new patent challenges. Originator companies would be under pressure to deliver more new medicines. Finally, patients and taxpayers would obtain lower prices on medicines due to earlier generic entry and more competition.

⁶⁷⁰ The concept of intervention should not be understood as a formal intervention as foreseen in the legislation but rather as an informal submission.

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approaches to the disclosure of confidential information taken by different national authorities (Chapter D.2.3.). Companies also call for further international harmonisation in the area of marketing authorisation, mostly between Europe and the United States to reduce unnecessary regulatory divergences (Chapter D.2.4.). Finally, generic companies call for action against negative advertising (see Chapter D.2.5.).

(1364) Finally, during the public consultation, health insurers argued that – next to safety, efficacy and quality – a fourth condition should be introduced for obtaining marketing authorisation of a new medicine: evidence of "added value" over and above existing treatments. This issue is not dealt within this section, but in Chapter D.3. summarising the comments and observations on procedures governing pricing and reimbursement status.

2.1. Market Access Delays Due to Regulatory Backlogs in National Agencies

(1365) Both originator and generic companies reported about obstacles to obtain market authorisations for their products. They claimed that there are approval backlogs and limited slot availabilities. According to the companies, lack of sufficient resources and inefficient procedures at national agencies were identified as key factors causing the delays. Other reasons include the increasing workload of certain agencies, the restricted number of Member States (agencies) acting as Reference Member State and the limited number of specialised assessors in certain agencies.

(1366) Companies can face delays and very late slot openings to submit their files. The time delays are encountered during both the Decentralised Procedure (DCP⁶⁷¹) and the Mutual Recognition Procedure (MRP⁶⁷²) (in the validation phase, 'stop the clock' phase and post-procedure close) or during procedures concerning marketing authorisation for variations⁶⁷³. Indeed, companies reported that slots are scarce in certain national agencies and require careful planning. In some agencies, first slots are only available from 2010.

(1367) Contributors highlight several possibilities to address these issues such as increasing resources and capacity building at national agencies or a rebalancing of the responsibilities within the network of EU medicines authorities. They also suggest an increased possibility to use the centralised procedure, for which less obstacles/delays are reported.

⁶⁷¹ For further details see Chapter B.2.2.

⁶⁷² For further details see Chapter B.2.2.

⁶⁷³ Changes subsequent to the placing of medicines on the EU market (e.g. change in the production process, change in the packaging, change in the address of the manufacturer etc.) are called 'variations'. Variations to the terms of a marketing authorisation are subject to the requirements of EU law for which currently applies the Commission regulations (EC) No 1084/2003 and 1085/2003 and from 1 January 2010 the Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (Official Journal L 334, 12/12/2008 p. 7-24).

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Comments of Originator Companies

- (1368) According to originator companies, the time taken by the competent authorities to issue marketing authorisations for their medicines shortens the exclusivity period during which costs can be amortised and a profit can be earned and effectively postpone access for patients to originator medicines.⁶⁷⁴

One originator company commented on delays:

"The current Mutual Recognition and Decentralised Procedures are not improving patient access to medicines owing to the delays in initiating these procedures as a result of backlogs at the Competent Authorities. The legal deadlines for granting a marketing authorisation or 'vary its terms' as necessary to comply with consensus opinions or Commission's decisions are often not complied with."

A second originator company corroborated these observations:

"A recent survey among our affiliates revealed that considerable delays can be observed in registration procedures which particularly acts:

- national line extension applications: validation phases often take several months to above one year before the actual review starts

- all applications: delays are most often experienced in the national implementation phase due to lengthy discussions on texts but also pack designs resulting in delayed market access."

- (1369) Originator companies also complained about the difficulties to obtain a slot, in particular when using DCP or MRP.

An originator company stressed:

"In addition, national health authority resources seem to be stretched, with some health authorities announcing that they are fully booked as Reference Member State (RMS) for DCP/MRP for the next 18-24 months. This clearly represents a barrier to an innovative company wishing to use this procedure if they cannot nominate a reputed Health Authority of their choice as RMS."

Comments of Marketing Authorisation Bodies

- (1370) In reply to the requests for information sent in May 2008, some agencies pointed out that they are already "fully booked" for time slots in 2009 and 2010 where they act as Reference Member State in the DCP, i.e. more than two years in advance. Indeed, as also highlighted by several companies, several agencies in popular Reference Member

⁶⁷⁴ In this respect it goes without saying that the effective exclusivity period is only shortened if the LoE is based on patents/SPC. If it is based on data exclusivity the protection period only starts running as of the granting of the MA, i.e. the duration of the grant procedure is irrelevant.

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States have responded that they face certain capacity problems, mainly related to lack of resources.

As one agency put it:

"Yes, there are delays due to the heavy workload at the National Competent Authorities. Not all National Competent Authorities are currently willing to act as Reference Member State in MRP/DCP – therefore those agencies which are actively participating are fully booked one or two years in advance."

Comments of Generic Companies

Generic companies generally confirm the observations by originator companies. One company observed:

"The problem is that the majority of procedures (77%) are run by 4 Member States (DE, DK, UK, and NL). These Member States are considered to run the procedures most efficient. Due to this imbalanced situation applicants suffer from significant delays in obtaining a date for submitting an application to start a DCP. - Since generic medicines account for 80 % of all DCPs this problem mainly affects generic applications and puts generic product's market entry upon patent expiration at risk."

And a second generic company emphasised:

"The role of Reference Member States is, for the most part, undertaken only by a small group of Member States, whereas other Member States hardly even act as a Reference Member State."

- (1371) Generic companies wonder what the underlying reasons for the observed bottlenecks are. They primarily point to the lack of adequate resources of certain agencies (as already mentioned). Others also argue that there is a misuse of procedures by some applicants, who make "unnecessary" or parallel bookings, possibly also to delay access for other applicants.

Two generic companies stressed:

"The apparent misuse or perhaps abuse of the slot booking system should be investigated as a matter of urgency [...]. In a recent request for a 2009 submission slot to a Member State for a product with patent expiry in 2010, we were offered in slot in January 2013."

"With DCP's you have to book 18 months ahead to get a slot for a product and if you experience any delay in development you miss your slot and lose a year."

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Observations by the Commission Services

- (1372) The Commission services note that stakeholders consider that the legislative changes introduced in 2004⁶⁷⁵ have contributed to further clarify and streamline procedures. However, stakeholders' comments on delays due to regulatory backlogs in national approval systems, beyond 210 days of receipt of a valid application for marketing authorisation, have to be taken seriously, as they may lead to delayed access for European patients to both originator and generic medicines and could put the effectiveness of the legislation into question.⁶⁷⁶
- (1373) In this respect, the Commission services remind all stakeholders of their important role in the process. Applicants are reminded of their obligations to submit complete files, which do not force agencies to stop the clock and create additional workload. Member States and agencies are invited to fully respect the deadlines that are laid down under the applicable Community law (within 210 days upon receipt of the application for most procedures).
- (1374) Moreover, the Commission services will provide, full support to the EMEA and the national agencies to assess how resources and capacity problems may be solved within the network of national authorities and invites Member States to actively contribute to the efforts for speeding up and streamlining administrative procedures to reduce bottlenecks and delays.⁶⁷⁷
- (1375) As outlined in the Communication of 10 December 2008 on the future of the pharmaceutical sector⁶⁷⁸, the Commission services consider that the network of EU medicines authorities requires optimisation to improve its efficiency, minimise the regulatory burden it generates and thus speed up market access for medicines. The ongoing EMEA review provides a first opportunity for this analysis.

⁶⁷⁵ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1 (as last amended by Regulation (EC) No 1394/2007, OJ L 324, 10.12.2007, p. 12) and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67 (as last amended by Directive 2004/27/EC, OJ L 81, 20.3.2008, p. 45).

⁶⁷⁶ The Commission services note that despite the concerns relating to delayed marketing authorisation decisions the effective protection period for originator products increased in recent years. As set out in more detail in Chapter B.1.2., the effective exclusivity period lasting from product launch to the first generic entry increased from approximately 10.5 years in the year 2000 to slightly above fourteen years in 2007. One possible explanation could be the shorter development periods as set out in the same chapter.

⁶⁷⁷ The Heads of Medicines Agencies (HMA) have already started to analyse issues related to resource bottlenecks in DCP/MRP. A Task Force identified several problems and obstacles and proposed possible solutions, such as changes in national legislation, see www.hma.eu.

⁶⁷⁸ Communication from the Commission to the European Parliament, the Council, The European Economic and Social Committee and the Committee of the Regions "Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector" COM(2008) 666

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2.2. Discrepancies in the Implementation of the EU Regulatory Framework

(1376) Pharmaceutical companies generally welcomed the further harmonisation resulting from the review of the European pharmaceutical legislation in 2004. Nevertheless, companies still have concerns linked to the fact that the EU regulatory system continues to appear fragmented (for instance in comparison to the USA). Stakeholders commented that the discrepancies in the implementation of the EU regulatory framework and other inconsistencies between national systems may lead to burdens for pharmaceutical companies and disparities in access to medicines among patients in different Member States. Generic companies also mentioned problems related to the so-called Second Medical Use Patents under the Centralised Procedure.

(1377) Industry recognised that the existence of three different procedures, CP, DCP and MRP, and the 27 national agencies and the European medicine agency, provide a certain number of possibilities for marketing authorisation in comparison with the approach used in the USA.⁶⁷⁹ Nevertheless, some companies considered that the EU regulatory system was creating more complexity than necessary.

Comments of Originator Companies

An originator company comments:

"[The company] very much appreciates the successful development of the internal market and the regulatory procedures in Europe to achieve this. However, it has to be recognised that Europe remains a complex regulatory regime to operate in, with its mixture of centralised, decentralised and national controls. The FDA regulates a single country market whereas in Europe companies have to operate with the 27 Member States, the EEA countries, the different languages and residual differences in national requirements."

(1378) Disparities between different regulatory agencies as regards the assessment criteria are of significant concern for companies. Despite the European regulatory framework, companies reported the increasing volume of data requested during the evaluation procedure and the need for duplicative assessments for certain national agencies (which possibly distrust the assessment carried out by other agencies). A number of companies suggested that more coordination should be developed among marketing authorisation agencies (as well as between MA agencies and pricing and reimbursement bodies). Part of the industry also called for further work in the definition of specific elements requested during the evaluation procedure. Some originator companies specifically expressed a need for Europe-wide consolidation of the requirements in the design of clinical trials. In addition, some originator companies

⁶⁷⁹ In the USA, the FDA is the sole agency in charge of the assessment of applications for marketing authorisation.

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expressed their interest in commonly validated biomarkers⁶⁸⁰ and surrogate clinical endpoints⁶⁸¹ in order to minimise the duplication of clinical trials.

One originator company claims:

"Most authorities have increased the burden of efficacy and safety required to be demonstrated in order to obtain approvals."

A second company comments:

"The conduct of multi centre multi national clinical trials in Europe remains difficult and [the company] would welcome the earliest possible introduction of an optional centralised procedure for European multi- national clinical trials."

A third company reports:

"Implementation of the Clinical Trials Directive requirements is cumbersome, creates a great drain on resources and is not consistent across Member States. Member States have adopted different approaches in implementing the Directive, so the benefit of a single approach has been partially negated. More coordination, agreement on definitions and less country-specific requirements, which go beyond the Directive, is clearly needed."

(1379) As regards data exclusivity, originator companies agree that the European data exclusivity framework (for details see Chapter B.2.2.) is well established⁶⁸². However, the major issue raised by companies in the current data exclusivity system remains the partial implementation of Directive 2004/27/EC in several Member States (see for example quote in the next box).

(1380) Some originator companies expressed concern about the shorter periods of protection for their data and market exclusivity for their products in some Member States, resulting in a lower return on their investment than might have been expected.

One originator company notes:

⁶⁸⁰ A biomarker is a measurable characteristic that is an indicator of normal biologic processes, pathogenic processes, and/or response to therapeutic or other interventions.
<http://www.emea.europa.eu/pdfs/human/ich/43798606en.pdf>.

⁶⁸¹ In clinical trials, a surrogate endpoint or surrogate variable is a variable that provides an indirect measurement of effect in situations where direct measurement of clinical effect is not feasible or practical.
<http://www.emea.europa.eu/pdfs/human/ich/036396en.pdf>.

⁶⁸² The new framework, commonly referred to as 8+2(+1), will effectively affect generic entry as from 2013 when the first originator medicines lose exclusivity under the new rules.

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"All 27 members of the European Union should currently have implemented the harmonised "8+2+1" protection contained in the new pharmaceutical legislation. Nevertheless, four Member States have refused to incorporate the "8+2+1" protection into their national marketing authorisation laws. For those countries (Hungary, Latvia, Malta and Poland), data protection remains limited to 6 years for products authorised either through the Mutual Recognition Procedure, the new Decentralised Procedure, or their national procedures, and [...] considers these situations as deviations from the requirements of European regulations."

- (1381) In addition, companies suggested building on this framework to improve access to medicines. Depending on the specific interests of originator and generic companies, the comments received were either in favour of extending or reducing the exclusivity period(s). Not surprisingly, originator companies would favour extending the data exclusivity framework as reward for innovation, in particular when additional indications for a pharmaceutical could be proven.

Two originator companies suggested:

"The current data exclusivity rules do not encourage the development of new indications."

"The data protection offered to new clinical indications is only one year for the first new "significant" indication and absent for any following new indication. This lack of protection for subsequent indications commercially limits companies' ability to make the usually significant investment needed for the development of such a new indication and creates a barrier to entry."

Comments of Generic Companies

- (1382) Generic companies mentioned in particular that mutual recognition between Member States should be further improved as national agencies have developed different practices when dealing with files handled originally by agencies of another Member State. Second, generic companies highlighted that national law or the procedural rules of agencies establish additional requirements over and above what is required under European law:

"Some authorities require additional safeguards over and above the requirement to show bioequivalence to the originator product."

- (1383) Generic companies also reported obstacles not directly related to the implementation and enforcement of the EU regulatory framework, but created by so-called second medical use patents under the Centralised Procedure. Second medical use patents cover, for example, different new indications. They may differ from country to country. For example, an originator company may have obtained a marketing authorisation via the centralised procedure (EU27-wide) for the first indication which is not or no longer patent-protected and a second indication in only a few Member States which is still patent-protected (this could be the result of a strategy or the fact that courts rejected the patent application in some Member States or different national patent expiry dates). The Summary of Product Characteristics (SmPC) of the originator product covers both indications.

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- (1384) When a generic company wishes to apply for a marketing authorisation under the Centralised Procedure, the resulting SmPC annexed to the marketing authorisation will be the same throughout the Community, even if certain indications are still patent protected in a few Member States. Problems may arise when the generic company markets its products in those Member States where the reference product is still protected by patents on certain indications.
- (1385) Generic companies have highlighted the particular relevance of this issue for biosimilar medicines, which can only be approved under the Centralised Procedure. Some companies called for a change in legislation to allow approval of the full SmPC but with the removal of the infringing product information only in the markets covered by second use patents.

Two generic companies explained:

"For generic companies the key obstacle for using the Centralised Procedure is the "usage patent" issue, i.e. the fact that on the one hand it is mandatory in the Centralised Procedure to have an identical SmPC in all EU Member States, on the other hand there may be a patent-protected indication in individual countries."

"Generic manufacturers are also dissuaded from seeking approval for products under the Centralised Procedure which are protected by national 'second medical use' patents."

- (1386) As regards data exclusivity, generic companies would prefer shorter protection for new aspects of products considered less innovative, such as combination products.

Observations of the Commission Services

- (1387) Legislative initiatives of the Commission and continuous action to enforce the European legal framework have led to improved marketing authorisation procedures and the harmonisation of data protection rules in the EU. Nevertheless, the Commission services recognizes that divergences in the implementation of Community legislation, in assessment criteria and methods between different regulatory agencies (such as variations, design of clinical trials, effectiveness of medicines) can be a concern for companies and may lead to regulatory fragmentation and market access problems for companies.
- (1388) Effective enforcement as well as several actions by the Community institutions to remedy this situation are underway such as the implementation of the new Regulation on variations⁶⁸³ and the ongoing efforts in the network of national marketing

⁶⁸³ This has already been addressed in Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (Official Journal L 334, 12/12/2008 p. 7 - 24).

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authorisation bodies.⁶⁸⁴ Where necessary, infringement actions will need to be considered.

- (1389) The Commission services also call upon Member States and agencies to make better use of the possibility of mutual recognition of marketing authorisations by enhancing procedures and reducing administrative burdens on companies, enabling full mutual recognition without additional requirements imposed on companies. It should be stressed that such additional requirements are not compatible with EU legislation and that the Commission services will be vigilant that infringements will be followed up.
- (1390) The Commission services also underlines the need for stronger coordination between agencies in order to avoid as far as possible discrepancies in the application of the legal framework, making full use of the existing instruments such as the coordination groups for mutual recognition established by Directives 2001/83/EC or the various Community databases on medicinal products run by the EMEA. It calls on all actors to provide the necessary financial and human resources for the smooth operation of this cooperation. Marketing authorisation bodies are encouraged where possible to transfer upon request and without delay all information needed by pricing and reimbursement bodies (in particular on bio-equivalence) to avoid or at least limit duplication of efforts.
- (1391) As regards data exclusivity, the Commission services have always been committed to verify that a good implementation of the legislation takes place and will continue to do so in the future. The system of data exclusivity is an element that can contribute to the triggering of innovation in the EU. At the same time the interests of the originator and generic industry need to be balanced carefully. The development and improvement of the data exclusivity system will thus play an important role in the years to come for the definition of the EU's future innovation strategy.
- (1392) The Commission equally notes the comments from stakeholders that the data exclusivity framework should be used to improve access to medicines. The Commission is committed to the development of an EU pharmaceutical framework for the 21st century which promotes innovation in particular in areas with unmet medical needs. In its Communication of 10 December 2008 on a Renewed Vision of the Pharmaceutical Sector, the Commission announces that it will adopt a report on the use of personalised medicines and ‘-omics’ technologies in pharmaceutical research and development and on the possible need for new Community instruments to support them, by 2010.⁶⁸⁵ This report will provide an opportunity to consider the current data

⁶⁸⁴ For instance, the Coordination Group for Mutual Recognition and Decentralised Procedures – Human CMD(h), proposed to reduce national requirements and has asked the Heads of Medicines Agencies to reconsider national requirements. See: http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h/cmdh_pressreleases/2009_03.pdf

⁶⁸⁵ With the emergence of new technologies like pharmacogenomics and patient-specific modelling and disease simulators, personalised medicine is now on the horizon. In the long term, doctors may be able to use genetic information to determine the right medicines, at the right dose and time. This field is already affecting companies' business strategies, the design of clinical trials and the way medicines are

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exclusivity system, and its ability to contribute to innovation and improve access to medicines.

- (1393) As far as medical use patents under the centralised procedure are concerned, the Commission services refer to the fact that a workable solution to address the issue has been found by allowing such products to obtain more than one marketing authorisation, with a different pattern of indications or pharmaceuticals forms to take account of existing patents, coupled with fee reductions to limit additional costs.

2.3. Possibilities for Third-Party Intervention at Marketing Authorisation Bodies

- (1394) As outlined in Chapter C.2.5., the sector inquiry findings highlight that interventions by originator companies before marketing authorisation bodies occurred in a significant number of cases when generic companies requested regulatory approval for their generic versions of the originator product. For example, originator companies claimed in their interventions that generic products were less safe, less effective and/or of inferior quality. They also argued that marketing authorisations and/or obtaining pricing or reimbursement status could violate their patent rights, even though marketing authorisation bodies may not take this argument into account. The interventions by originator companies often focused on high-turnover products. Interventions can lead to delays to market entry of originator or generic products. Originator companies believe they have generated significant additional revenues as a result of such practices.
- (1395) Whereas these interventions concern company practices, they have to be seen against the background of the regulatory framework which enables or prevents companies to approach regulatory bodies.
- (1396) Some of the comments made in relation to possibilities for third-party interventions at marketing authorisation bodies concern substantive arguments (such as patent linkage or claims by companies that competitors' products are not equivalent, less efficient or less safe) whereas others concern aspects related to procedural considerations (such as access to information or the standing of third parties in application procedures).

Comments of Generic Companies

- (1397) In their submissions to the public consultation, generic companies confirmed their view that originator companies intervene in the evaluation process of generic medicines by authorities. Originator companies generally claim that generic products are either less safe, less effective and/or of inferior quality although they might not even know the content of the generic application. In this light, generic companies argued during the public consultation that the identification of the risk to public health should come from the agency/assessor (based on the data from the generics file) and not from the assumptions coming from the originator company. Generic companies

prescribed. Although it is too early to say whether '-omics' technologies will indeed revolutionise the sector, the Commission closely monitors the area and will reflect on how it can support its development.

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also reported about instances of allegedly inaccurate information provided by originator companies to national agencies.

- (1398) In addition, patent linkage (see Chapter B.2.2. for the definition of patent linkage and Chapter C.2.5. for further considerations) has been reported in some countries at the time generic companies submit a file. Generic companies claim that some agencies or courts requested certification of non-infringement of the patent of the product while linking marketing authorisation to the patent of the originator reference product is clearly not allowed under Community law.

A generic company noted:

"Decisions of national health authorities to grant marketing approval or reimbursement status to a generic product during the period of patent protection should continue to be made independently of the patent status of the reference product and should not be affected by the issuance of legal proceedings by an originator against a generic company unless so ordered by the national courts."

- (1399) Transparency and disclosure of information on evaluation procedures of pharmaceutical products is applied according to national confidentiality rules. This may lead to variations in rules governing access to information across Europe. According to the EU regulatory framework for pharmaceuticals, information about a marketing authorisation, SmPC and the assessment report are made publicly available after the grant. Due to various confidentiality rules, some national authorities may already disclose information on a marketing authorisation application made by a generic company before the decision.

- (1400) It was reported that most of the access to information requests are made by originator companies and concern the application and evaluation of generic products. This may allow the originator company concerned, for example, to react to the marketing authorisation application of the generic company and possibly initiate an action. Some generic companies complained about these differences in the Member States and stressed the impact early release of this information can have on them. Generic companies expressed concerns that greater involvement of originator companies in their marketing authorisation procedures could be used to delay the marketing of their products.

An industry association commented as follows:

"[originator company] did already know about generic MA's before they were granted: breach of confidentiality."

A generic company reported:

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"While we recognise the benefits for patients for increased transparency in some cases caution must be exercised in what type of information is released and at what time point during the generic registration procedure. [...] In one MS it became apparent that a Brand company had information from our submission letter and information on e-mails giving responses to questions/commitments including the name of company personnel. We had not authorised release of these documents. [...] Any data released on our applications pre-launch should be carefully considered and should only be done with the approval of the applicant/MAH."

- (1401) Generic companies also reported about third-party observations against a marketing authorisation decision which may lead to a suspension of this marketing authorisation immediately after grant (outside or in addition to court proceedings). Several cases have been reported to the Commission services. According to this submission, the Commission services should re-confirm that suspensions of marketing authorisations should only be possible for the reasons spelled out in Directive 2001/83/EC, i.e. in case of serious health concerns.

Comments by Regulatory Agencies

- (1402) One agency stressed that, when contacted by originator companies, the contact is usually general, and that the originator already seems to know about the marketing authorisation applications.

An agency reported:

"Approaches by the "originator company" during the procedure may take place without certain knowledge whether an application by a "generic company" has actually been submitted. However, in most cases the originator company knows that an application by a "generic company" has been submitted."

Comments of Originator Companies

- (1403) In their observations submitted during the public consultation, originator companies acknowledged that they do intervene at marketing authorisation bodies, although they assert that complaints are exceptional and not "a standard instrument". Moreover, they pointed out that, in their view, contacts with regulators – in a highly regulated industry – was essential and in the public interest. Companies needed to be free to come forward with *bona fide* concerns as to generic safety, quality or counterfeits. The originator company would be very knowledgeable about its products and the risks posed by non-compliant generics. Originators must be permitted to raise any legitimate concerns. It was ultimately up to the health authorities to decide whether a concern raised by an originator company will be justified.

Observations by the Commission Services

- (1404) Whereas the Commission services acknowledge that some interventions in administrative proceedings before market authorisation bodies can contribute to public health, other interventions might lead to delays to the market entry of medicines. As outlined in Chapter C.2.5., in relation to a sample that was investigated in depth, it appears that marketing authorisations were granted on average four months later for generic medicines in cases in which an intervention took place.

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- (1405) As regards the substantive issues mentioned in this chapter, the Commission services would like to remind all stakeholders that Article 8 of Directive 2001/83/EC sets out the requirements which have to be fulfilled by an applicant when he submits an application for marketing authorisation in the European Union. The patent status of the reference medicinal product (or of an active substance contained in the reference medicinal product) is not set out as a requirement to be considered for the validation or assessment of an application for marketing authorisation for a generic medicinal product.
- (1406) Furthermore, it follows from Article 81 of the Regulation 726/2004 and Article 126 of Directive 2001/83/EC that an authorisation to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in Regulation and the Directive.⁶⁸⁶ Accordingly, since the status of a patent (application) is not included in the grounds set out in the Regulation and in the Directive, it cannot be used as an argument for refusing, suspending or revoking a marketing authorisation.
- (1407) The Commission services have already addressed patent linkage issues and will continue to monitor the application of Community law and strictly enforce the applicable rules, for instance, act against patent linkage.
- (1408) The Commission services would like to point out that marketing authorisation procedures are bilateral proceedings between the applicant for marketing authorisation and the administration, during which the administration must take into account the applicant's interest in obtaining marketing authorisation and the public interest in the protection of human health.⁶⁸⁷ Third party submissions and even less so formal interventions during the assessment of an application for a marketing authorization are not explicitly foreseen in Community pharmaceutical legislation. However, given the duty of the competent authorities to consider any information which may impact on the product's assessment (safety, efficacy, quality), marketing authorisation bodies might not be able to simply disregard information submitted by third parties during the marketing authorisation procedure.
- (1409) Irrespective of the reason for which a submission is made, Member States and agencies should ensure that the submissions by third parties are well documented, made transparent towards the applicants and should make all necessary efforts that the intervention does not lead to delays for the applicant. In the case of clear indications that a submission by a stakeholder was primarily made to delay the market entry of a competitor/applicant, the injured party and stakeholder are invited to bring evidence of practices which they judge questionable under European and/or national competition rules to the attention of the relevant competition authorities.

⁶⁸⁶ See, for instance, the Judgements of the Court Judgements in Cases C-84/06 of 20 September 2007 and in Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03 of 9 June 2005, ECR I-5141

⁶⁸⁷ Judgement of the Court of First Instance in case T-326/99, Olivieri vs. Commission.

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(1410) Depending on the national legal frameworks, companies or health insurers may also pursue damage claims under national legislation in case of proven foregone revenues or savings due to unfounded interventions.

2.4. More Harmonisation at International Level

Comments of Originator companies

(1411) Companies, mostly originator companies, highlighted the importance of being able to design global strategies for the development of their product pipeline, and, in this context, welcomed the international regulatory harmonisation that has already been achieved (in particular the initial outcomes of the International Conference for Harmonisation). However, the industry reiterated that differences in requirements for the development and marketing authorisation of pharmaceuticals, for example, in two major markets as the USA and the EU, can be a major burden for their business and called for further harmonisation of procedures and substantive criteria.

Two originator companies stress:

"At an operational level many of the challenges/regulatory barriers faced by the industry are similar in the EU and US, and reflect the nature of global drug development. This is why bi- and multi-lateral initiatives to harmonise regulatory requirements and practices (e.g. International Conference on Harmonisation, Transatlantic Cooperation in the Regulation of Pharmaceutical Initiative, Mutual Recognition Agreements, etc) are so strongly supported by industry."

"Transatlantic regulatory cooperation under the EC, EMEA and FDA collaboration has allowed each side to share common experiences and gain an understanding of each other's regulatory system. However, little has been shown to indicate that each side strives to reduce unnecessary differences in regulations, reduce associated costs to the consumer and industry and reduce time to market."

(1412) Scientific advice and the design of clinical trials are the two areas for further international coordination raised by industry.

(1413) The scientific advice is a crucial step in the development of a product since it offers the possibility for a company (1) to exchange information with a regulatory agency on the steps foreseen for the development of a product and (2) to receive an official scientific advice on the development process by the regulatory agency. Companies indicated that they were facing differences between scientific advice from the USA and Europe, whilst more harmonisation/international consistency would be appropriate.

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An originator company confirmed:

"Scientific advice is specific to the agency providing it, and opinions and requirements between agencies, esp. FDA and EMEA, often differ, which results in additional development time and burden (e.g. additional studies) on the originator company. Companies can seek Scientific Advice in parallel from FDA and EMEA, to reduce time for feedback into the development process, and also in the hope that FDA and EMEA might agree on development elements, and needs, thereby limiting the time and expenditure to secure successful applications in both territories. In practice the process has not worked effectively for industry and we continue to conduct programs to satisfy the separate needs of both agencies rather than being able to often find a shared agreement which could reduce overall development time and spend. FDA and EMEA attribute the lack of success of the parallel scientific advice process to industry's lack of enthusiasm. Industry views are that in the absence of a true joint advice from the two agencies there is little benefit in the current "parallel" advice process. Legal restrictions imposed on the agencies mean that a true joint scientific advice is not possible."

- (1414) As regards evaluation of the clinical efficacy of products, companies explained that the requirements expected for the clinical trials of the same product can differ between the EU and the USA. More specifically for paediatric studies, different requirements lead to USA and European individual paediatric study plans for the same product. The impact for the industry in terms of the number of clinical trials being launched and evaluation of the scientific data is significant. From what companies say, USA-EU streamlining of the clinical phase of the development of pharmaceuticals would help to lessen regulatory burdens.

One originator company reported:

"A further complexity is that it can be difficult registering in Europe a product already approved in the USA since there may be a lack of global consensus on the appropriate design of clinical trials."

A second originator company stressed:

"Another barrier to the entry is the recent European requirement for Pediatric Studies for new drugs and for new indications for existing products. [...] There is no such comparable requirement in the US for new indications. For new drugs, there is a similar requirement, however, the pediatric studies required in the EU and in the US are usually very different. Accordingly, international companies often need to perform two separate Pediatric Study Plans, which require additional resources and create an additional barrier to entry."

Comments of Health insurers

- (1415) During the public consultation of the Preliminary Report, several organisations representing health insurers provided cautious support for more international harmonisation. However, according to these organisations, this should not lead to a lowering of existing standards in the EU. These organisations also request that further international harmonisation should lead to an improvement of data quality.

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Observations of the Commission Services

(1416) As outlined in its recent Communication of 10 December 2008 on the future of the pharmaceutical sector,⁶⁸⁸ the Commission services agree that further international harmonisation of marketing authorisation procedures and requirements has the potential to considerably reduce the costs of market access and innovation by reducing unnecessary regulatory divergences. Companies would be able to spend more funds on research and less on bridging unnecessary regulatory divergences. The Commission services will therefore further support international harmonisation and also use the EU-US Transatlantic Economic Council (TEC)⁶⁸⁹ and the Transatlantic Workshop on Administrative Simplification⁶⁹⁰ to bring about further simplification and convergence of rules. In addition, as outlined in the before mentioned Communication, joint upstream regulatory dialogue initiatives with the US and other third countries could prove to be successful and should be further developed.

2.5. Negative Advertsing

Comments of Generic Companies

(1417) In the course of the sector inquiry generic companies also complained about information campaigns organised by the originator industry questioning the quality of generic medicines. Certain originator companies claim in particular that generic medicines are less safe, less effective or otherwise inferior. Some originator companies or associations have also aimed to engage in negative information campaigns.

Observations of the Commission Services

(1418) The Commission services would like to recall that all medicinal products (whether originator or generic) authorised for placing on the Community market are subject to the same requirements of quality, safety and efficacy. Any campaigns which put this fact in question ignore the key principles for marketing authorisation in the EU and may mislead the public. The Commission urges Member States to take action, in particular on the basis of Article 97 of Directive 2001/83/EC, if any such campaigns are detected in their territory.

⁶⁸⁸ Communication from the Commission to the European Parliament, the Council, The European Economic and Social Committee and the Committee of the Regions "Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector" COM(2008) 666

⁶⁸⁹ http://ec.europa.eu/enterprise/enterprise_policy/inter_rel/tec/index_en.htm

⁶⁹⁰ http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/archives_en.htm, 30.11.2007.

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Summary

Whilst there is broad consensus amongst stakeholders that – overall – the European framework governing marketing authorisation works well, stakeholders report what they perceive to be shortcomings in implementation that lead to delays and unnecessary administrative burdens for companies.

The Commission will provide full support to the European Medicines Agency (EMA) and the national agencies to assess how resources and capacity problems may be solved within the network of national authorities and invites Member States to actively contribute to the efforts for speeding up and streamlining administrative procedures to reduce bottlenecks and delays. Moreover, as outlined in the Communication of 10 December 2008 on the future of the pharmaceutical sector, the Commission considers that the network of EU medicines authorities requires optimisation to improve its efficiency, minimise the regulatory burden it generates and thus speed up market access for medicines. The ongoing EMA review provides a first opportunity for this analysis.

Stakeholders also complained about perceived discrepancies with regard to the national implementation of the EU regulatory framework. Effective enforcement as well as several actions by the Community institutions to remedy this situation are underway such as the implementation of the new Regulation on variations and the ongoing efforts in the network of national marketing authorisation bodies. Where necessary, infringement actions will need to be considered.

The Commission calls upon Member States and national agencies to make better use of the possibility of mutual recognition of marketing authorisations by enhancing procedures and reducing administrative burdens on companies, enabling full mutual recognition without additional requirements imposed on companies. The Commission also underlines the need for stronger coordination between agencies in order to avoid as far as possible discrepancies in the application of the legal framework, making full use of the existing instruments such as the coordination group for mutual recognition established by Directive 2001/83/EC or the various Community databases on medicinal products run by the EMA. Marketing authorisation bodies are encouraged to transfer upon request and without delay all information needed by pricing and reimbursement bodies to avoid or at least limit duplication of efforts.

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Industry, most prominently generic companies, complained about the possibilities of originator companies to intervene in regulatory proceedings before marketing authorisation bodies and reported about diverging approaches to the disclosure of confidential information taken by different national authorities. The Commission recalls that marketing authorisation procedures are bilateral proceedings between the applicant and the administration. Third party submissions and even less so formal interventions during the assessment of an application for a marketing authorisation are not foreseen in Community pharmaceutical legislation. However given the duty of the competent authorities to consider any information which may impact on the product's assessment (safety, efficacy, quality), marketing authorisation bodies might not be able to simply disregard information submitted by third parties during the marketing authorisation procedure. In this light and irrespective of the reason for which a submission is made, Member States and agencies should ensure that the submission by the third party is well documented, made transparent towards the applicant and should make all necessary efforts that the intervention does not necessarily lead to delays for the applicant. Depending on the national legal framework, companies or health insurers may also pursue damage claims under national legislation in case of proven foregone revenues or savings due to unfounded interventions.

The Commission will continue to strictly enforce the applicable Community law and, for instance, act against patent linkage, as according to Community legislation, marketing authorisation bodies cannot take the patent status of the originator medicine into account when deciding on marketing authorisations of generic medicines. The Commission is also committed to ensuring that the new data exclusivity rules introduced in Community legislation in 2004 are fully implemented in all Member States.

The Commission equally notes the comments from stakeholders that the data exclusivity framework should be used to improve access to medicines. The Commission is committed to the development of an EU pharmaceutical framework for the 21st century which promotes innovation in particular in areas with unmet medical needs. In its Communication of 10 December 2008 on a Renewed Vision of the Pharmaceutical Sector, the Commission announces that it will adopt a report on the use of personalised medicines and ‘-omics’ technologies in pharmaceutical research and development and on the possible need for new Community instruments to support them, by 2010. This report will provide an opportunity to consider the current data exclusivity system, and its ability to contribute to innovation and improve access to medicines.

Companies also call for further international harmonisation in the area of marketing authorisation, mostly between Europe and the United States, to reduce unnecessary regulatory divergences. The Commission fully supports further international harmonisation as this has the potential to considerably reduce the costs of market access and innovation by reducing unnecessary regulatory divergences and points to the strategy for this area outlined in its Communication on a Renewed Vision of the Pharmaceutical Sector of 10 December 2008.

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In the course of the sector inquiry generic companies also complained about information campaigns organised by the originator industry questioning the quality of generic medicines. The Commission would like to recall that all medicinal products (whether originator or generic) authorised for placing on the Community market are subject to the same requirements of quality, safety and efficacy. Any campaigns which put this fact in question ignore the key principles for marketing authorisation in the EU and may mislead the public. The Commission urges Member States to take action, in particular on the basis of Article 97 of Directive 2001/83/EC, if any such campaigns are detected in their territory.

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3. Pricing and Reimbursement

- (1419) This section summarises the main comments received from various stakeholders regarding the pricing and reimbursement systems for pharmaceuticals in Europe. It also provides the Commission services' view on the comments and potential solutions to be implemented in cooperation with Member States.
- (1420) In this respect, reference is made to the recommendations of the Pharmaceutical Forum, the Commission Communication of 10 December 2008 on a Renewed Vision of the Pharmaceutical Sector and the in-depth monitoring of the functioning of markets in the pharmaceutical sector, which provide a framework to implement/follow up on the issues described in this section.⁶⁹¹ Depending on the final outcome of all these initiatives, the Commission services will examine the potential need for a review of the existing EU rules in the area of pricing and reimbursement (Transparency Directive 89/105/EEC).
- (1421) In their submissions, individual companies, their associations and other organisations have identified certain delays in accessing the market (Section D.3.1.). Stakeholders, and in particular originator companies, also expressed concerns about the uncertainty of prices when developing new products (Section D.3.2.). Finally, some mechanisms that could unleash competition forces to the benefit of consumers are described in the last subsection (Section D.3.3.).

3.1. Delays in Access to the Market

3.1.1. General Comments

3.1.1.1. Delays in pricing and reimbursement decisions

- (1422) The time-limits for pricing and reimbursement decisions laid down in the Transparency Directive (89/105/EEC) – namely 90/180 days – apply without distinction to originator and generic companies. Both originator and generic companies complain that in practice these deadlines are not respected and that they face delays in pricing and reimbursement decisions.

Comments of Originator Companies

⁶⁹¹ For details see recommendations of the Pharmaceutical Forum (adopted in October 2008, see <http://ec.europa.eu/pharmaforum/>), the Commission Communication of 10 December 2008 on the future of the pharmaceutical sector (Communication from the Commission to the European Parliament, the Council, The European Economic and Social Committee and the Committee of the Regions "Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector" COM(2008) 666) and the in-depth monitoring of the functioning of markets in the pharmaceutical sector (as announced in Objective 7 of the above referred Communication).

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(1423) Originator companies expressed concerns about the time taken by the competent authorities to issue pricing and reimbursement decisions for their innovative medicines as these delays would shorten the exclusivity period during which costs can be amortised and a profit can be earned. It would also delay access for patients to innovative medicines.

(1424) Several Member States are said to take significantly longer than the 90/180 days they are bound to respect for pricing and/or reimbursement decisions. It is highlighted that these authorities sometimes require additional information from companies before coming to pricing and reimbursement decisions, which can create part of the delays.

One originator company stated:

"In sum, varying and complex regulatory conditions in the EU, in particular pricing and reimbursement policies, faced by pharmaceutical companies cause significant delays in access to new medicines, and disparities in access to medicines among patients in individual Member States."

Another originator company stated:

"Member States have widely differing variations in their national policies relating to pricing and reimbursement approval, and in the time taken to grant a marketing authorisation. Due to these significant differences in the timetable [...] there can be serious consequences for the effectiveness of the distribution policies and in the availability of medicines to patients."

A third originator company wrote:

"In contrast to the situation in the U.S., the delays for obtaining reimbursement in many EU27 Member States are often considerable, ranging from a few months to several years."

(1425) In support of their claim originator companies referred to the bi-annual studies prepared by IMS on behalf of EFPIA, which set out the delays between marketing authorisation and effective patient access to new medicines in different EU Member States.⁶⁹² This so-called WAIT indicator reveals substantial differences in patient access to new medicines across the European Union.

(1426) The WAIT indicator does, however, not reveal which factors cause the delay, such as national pricing and reimbursement systems, administrative practices, business strategies or decisions of the marketing authorisation holders.

Comments of Generic Companies

⁶⁹² <http://www.efpia.org/Content/Default.asp?PageID=517>

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(1427) Producers of generic medicines also expressed concerns with respect to delays in pricing and reimbursement decisions. These delays do not only postpone access for patients but they also limit savings for the health bodies.

A major association of generic companies wrote:

"[...] an important source of delays [...] are the existing procedures for granting marketing authorisations and price and reimbursement status."

(1428) Therefore, tighter monitoring of the implementation of the Transparency Directive is suggested by several companies.

Comments during the Public Consultation

(1429) During the public consultation both generic and originator companies referred to a number of additional hurdles encountered in certain Member States. For example, in some countries, products which have received a reimbursement status must be placed on an official reimbursement list. However, companies claimed that an update of the reimbursement list only takes place at infrequent intervals (e.g. every three or six months). It has been argued that - even if pricing and reimbursement approvals are granted within the deadlines foreseen by the Transparency Directive - in practice market entry can be delayed by several additional months.

Observations of the Commission Services

(1430) In recent years, the Commission services have considerably stepped up their efforts to ensure the effective implementation of the Transparency Directive. Significant progress has been achieved in the transposition of the Directive in the national legal orders, including with respect to the time-limits. This work will be pursued in accordance with Objective 3 of the Commission Communication of 10 December 2008 on the future of the pharmaceutical sector, which stresses the importance of enhancing the application of the Transparency Directive.

(1431) All complaints submitted by pharmaceutical companies and other interested parties regarding potential infringements of the Transparency Directive are investigated and, where necessary, pursued by the Commission services. Since 2005, the Commission has examined and resolved a number of cases relating to the implementation of the Directive by Member States.⁶⁹³ Additional infringement actions will be considered where appropriate, in particular if there are indications that the procedural requirements of the Directive have not been introduced or adequately transposed into national legislations.

⁶⁹³ A total of 17 infringement procedures were investigated between January 2005 and January 2009. These procedures resulted in the following outcomes: seven cases were solved during the preliminary stages of the procedure through cooperation with the competent national authorities; two cases were referred to the European Court of Justice but solved before the end of the judicial procedure; one case led to a ruling of the European Court of Justice favourable to the Commission and was later resolved (C-311-07, Commission v. Austria), four cases did not reveal any incompatibility with the Directive and three cases are still on-going.

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- (1432) The Commission services urge upon all stakeholders to ensure that the time-limits of three or six months established by the Transparency Directive are respected and will continue to investigate all complaints pointing to an incorrect transposition or systematic disrespect of the Directive. Member States are reminded of their obligation to fully comply with these time-limits in order to avoid delays to the benefit of patients and applicant companies.⁶⁹⁴ The Transparency Directive 89/105/EEC lays down maximum time limits for pricing and reimbursement decisions, which do not preclude Member States from establishing quicker decision-making procedures where deemed appropriate. In order to ensure the effectiveness of the time-limits laid down in the Transparency Directive, no additional delays should occur following the positive decision to grant pricing and reimbursement status (e.g. through delayed updates of price and reimbursement lists). The Commission also draws the attention of stakeholders to the possibility to challenge the alleged failure of national authorities to respect the requirements of the Directive before the national courts and encourages affected parties to consider this possibility – including damage claims – when deemed necessary.
- (1433) Practices applied in some Member States in order to allow quicker pricing and reimbursement decisions may be of interest to other Member States. For instance, some Member States are reported to use "automatic/immediate pricing procedures" for generics: These procedures do not require any (detailed) assessment of pricing applications by the competent authorities, where corresponding originator product already benefits from such a status, with the effect that generic savings can start as soon as possible. Other countries have organised their system in such a way that reimbursement is automatically granted if the competent authorities have not decided on the reimbursement application within 90/180 days. Yet again other Member States allow for applications for pricing and reimbursement status already after obtaining a positive opinion from the CHMP (Committee for Medical Products for human use at EMEA).⁶⁹⁵
- (1434) The Commission services consider that such practices and other relevant experiences should be exchanged in the framework of the Transparency Committee and within the informal Network of Competent Authorities on Pricing and Reimbursement and carefully considered by all Member States. The Commission invites all Member States, in particular, to consider the introduction of national provisions granting automatic/immediate pricing and reimbursement status to generic products (i.e. without detailed assessment) where the corresponding originator product already benefits from reimbursement based on a higher price. This would considerably

⁶⁹⁴ The Commission services note that despite the concerns relating to delayed pricing and reimbursement decisions the effective protection period for originator products increased in recent years. As set out in more detail in Chapter B.1.2. the effective exclusivity period lasting from product launch to the first generic entry increased from approximately 10.5 years in the year 2000 to slightly above fourteen years in 2007. One possible explanation could be the shorter development periods as set out in the same chapter.

⁶⁹⁵ A non exhaustive list of such Member States are France, Italy, the Netherlands, Sweden and Denmark. For more information, see Chapter B.2.3.

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alleviate the administrative burden for all concerned and lead to faster access of generic products.

3.1.1.2. Additional Requirements - Double Assessment

(1435) Another area of concern, which can contribute to delays, is the (partial) double assessment of certain elements pertaining to the medicinal products. On the basis of companies' submissions, this type of administrative requirement seems to affect particularly generic companies.

Comments of Generic Companies

(1436) The generic industry stated that some pricing and reimbursement bodies request proof of absolute equivalence between generic versions and the originator product in order to grant pricing and reimbursement status and/or allow substitution. These requirements go beyond what is foreseen in the procedures for marketing authorisations. Some stakeholders suggested considering the equivalence between generic and originator products to be sufficiently proven once the marketing authorisation is granted.

A generic company stated:

"Some authorities require additional safeguard over and above the requirement to show bioequivalence to the originator product. For example, competent authority of country A have a much stricter requirement for equivalence for some products meaning that such products are effectively of limited interest in those markets even though they are freely substitutable in other markets in the EU."

Another generic company stated:

"The (country A) sickness fund is much stricter regarding the bioequivalence studies than the Health Authorities. Therefore sometimes registered generic products will not be reimbursed."

A third generic company stated:

"Law X in country A limits interchangeability of certain generic medicines and thus limits reimbursement. However the revision of legislation is being prepared."

(1437) According to generic companies, by requesting bio-equivalence data, pricing and reimbursement authorities give a tool to originator companies to intervene and delay the introduction of generic versions. It is stated that originator companies could thus prolong their period of exclusivity through minor, last minute changes to the originator product, for instance by modifying pack sizes (e.g. from 28 to 30 pills) or by amending the text of the patient information leaflet.

One generic company mentioned:

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"Originators have a tendency to launch new formulations or broaden indications just before patent expiry. The pattern is that it is more common for big products than for small products. This effectively protects their sales/market shares and delays launch of generics. Often these new formulations are approved by price authorities and recommended. In this way the substitution to generics is not granted and could even be that is not allowed until the generic has received approval for the broader indication."

Another generic company wrote:

"Originator product A caps switched to tabs 3-4 months before fall of patent with caps and tabs not substitutable regarding the national substitution list."

A third generic company stated:

"It is common for an innovator to change its product strength very near to the end of its patent life in order to prevent or delay generic entry."

(1438) The requirement of proof of absolute equivalence as an obstacle to market entry has been re-iterated by the generic industry also during the public consultation.

Observations of the Commission Services

(1439) The Commission services are of the view that the bio-equivalence of generics has to be assessed by the authorities responsible for granting marketing authorisations. Consequently, the Commission services consider it unnecessary for the pricing and reimbursement authorities to request bio-equivalence data and to re-examine the question of bio-equivalence. The Commission services invite pricing and reimbursement bodies to refrain from requesting additional data. However, in order to facilitate the tasks of pricing and reimbursement authorities, marketing authorisation bodies are encouraged where possible to transfer upon request and without delay the conclusions of bio-equivalence studies to pricing and reimbursement bodies.

(1440) In addition, the Commission services point out that variations to the terms of a marketing authorisation (e.g. modification of pack size, strength, pharmaceutical form, SmPC, etc.) are subject to the requirements of EU law^{696 697}. Variations to an existing innovator product do not trigger new periods of data protection. When an originator company changes the pack size, for example, approval is needed by the competent authority and an amendment of the marketing authorisation will be granted within the

⁶⁹⁶ Commission Regulation (EC) No 1084/2003 and 1085/2003 and from 1 January 2010 onwards the Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (*Official Journal L 334, 12/12/2008 p. 7 - 24*).

⁶⁹⁷ The Community legislation concerning variation applies only to the centralised marketing authorisations and national marketing authorisations arising from the mutual recognition, decentralised procedure and on the national authorisations those SmPC have been harmonized through Community Referral procedure. The Community legislation does not apply to the medicinal products authorised "purely" on the national level.

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same global marketing authorisation. This variation does not extend the data protection period nor does it prevent the generic producer from obtaining a marketing authorisation based on the old pack size.

3.1.2. Delays in Access to the Market for Originator Medicines

3.1.2.1. Cross-Border Reference Pricing

Originator companies attribute part of the delays to cross-border referencing systems used in a number of Member States (for a description see Chapter B.2.3.). As a consequence of these systems, originator companies would first aim at establishing prices in Member States where there is free-pricing, or where they can apply for pricing and reimbursement status after obtaining a positive CHMP opinion from EMEA/national marketing authorisation bodies⁶⁹⁸ or where they can obtain high prices. Only at a later stage, or not at all, would they apply for price/reimbursement decisions in the other Member States. Prices of originator products would therefore be relatively similar in all Member States and in line with the prices obtained in the first countries, often high-price countries (usually those with a higher GDP per capita).

(1441) One originator company wrote:

"One Member State's national pricing rules may strongly interfere with another Member State's, through international and/or national reference pricing [...]. This interference from country to country prevents the manufacturer from pushing for a tiered pricing approach within the EU common market."

Another company wrote:

"The system of international reference pricing within Europe is also a problem. It means that pharmaceutical companies' negotiations with national payers feed over into other markets, which may face completely different circumstances."

Observations of the Commission Services

(1442) The sector inquiry confirmed that several Member States use cross-border referencing systems for their pricing decisions. These systems can be useful as a benchmark and can be particularly interesting for certain Member States (for instance smaller Member States) that might have fewer possibilities to carry out thorough assessments of the added value of a medicine over and above the existing medicines.

(1443) However, the Commission services are also of the view that cross-border referencing can lead to delays in market entry and to circular referencing. In particular, when official list prices (which do not show the significant hidden discounts granted by companies) are used for establishing reference prices in another Member State,

⁶⁹⁸ For more information, see Chapter B.2.3.

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reference pricing shows its downsides. In such cases, cross-referencing does create room for misuse as explained in Chapter B.2.3.

3.1.2.2. *Fragmented Decision Making*

(1444) Another factor mentioned as creating delays is the trend towards fragmented decision-making at a more regional/local level, or even at hospital level. This latter factor is driven by the increasing number of originator medicines used in hospitals. Such fragmented decision-making requires additional negotiations with additional parties, which can create further delays and result in higher transaction costs.

One originator company mentioned:

"National reimbursement decisions are in many European countries only the first step (the condition sine qua non) in a variety of further negotiations with regional (e.g. in country A and B) and local (e.g. in country C) budget holders, or, in the case of product X, with individual hospital in some European countries. This adds further to the waiting period [...]."

Another originator company wrote:

"The consequence is an unequal access of the European population to innovative medical care [...]."

Observations of the Commission Services

(1445) The Commission services are of the view that it is up to the Member States to decide how medicines are purchased. In practice, the fragmentation might give companies the opportunity to achieve at least a certain market presence, which it might not be able to achieve in a system characterised by a monopoly buyer. At the same time it is of course correct that a more fragmented decision-making process has an impact on the transaction costs to market the products.

3.1.3. *Delays in Access to the Market for Generic Medicines*

3.1.3.1. *Patent Linkage*

(1446) One of the most prominent concerns raised by generic companies at pricing and reimbursement level is the issue of patent linkage, i.e. the refusal by national bodies to grant pricing and reimbursement status to a generic product, unless the applicant can demonstrate to the satisfaction of the national body that the generic product would not infringe valid patents.

(1447) In Sweden, a recent court case initiated by an originator company dealt with the request of a generic company for pricing and reimbursement status when the originator product was still under SPC protection. The originator company tried to link the granting of the pricing and reimbursement status with the patent status, but its arguments were not upheld at the level of the Court of Appeal. However, this is not the approach taken by the competent authorities in all Member States. The table below provides a few examples of patent linkage at pricing and reimbursement level in the

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EU reported during the sector inquiry and embedded in the local pricing and reimbursement regulation.

Table 37: Some examples of patent linkage at pricing and reimbursement level in Europe

Germany	Authority to organise administration to enter market and obtain reimbursement	One of the new clauses obliges each applicant for a generic product to prove its patent-free status, namely by accompanying the application with written consent or confirmation from the respective originator company concerning status.
Hungary	Pricing & Reimbursement bodies	Authorities require generic companies to make a statement about the patent status as part of a regulatory submission. Originator companies claim infringement of their patent rights and block the reimbursement procedures.
Portugal	Authority in charge of pricing Courts	The body in charge of price approval (Ministry of Economy (DGAE)) has a policy of not granting price approval for pharmaceutical products where a litigation case is pending. As a result, factual market introduction can be delayed for several months. (Originator companies also take legal action against certain price approvals and reimbursement decisions.) Altogether, more than 50 court cases are currently pending.

Source: Pharmaceutical Sector Inquiry

(1448) Originator companies are regularly mentioned as the drivers behind patent linkage as they intervene before the authorities claiming that their products are still patent protected and that therefore no pricing and reimbursement status can be granted to the generic product. The issue is described in more detail in the earlier chapters of this report, in particular Chapter C.2.5.

(1449) During the public consultation it has been submitted by an organisation representing social health insurers that they would welcome the clarification of the legal framework applicable to patent linkage at the level of pricing and reimbursement.

(1450) Some generic companies requested the introduction of provisions at pricing and reimbursement level which would clarify that generic companies can submit a file for pricing and reimbursement decision without being considered to infringe the patent of the reference product. During the public consultation, a national association representing originator companies stated that such a provision already exists in Belgium.

Observations of the Commission Services

(1451) As demonstrated in Chapter C.2.5. alleged claims of potential patent infringements can significantly delay the pricing and reimbursement decision for generic products.

(1452) The Commission services consider that the enforcement of patents should not be the responsibility of the regulatory authorities. National bodies responsible for marketing authorisations or for pricing and reimbursement decisions are neither equipped, nor competent to determine the validity or potential breach of patents. It is the sole responsibility of generic companies to take due account of existing intellectual and industrial property rights. In case of a potential infringement of these rights, the patent holder may seek redress against the generic company before the competent national

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courts. Patents can also be enforced through interim injunctions preventing the generic company from entering the market or forcing it to leave the market immediately. In case the generic company launched the product despite the fact that the originator product was still patent protected, originator companies can also ask for damages.

(1453) The Commission services note that the Transparency Directive requires Member States to set out objective and verifiable criteria for granting pricing and reimbursement status to medicines, so that the competent national authorities must not add criteria or assessments which are not foreseen by national law. It is also considered that assessments of the patent status and of bio-equivalence should fall outside the competence of pricing and reimbursement bodies, as they are neither equipped nor competent to deal with these issues. The entry of generics is also affected where authorities in Member States consider that pricing and reimbursement applications constitute a patent violation. In this respect it is underlined that EFPIA, the European association representing originator companies, submitted in the context of the public consultation on the Preliminary Report that applications for marketing authorisations by generic companies would not amount to a violation of patent law. The same logic should apply to applications for pricing and reimbursement status.

3.1.3.2. Third Party Interventions

(1454) Generic companies mention that originator companies intervene⁶⁹⁹ when a generic company files for pricing and reimbursement status. The originator company's arguments are often based on safety issues, bioequivalence and patent linkage (see above). However, as seen in Chapter C.2.5., intervention and litigation does also take place regarding reference pricing as originator companies may have a commercial interest in keeping generic products out of the reference price group for their products as this might adjust the price and reimbursement of the originator product (downwards).

(1455) During the public consultation it was submitted by a European consumer association that pricing and reimbursement procedures should be independent and that any undue external intervention should be prosecuted.

Observations of the Commission Services

(1456) The Commission services would like to reiterate that pricing and reimbursement procedures are bilateral proceedings between the applicant for pricing and reimbursement and the administration, during which the administration must take into account the applicant's interest in obtaining pricing and reimbursement status and the public budget (constraints).

(1457) Moreover, the Commission services are of the opinion that the pricing and reimbursement authorities are not the appropriate authority to determine as to whether

⁶⁹⁹ The concept of intervention should not be understood as a formal intervention as foreseen in the legislation but rather as an informal submission.

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a product is effective and safe and are not equipped to do so. The same holds true as outlined above for alleged violations of intellectual property rights. In this context, Member States should disregard third party submissions raising such issues. The Commission services remind the Member States that the Transparency Directive obliges them to set out objective criteria for granting pricing and reimbursement status to medicines. Also national bodies must not add criteria or assessments which are not foreseen by national law.

(1458) In this light, the Commission services also consider the use of reference price groups to be a national decision, if foreseen under national law.

(1459) Finally, irrespective of the reason for which a submission is made, the Commission services encourage Member States to ensure that interventions by third parties are in general well documented, made transparent towards the applicant and do not lead to delays in processing the price and reimbursement decisions. In the case of clear indications that a submission by a stakeholder was primarily made to delay the pricing and reimbursement of a competitor/applicant, the injured party and stakeholder are invited to bring evidence of practices which they judge questionable under European and/or national competition rules to the attention of the relevant competition authorities.

3.2. Uncertainty of Prices/Reward

3.2.1. Assessment of Added Value

(1460) In determining price and reimbursement levels, Member States are increasingly focussing on the assessment of the "added value" of an innovative medicine. Two main aspects can be distinguished when added value assessments are performed: the scientific examination of the therapeutic value limited to the merits of the new medicine in comparison to existing alternatives and the cost effectiveness aspects, which are also closely linked to budgetary considerations in a Member State.

(1461) Originator companies submit a number of observations with respect to problems that, in their view, are caused by the diverging practices of Member States.

Comments by Originator Companies

(1462) Originator companies expressed concerns about the discrepancies between the national assessment systems to determine prices and grant reimbursement status. In their view, this would significantly reduce the predictability of future prices and reimbursement levels and, therefore, complicate investment decisions. It would also lead to higher transaction costs. While larger companies are in a position to bear such a high transaction cost, smaller companies might be forced to limit their activities to a selected number of (the biggest) EU markets.

A major originator company stated:

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"Some pricing and reimbursement decisions in Europe are extremely opaque. Criteria used by Member States are often limited to vague and ill-defined concepts without further specification or explanation to the point that they contravene the objectivity and verifiability requirements of the Transparency Directive."

Another originator company wrote:

"The content of the national P&R filings varies widely within the 27 Member States. Local requirements [...] lead to country-tailored applications. In practice, these differences require additional manpower and resources, and increase the time for readiness."

(1463) In addition, Member States were reported to have different views on what they consider to be the "added-value" of an innovative medicine. All Member States consider clinical/therapeutic progress. Many also consider benefits in the quality of life, although it is claimed that this aspect is difficult to measure objectively and thus to translate into prices or reimbursement decisions. In addition, a few Member States look at the broader economic benefits of innovative medicines, such as savings in hospital admissions, in particular when they have horizontal healthcare budgets (i.e. budgets jointly covering pharmaceuticals and hospitals).

(1464) Companies are also concerned about the differing use of Health Technology Assessments (HTA) on which EU Member States have started to rely to measure the value of innovative medicines and to support their pricing policies. If based on clearly defined criteria and consistently applied, HTA should help national authorities to reward those innovations that offer most value to their national health policy.

An originator company stated:

"[...] However, HTA methodologies are still not advanced and mature to the extent that is required to fully capture the dynamic aspects of drugs. At the same time the scientific robustness of these methods is considerably over-rated."

Another originator company wrote:

"Public authorities can also set unrealistic standards of proof for innovative products, as a de facto means of cost-containment through access restriction. To begin with, authorities may demand proof of efficacy at levels that clinical trials are not designed to provide, as a prerequisite for reimbursement."

A third originator company mentioned:

"The absence of EU generally accepted HTA standards and requirements, and the variation in evaluation processes (ex-ante, ex-post) across countries and regions, increase cost and complexity to bring innovation to the market. A study, for example, that will lead to market access in Country X, may not meet the specific requirements for market access in country Y."

One originator company suggested the:

"Definition of a common set of data at the EU level to support P&R (to be complemented ideally with national data when available)."

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(1465) In this regard, it has been submitted during the public consultation that predictability in pricing and reimbursement, and hence certainty as regards the eventual reward, could be significantly increased through enhanced cross-border collaboration between national competent authorities (e.g. EU collaboration on the development of common definitions of the expected value of innovative medicines, of common data sets, of common HTA methodologies and, ultimately, of common assessments) as well as through joint evaluations of the impact of pricing and reimbursement practices and exchanges of experiences between Member States.

(1466) Some companies have suggested organising early dialogue between pricing and reimbursement decision-makers and companies to clarify the expected value and required proof of this value, and thus to reduce uncertainty. During the public consultation, an organisation representing social health insurers supported the view that early dialogue between originator companies and pricing and reimbursement decision makers during the clinical development phase could help to clarify expected value and required proof of value with the aim of speeding up the decision-making process.

An originator company also asked for the:

"Possibility to discuss with P&R decision makers, during the clinical development phase, the data necessary to reasonably reduce uncertainty."

Observations of the Commission Services

(1467) While there is general interest in cross-border collaboration on scientific aspects of added value assessments, cost effectiveness analysis is rather dependant on the budgetary situation and health priorities of each Member State.

(1468) As regards the scientific aspects, the Commission services underline that duplications in assessments should be avoided. The scientific assessment of whether a medicine has an added value over and above existing medicines should in principle lead to the same outcome irrespective of the Member States concerned. Discrepancies between Member States in the assessments often lead to high costs (because assessment in every Member State takes place in a slightly different form and in particular small Member States do not necessarily have the expertise to perform their own assessments), which are ultimately borne by the consumers/tax payers. Different assessment processes also bear the risk of diverging views.

(1469) The Commission services believe there is room for convergence of the scientific aspects of health technology assessments. The Commission services are of the opinion that some follow-up should take place on this by Community action.

(1470) In this light, it is noteworthy that the Commission services have already taken steps to further strenghten the collaboration between national HTA authorities. Important progress has been made in this area by the Pharmaceutical Forum Working Group on

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Relative Effectiveness during 2005 – 2008⁷⁰⁰ and the work of the EU network on HTA (EUnetHTA). A Joint Action on HTA has just been submitted for funding under the Public Health Programme⁷⁰¹. In addition, the Commission's proposal on the implementation of patients' rights in cross border healthcare contains a provision for further cooperation on health technology assessment. However, cost effectiveness analysis is rather dependent on the budgetary situation and health priorities of each Member State. Moreover, the Communication of 10 December 2008 on the future of the pharmaceutical sector encourages the exchanges of data between Member States on relative effectiveness.⁷⁰²

3.2.2. Restriction in Use

(1471) It has also been stated by originator companies that some authorities complement their pricing and reimbursement decisions with rules on the use of new prescription medicine. These rules, which can be considered as a kind of rationing, often include conditions that may significantly reduce the potential patient population. In other cases, the rules require additional administration from doctors in order to obtain specific approval for reimbursement, which restricts the uptake of these originator medicines.

A major originator company wrote:

"Many new prescription medicines are subject to complex reimbursement conditions. They [doctors] are therefore discouraged from informing their patients about new products. As a result, it is hard for potential entrants to differentiate their prospective new products from existing (but potentially inferior) treatments within the same therapeutic class. This restriction disproportionately disadvantages new innovative products at the expense of old and familiar ones."

Another originator wrote:

"The use of therapy guidelines and formularies prevents the use of new products or restrict the usage of the originator to an extremely limited group of patients (sub-groups of the population) is perceived as an entry barrier in some countries."

(1472) On the other hand, a platform of health insurers strongly defended the strategy of restricting the use of some new medicines during the public consultation. They claim that the rules restricting use are applied not only for economic reasons for new

⁷⁰⁰ The Pharmaceutical Forum has established good practice principles for relative effectiveness assessment and a check-list on the use of the agreed principles.

⁷⁰¹ Commission Decision of 23 February 2009 on the adoption of the Work Plan for 2009 for the implementation of the second programme of Community action in the field of health (2008 to 2013). A Joint Action on Health Technology Assessment has been submitted for funding under the Health Programme 2009. For more information about the Public Health Programme, see <http://ec.europa.eu/eahc>.

⁷⁰² Please see Objective 5 of the Communication.

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medicines that are expensive and whose place in therapy (added therapeutic value) is unclear, but also for safety reasons.

Observations of the Commission Services

(1473) The Commission services reiterate again that it is the task of marketing authorisation bodies and not the financiers of healthcare to decide whether a medicine is safe or not. This needs to be done for all indications. However, the Commission services acknowledge that a reimbursement decision is a national issue and that Member States are bound to budgetary constraints. In case restrictions are used because the added therapeutic value is unclear, all patients should receive the medicine within a monitored context, so that more data and information are generated to increase clarity on the added therapeutic value.

3.3. Mechanisms that Unleash Competition Forces

(1474) As explained in Chapter B.2.3., many Member States apply multiple practices to control spending on the supply of pharmaceuticals. Some of them are a cause for concern for pharmaceutical companies.

3.3.1. Originator-Generic Price Linkage

(1475) One of the key concerns expressed by generic companies is the existence, in some Member States, of a linkage between the prices of generic products and the prices of originator products (for a description of this practice, see Chapter B.2.3.).

(1476) It was claimed by generic companies that by using price linkage national authorities provide a tool to originator companies to influence the prices of its generic competitors. The originator company may, for instance, force down the prices of generic competitors to a level where it is no longer profitable for them to sell the generic version. Of course, price reductions are in any case to be expected once generic versions enter the market. It is therefore difficult to identify the exact reasons behind sharp price reductions by the originator company, particularly if they are not sustainable.

A generic company wrote:

"This system enables originator companies to force generic pharmaceutical companies off the market by constantly lowering prices of branded products."

Observations of the Commission Services

(1477) Pricing and reimbursement policies fall within the scope of national competence. However, the Commission services take the view that Member State policies do not always allow to realise the full potential savings which generics can offer. In particular, the Commission services are doubtful about the benefits of price linkage.

(1478) According to the econometric analysis carried out in the context of the sector inquiry, price caps and mandatory discounts for generics have proven to lower the number of entrants. Whilst they might induce stronger price competition and sharper price

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decreases in the shorter term lead, in the longer run they seem to lead to higher prices in comparison with the non-cap regimes.⁷⁰³ One tentative explanation for this observation is that price caps give companies a focal point where to price their products.

- (1479) Moreover, it is considered to be very difficult to set the right cap level for a generic medicine. If the initial price reduction is too high, it will deter entry altogether, an issue raised in particular with respect to biotech products. If the initial price reduction is too low, there is a risk that the potential of additional price reductions (e.g. through discounts to the wholesaler or pharmacist) sticks in the distribution system and is not passed on to the consumers.
- (1480) Open price competition between generics therefore seem to be the preferred policy option. As stated in the Guiding Principles⁷⁰⁴ adopted by the Pharmaceutical Forum, price linkage practices allow originator companies to "out-compete" generic companies through consecutive price-reductions. By opposition, open price competition may lead to effective cost-containment and significant reduction in prices. To ensure these savings, the national authorities need to provide for a flexible, adaptive pricing system with sufficient competition among manufacturers, wholesalers and pharmacists.

3.3.2. *Tendering and Related Models*

- (1481) In a number of Member States health insurers have recently become active in containing prices through tendering procedures. The first experiences with the preference policy in the Netherlands show significant price reductions of off-patent products (see Chapter B.2.3.). This system has led to significant costs savings which can result in direct benefits for consumers.

Comments of Originator Companies

- (1482) All originator companies mention that the over-regulated pricing and reimbursement landscape leads to significant insufficiencies in generic savings. According to many originator companies, the results of the tendering procedures used in the Netherlands demonstrate the significant savings potential within the generics market. According to the originator companies it would be appropriate to use the additional savings to better reward the innovative efforts of the originator companies (so called "head room for innovation").

Comments of Generic Companies

⁷⁰³ For more information, see Chapter B.1.3.

⁷⁰⁴ "Guiding Principles for good practices implementing a pricing and reimbursement policy", adopted by the Pharmaceutical Forum in July 2007. (see http://ec.europa.eu/pharmaforum/pricing_en.htm)

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(1483) Generic companies and their associations have raised concerns regarding tendering systems. The main criticism relates to the alleged emergence of oligopolistic structures in the medium and long term and the exclusive focus on pricing, thereby disregarding "other forms of added value to patients". It is also pointed out that tendering could entail negative effects in the mid-term, including risks of supply interruptions and disincentives for the supply chain actors. Moreover, it was argued that companies that are not successful in bidding in a tender and cannot market their products would lose their marketing authorisation after a period of time. Reapplying for a marketing authorisation or maintaining it is expensive and could constitute an additional barrier.

Observations of the Commission Services

(1484) The Commission services believe that tendering can be a valuable mechanism to bring down prices to the benefit of consumers, in particular in situations where, because of regulatory or other factors, no or very little price competition takes place and price reductions stick in the supply chain. The introduction of a mechanism where suppliers have to compete with each other to become a preferred supplier of a health insurer (and its patients) can be an important step in the direction of more competition at the level of the patients. It may also lead to more competition between insurance schemes to the extent they exist in the same Member State. Obviously, when considering such measures public procurement rules and - to the extent applicable - competition law need to be respected (for more information see Chapter B.2.3.). In any event, it is very important that the cost reductions obtained by health insurers truly benefit patients through lower health insurance premiums than would otherwise have applied.

(1485) In the Commission services' view, a number of other factors should be taken into account to assess the possible mid- and long-term effects of the introduction of tendering. These factors include (without claiming completeness):

- the transparency given to the prices of the generic company that won the tender process (making the prices available to the general public allows health insurers not engaging in the tender process to free ride on the efforts of the other insurers and reduces the scope of competition between them),
- the way the national health scheme is organised (one public reimbursement body or a variety of [possibly competing] health insurance companies in the market, which can have different preferred suppliers and can carry out tenders at different times with different conditions);
- the number of successful bidders (in particular in Member States characterised by one public health scheme deciding on the preferred supplier, there would seem to be a need to ensure that more than one supplier is selected, e.g. by appointing more suppliers for the same region or different suppliers for different regions in larger Member States);
- the duration of the contracts (in order to ensure that significant quantities come back to the market regularly and after not too long intervals, allowing non-successful bidders to re-enter; at the same time the duration must be long enough to ensure that economies of scale can be realised and the transaction costs are not too high);
- the number of products subject to tender and the bundling of products in one tender (in relation to the latter, the Commission notes that according to a new

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law which entered into force in Germany on 1 January 2009⁷⁰⁵ tenders covering several substances - so-called portfolio contracts - are no longer possible unless exceptional circumstances, this should facilitate the participation in tenders by SMEs);

- the fact that when loss of exclusivity approaches, tenders should be timed in such a way that generic companies can effectively participate.

(1486) The OECD in a recent study⁷⁰⁶ of the pharmaceutical market reached the conclusion that tendering systems can lead to significant savings in cases where the purchasing power is great (as through public health insurers) and if there are multiple potential sources for the product as it is typically the case after generic entry.

3.3.3. Demand Side Practices – INN Prescription

(1487) As regards the demand side practices, associations of payers/mutualities have generally expressed support during the public consultation for INN prescription and compulsory substitution. INN prescription means that the physician prescribes an active substance rather than a brand. With compulsory substitution at the pharmacy level, the pharmacist is obliged to dispense the cheapest generic version available.

(1488) In particular, one submission received during the public consultation suggested a number of ways to encourage the introduction and use of INN prescription. For example, the development of a special software to assist doctors and pharmacists in INN prescription and dispensing was proposed. In addition, a list containing branded medicines, corresponding INNs and respective prices should be prepared by the competent body and made available to the public.

Observations of the Commission Services

(1489) The inquiry's results indicate that INN prescription promotes quick access to the market of generic medicines.

(1490) Moreover, the econometric analysis on the impact of generic entry carried out in the context of the sector inquiry indicates that in Member States with compulsory generic substitution for pharmacists, the number of generic entrants tends to be higher, price competition to be tougher and generic market share of generics to be stronger in the longer run. In addition, the sector inquiry showed that where Member States encourage doctors to prescribe the INN, this appears to reinforce price competition. The same holds true for policies involving differential co-payment for patients, reimbursement of medicines at the level of the lowest priced product and a frequent adjustment of reimbursement levels to take account of price developments in the market.⁷⁰⁷

⁷⁰⁵ Gesetz zur Weiterentwicklung der Organisationsstrukturen in der GKV.

⁷⁰⁶ OECD Health Policy Studies 2008: Pharmaceutical Pricing Policies in a Global Market, p. 150

⁷⁰⁷ For more information, see Chapter B.1.3.

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(1491) In this light the Commission invites Member States that want to fully benefit from the potential of generic savings to consider – to the extent not yet done – policies facilitating rapid generic uptake and/or generic competition. The Commission will facilitate cooperation between Member States and the exchange of best practices on generic policies in the framework of relevant discussion platforms, such as the Transparency Committee established by Directive 89/105/EEC.

3.3.4. Therapeutic Reference Pricing

(1492) Most Member States consider medicines to be equivalent and substitutable only when they have the same active ingredient, the ATC-5 level (some Member States have even stricter requirements for equivalence, as mentioned above). This means that therapeutic reference pricing usually applies when the originator product has lost exclusivity and generic versions enter the market.

(1493) Nevertheless, some Member States are less strict in their definition of equivalence and consider that medicines with related active ingredients are also substitutable (ATC-4 level, as applied in particular in Germany). This creates much larger groups of medicines – also called clusters – all subject to the same amount of reimbursement (jumbo groups). These groups can include patent-protected products of originator companies as well as off-patent originator products and their generic versions. The presence of these generic versions will significantly reduce the level of reimbursement for all medicines in the group, including the products still covered by exclusivity.

Comments of Originator Companies

(1494) The concern voiced most strongly by originator companies is the introduction of these "jumbo groups". It is considered to be a lack of recognition of the (incremental) added value provided by the medicines covered by exclusivity.

(1495) Another concern relates to the establishment of the standard amount of reimbursement per group. It is often suspected that all competitors will align their prices on this amount, which will thus take away any incentive for further competition and reductions in the official list prices, although competition can continue vis-à-vis pharmacists, thereby reducing pharmacy purchase prices.

An originator company wrote:

"Reference pricing restricts competition by creating artificial price floors at non-competitive price levels. The most extreme example of market failure in this respect is the creation of very broad therapeutic categories of medicines, including both in-patent products and off-patent/generics, to derive an average reference price. This pulls down the price of innovative products but artificially lifts the price of generics. Apart from undermining intellectual property by rewarding imitation while artificially penalising breakthrough innovation and the benefits of incremental innovation, these systems reduce patient access to the newest and best medicines, and those medicines best suited to individual patient needs. Competitive pricing should thus apply to off-patent products, which would stimulate the development of dynamic and competitive off-patent markets."

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Comments of Generic Companies

- (1496) Generic companies, on the other hand, prefer broad groups of substitutable reference products, thus extending the potential market of a generic. They claim that originator companies try to restrict the scope of reference groups.

A generic company mentioned:

"Patent owners have also appealed to the Courts in an attempt to suspend or prohibit the creation of homogenous groups and reference prices for generic medicines. The homogenous groups and the reference prices are automatically suspended for months by the simple fact that the administrative preliminary injunctions are filed in court."

Observations of the Commission Services

- (1497) The Commission services believe that it is up to each Member State to decide whether such practices fit within their national pricing and reimbursement policies. The Commission services also refer to the work of the Pharmaceutical Forum on best practices for prices and reimbursement policies, aiming to obtain a balanced outcome in terms of optimal use of resources, reward for innovation and access for patients.⁷⁰⁸ However the Commission Services take the view that Member States' policies applying therapeutic reference pricing do not always allow to realise the full potential savings which generics can offer.

3.3.5. Payback

- (1498) In some Member States, companies conclude agreements with reimbursement bodies with respect to the amount of medicines that will be reimbursed per year. When more medicines are sold than anticipated, through "payback" systems, companies have to return the additional revenues to the reimbursement authorities.

Comments of Originator Companies

- (1499) Payback systems are seen as an inverse incentive by originator companies as, from a business point of view, it is a punishment for being successful in the market.

An originator company wrote:

"[...] whereby biopharmaceutical companies are required to repay a fixed percentage of the revenue generated and which may be conditional on whether thresholds are met (e.g., an overrun of the national healthcare budget or companies exceeding certain pre-determined sales volumes). The negative impact of such arrangements is considerable."

⁷⁰⁸ The use of (therapeutic) reference pricing has been evaluated within the Working Group Pricing's Toolbox exercise (see: http://ec.europa.eu/pharmaforum/docs/pricing_toolbox_en.pdf).

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Another originator company wrote:

"[...] implemented by some Member States it is highly punitive and often applied ad hoc and thus disruptive of business planning. These are budget management tools that disproportionately penalise industry for budget overspend."

Comments of Generic Companies

(1500) When a payback system is applied to products that are subject to generic competition, it has been argued by the generic side that not all parties are always invited to the meetings when the payback is "negotiated" whereas all parties in the end will have to bear part of the extra costs.

Observations of the Commission Services

(1501) The Commission services believe that it is up to each Member State to decide whether payback systems are adequate for their national pricing and reimbursement policies. In addition, when concluding a "payback" deal, the company involved accepts the conditions set out. These agreements are the result of negotiations between companies and reimbursement authorities.

(1502) All companies subject to the payback should be represented in the negotiation of the system/conclusion of the deal.

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Summary

During the sector inquiry, many stakeholders expressed concerns as regards the delays and uncertainties faced in procedures regarding the pricing and reimbursement status of medicines. Originator companies argued that this would deny patients access to innovative medicines and shorten the period during which the companies enjoy exclusivity. Generic companies argued that such delays limit savings for health bodies.

Key elements of the relevant context for the Commission's strategy in this area are based on the Recommendations of the Pharmaceutical Forum, the Commission Communication of 10 December 2008 on a Renewed Vision of the Pharmaceutical Sector and the in-depth monitoring of the functioning of markets in the pharmaceutical sector. Depending on the final outcome of all these initiatives, the Commission will examine the potential need for a review of the existing EU rules in the area of pricing and reimbursement (Transparency Directive 89/105/EEC).

The Commission urges all stakeholders to ensure that the time-limits of three or six months established by the Transparency Directive 89/105/EEC are respected and will continue to investigate all complaints pointing to an incorrect transposition or systematic disrespect of the Directive. The Commission also draws the attention of stakeholders to the possibility to challenge the alleged failure of national authorities to respect the requirements of the Directive before the national courts and encourages affected parties to consider this possibility – including damage claims – when deemed necessary.

The Transparency Directive 89/105/EEC lays down maximum time-limits for pricing and reimbursement decisions, which do not preclude Member States from establishing quicker decision-making procedures where deemed appropriate. In order to speed up pricing and reimbursement decisions for generic products, the Commission invites Member States to consider the introduction of national provisions granting automatic/immediate pricing and reimbursement status to generic products (i.e. without detailed assessment) where the corresponding originator product already benefits from reimbursement based on a higher price. This would considerably alleviate the administrative burden for all concerned and lead to faster access of generic products.

According to generic companies, delays with respect to pricing and reimbursement decisions are sometimes the result of additional requirements, e.g. information on the patent status or an additional evaluation of the bio-equivalence between the originator and the generic product. These additional requirements, requested by the pricing and reimbursement bodies, seem to provide a tool to originator companies to intervene and hence to prolong a given procedure.

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The Commission notes that the Transparency Directive requires Member States to set out objective and verifiable criteria for granting pricing and reimbursement status to medicines, so that the competent national authorities must not add criteria or assessments which are not foreseen by national law. It also considers that assessments of the patent status and of bio-equivalence should fall outside the competence of pricing and reimbursement bodies, as they are neither equipped nor competent to deal with these issues. The entry of generics is also affected where authorities in Member States consider that pricing and reimbursement applications constitute a patent violation. In this respect it is underlined that EFPIA, the European association representing originator companies, submitted in the context of the public consultation on the Preliminary Report that applications for marketing authorisations by generic companies would not amount to a violation of patent law. The same logic should apply to applications for pricing and reimbursement status.

In this context, originator companies should not intervene before the pricing and reimbursement authorities in order to raise bioequivalence issues or a potential patent violation by the generic applicant. The Commission considers the pricing and reimbursement procedures as bilateral proceedings between the applicant and the administration. Since the pricing and reimbursement authorities are not competent to assess patent, bioequivalence or safety issues, Member States should disregard third party submissions raising such issues. They should also ensure that interventions by third parties are in general well documented, made transparent towards the applicant and do not lead to delays in processing the price and reimbursement decisions.

Originator companies attribute amongst others part of the delays for originator medicines to cross-border referencing systems used in a number of Member States, and part to the trend towards fragmented decision-making at a more regional/local level. The Commission – whilst fully acknowledging national choices – points to the findings of the sector inquiry that cross-border referencing can lead to delays and creates sometimes room for misuse (hidden discounts on published price lists used for reference pricing). Regarding the fragmented decision-making, the Commission underlines that this is an issue to be dealt with by Member States.

Stakeholders and in particular originator companies, also complained about the uncertainty of prices/reward when developing new medicines. The duplication of national assessments that try to establish the "added value" of the new medicine over and above existing medicines was specifically mentioned. There is general interest in cross-border collaboration on scientific aspects of added value assessments. In this respect the Commission points to the fact that the duplication of the scientific assessments in the Member States results in additional costs, which are ultimately borne by the consumers/tax payers. Also there is a risk of contradicting decisions on essentially the same questions. Moreover, at this stage smaller Member States do not always have the means for the scientific assessments and thus do not benefit from the possibilities available to larger Member States. Thus a Joint Action on Health Technology Assessment has just been submitted for funding under the Health Programme 2009. In addition, the Commission's proposal on the implementation of patients' rights in cross border healthcare contains a provision for further cooperation on health technology assessment. However cost effectiveness analysis is rather dependent on the budgetary situation and health priorities of each Member State.

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Finally, comments were received on national mechanisms that could foster competition forces in the pharmaceutical sector, in particular in the generic sector.

Econometric analysis on the impact of generic entry carried out in the context of the sector inquiry tend to indicate that national regimes with compulsory generic substitution for pharmacists and encouraging doctors to prescribe the substance (as opposed to a particular brand) appear to be favourable to price competition and the level of generic penetration. The same holds for policies involving reimbursement of medicines at the level of the lowest priced product and a frequent adjustment of reimbursement levels to take account of price developments in the market. Likewise, differential co-payment for patients further appears to favour price competition. By contrast, the use of price caps for generic medicines appears not favourable to price competition or generic penetration.

In this light the Commission invites Member States, to the extent not yet done, to consider policies facilitating rapid generic uptake and/or generic competition. Different possible policies to achieve this goal are currently being discussed in the context of the Transparency Committee established by Directive 89/105/EEC.

Certain Member States have achieved significant savings to the benefit of consumers when health insurers carried out tender or similar processes for certain generic products. These systems can help ensure that price reductions offered by generic companies do not stay in the distribution system, but are passed on to consumers. Whilst tenders can be a very powerful tool to reduce costs for public health budgets, the medium and long term effects need also be considered when setting the tender conditions (e.g. duration of award period should not lead to market foreclosure). Compliance with European law (e.g. public procurement law) when carrying out such tenders is also essential.

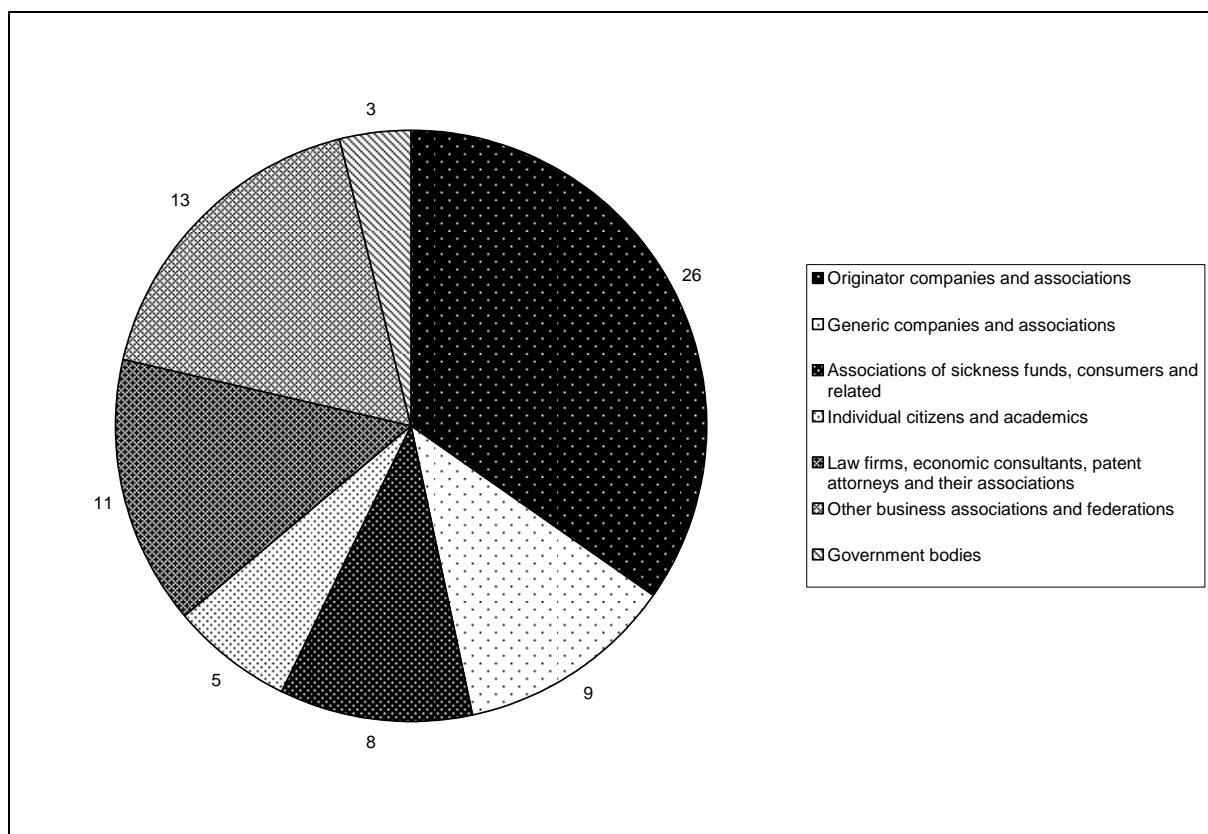
The Commission will facilitate cooperation between Member States and the exchange of best practices on generic policies in the framework of relevant discussion platforms, such as the Transparency Committee established by Directive 89/105/EEC.

E. RESULTS OF THE PUBLIC CONSULTATION

1. Introduction

(1503) The public consultation on the Preliminary Report was launched on 28 November 2008 and ran until 31 January 2009. 75 formal submissions were received. Respondents represent a wide variety of stakeholders and included originator companies and associations of originator companies, generic companies and their associations, other business associations and federations, public bodies such as the European Patent Office, associations of sickness funds, associations representing intellectual property lawyers, law firms and academics. An overview is provided in Figure 167.

Figure 167: Number of stakeholders by category that submitted comments during the public consultation



Source: Pharmaceutical Sector Inquiry

(1504) The comments and observations received on the Preliminary Report were thoroughly analysed and led to certain adaptations of the specific chapters of the report. The present chapter discusses the most important comments, but is not an exhaustive description of all submissions received during the public consultation.⁷⁰⁹ The first

⁷⁰⁹ The non-confidential versions of these submissions are available at: http://ec.europa.eu/competition/consultations/2009_pharma/index.html.

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section deals with comments that are of a general nature and are relevant for the entire Preliminary Report. Subsequently, comments concerning specific chapters are summarised. Where comments concern more than one chapter, they are discussed under the most relevant chapter heading. Comments relating to methodology are handled in the specific chapters.

2. General Comments

- (1505) Respondents to the public consultation representing different categories of stakeholders welcome the Preliminary Report. In general, the submissions received show limited controversy about the factual findings, but some disagreement – in particular from parties representing the interests of originator companies – about the question of which conclusions to draw from these findings.
- (1506) Generic companies and their associations submit that the findings of the Preliminary Report confirm the experience of the generic industry insofar as the behaviour of originator companies is correctly stated to be a significant factor in delays to the entry of generic medicines. They underline that generic companies when seeking to launch new generic products in EU markets frequently encounter the use of multiple tool-box-strategies by an originator company in relation to a single medicine and across a range of Member States.
- (1507) Respondents that represent the interests of the health insurance sector and of consumers state that the Preliminary Report confirms their concerns relating to delays of generic market entry and to the decrease in innovation, calling for urgent action to remedy the problems highlighted in the report. An association representing health insurers points out that the report provides an impressive set of data, facts and figures, giving a solid global as well as detailed overview of the situation of competition in the pharmaceutical sector, and that the report represents a very valuable tool to understand the strategy underlying the pharmaceutical industry's behaviour during the whole life-cycle process of a medicine.
- (1508) An association representing the interests of European consumers also considers that the Preliminary Report provides a unique overview of the situation of competition in the pharmaceutical sector as well as a considerable amount of information, facts and figures. Moreover, the association finds its concerns about the problems affecting the pharmaceutical sector confirmed by the findings of the report, in particular with regard to the lack of innovation and the delay of generic market entry.
- (1509) Associations of originator companies as well as other stakeholders representing industry interests and/or active in the area of patenting take a more critical view. They consider that the tone and attitude of the Preliminary Report and of the section on patent strategies was pejorative towards the pharmaceutical industry, in particular towards originator companies. Some stakeholders also claim that certain terms such as "toolbox", "delayed entry of generics" or "defensive patenting" were used in a

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pejorative way.⁷¹⁰ Similarly, some stakeholders argue that companies' tactics mentioned as part of the "toolbox" are completely legitimate but implied to be wrong, unethical and anticompetitive. At the same time, originator companies and some law firms regret that the Preliminary Report did not provide competition law guidance.

- (1510) It should be underlined that the Preliminary Report expressed a clear support for strong patents and innovation. It did not judge the patent strategies but merely analysed which patent strategies exist, what might be their objective, and whether they have any specific effect. As far as particular terms are concerned, these were found to be used by originator companies in their own documents, many of which had strategic character. Companies' strategies were described, but the Preliminary Report did not contain any legal or normative assessment. Competition law guidance is not the objective of a sector inquiry, which is part of the Commission's power of investigation for a specific sector. It should however be noted that the Commission has already issued guidelines on the use of certain practices and agreements on intellectual property rights in its Regulation on the application of Article 81(3) of the Treaty to categories of technology transfer agreements.⁷¹¹ Moreover, as a matter of general policy, the Commission has in the past only considered providing specific guidance concerning particular issues where previous cases have clarified the application of competition rules.
- (1511) Originator companies and their associations submit that the Preliminary Report has not established causality between the company practices described in the Preliminary Report and the delays of generic market entry that were observed. Moreover, they argue that the Preliminary Report shows the lowest average delay of generic market entry in the most valuable markets where, according to the report, originators employ multiple instruments from the tool-box in order to prolong the life cycle of their medicines. Respondents from the generic industry, on the other hand, consider that the Preliminary Report identifies well the tool-box approach followed by originator companies and that originators' strategies do indeed delay generic entry to the detriment of European patients and taxpayers.
- (1512) It should be noted that the delays of generic market entry ("time to entry") established in the Preliminary Report relate to the difference in time between loss of exclusivity of the originator medicine concerned and first generic entry. The Preliminary Report did not suggest that the observed delays were exclusively due to company behaviour, but emphasised that practices employed by originator companies may contribute to the delays. Measuring precisely to what extent the instruments did actually cause such delays would only be possible on the basis of an in-depth analysis of each individual

⁷¹⁰ This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying interventions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

⁷¹¹ See Commission Notice – Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements, Official Journal C 101, 27.4.2004, p 2-42; Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements, Official Journal L 123, 27.4.2004, p. 11-17.

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case. On the basis of concrete cases concerning the main practices investigated, the sector inquiry uncovered that delays due to originator companies' interventions in regulatory processes do occur. This also concerns high-turnover medicines. As explained in the respective chapters of the report, also patent strategies and their enforcement can lead to later market entry of generic companies than could be expected. It is also submitted that settlements leading to controlled entry of generic products curb benefits of generic entry for public health schemes quite apart from possibly delaying generic entry in return for a so-called reverse payment from the originator to the generic company. As to the (on average) shorter delays of generic market entry for the best-selling medicines, it should be kept in mind that in the case of these medicines even shorter delays can have a more significant adverse impact on public health expenditure than longer delays for other products due to the high turnover of the medicines concerned.

- (1513) Some originator companies and associations of originator companies also consider that the Preliminary Report does not adequately reflect the reasons why the number of new molecular entities reaching the market has decreased over time. In their view this decrease is due to (i) the R&D process becoming more and more complex, (ii) factors relating to the regulatory framework, (iii) a lack of reward for incremental innovation, and (iv) the specific structure of the pharmaceutical market and its price regulation. A number of respondents representing the originator industry also submit that incremental innovation is an important part of the innovative process and that it can lead to significant therapeutic improvements for the benefit of patients. Some of these respondents claim that the Preliminary Report did not appear to value incremental innovation and they question whether the number of new molecular entities does in fact adequately measure the rate of innovation in the sector. In the same context a number of respondents state that the distinction between primary and secondary patents, used in the Preliminary Report, is not an established technical term in patent law, and that the Preliminary Report implies that secondary patents, which protect incremental innovation, are of a lesser value or strength.
- (1514) The Commission services observe and confirm again that it was not the intention of the Preliminary Report to put into question the merit of incremental innovation that provides benefits to patients. For instance, incremental innovation that leads to less side effects or easier administration resulting in better compliance are very valuable to many patients. As to the question of how to best measure the development of innovation in the sector, it should be noted that the industry itself frequently uses the number of new molecular entities approved as an indicator of innovation. Similarly, the distinction between primary and secondary patents is made in documents obtained from originator companies. It is obvious that all patents invariably need to meet uniform patentability criteria, and that the distinction between primary and secondary patents is not a technical term in patent law, but is used to describe certain phenomena from a commercial perspective. As explained in the report, in certain cases secondary patents may be used as one of the means to extend the exclusivity period of a product to the detriment of health insurance schemes and ultimately consumers. This is also recognised in the strategy documents of the originator companies quoted in the report.
- (1515) In their submissions, several stakeholders highlight the important role of the regulatory framework for the pharmaceutical sector. Some commentators, mostly originator companies, are of the opinion that the Preliminary Report does not fully recognise the role of the regulatory framework and the impact of European and national regulation

on company behaviour. It should be kept in mind that a sector inquiry is an instrument of Regulation (EC) No 1/2003. Consequently, the primary focus of the inquiry is on company behaviour. Nevertheless, the Preliminary Report also looked at the role of the regulatory framework and highlighted its importance for the way the market functions. Moreover, an entire chapter of the Preliminary Report was dedicated to stakeholders' comments on the regulatory framework. As foreseen, the Final Report further deepens this analysis.

- (1516) Originator companies and their associations submit that the sector inquiry should also analyse competition between generic companies and potential savings that could be achieved, for instance, by comparing generic prices in the EU to those in the US. It is, however, not clear from these submissions whether the respondent originator companies and associations are implying that the benefit of generic competition is not fully passed on through the distribution chain to consumers, or if their intention is to criticise an alleged lack of competition between generic companies in terms of ex-factory prices. In relation to the suggested comparison between the EU and the US it remains unclear if the respondents are concerned about the absolute level of generic prices in the EU or about the price decrease (in % of the former originator product's price) pursuant to generic market entry. In the latter case it has, obviously, to be kept in mind that originator medicines are generally more expensive in the US than in the EU.
- (1517) The Preliminary Report already covered certain aspects of generic competition, such as the price and volume developments of prescription medicines pursuant to generic entry. As envisaged, the Final Report features additional analysis, for instance, of the impact of the number of generic entrants on price developments or of the effect of national price caps and other policies on generic competition. Furthermore, no particular structural issues in the market for generic medicines have been put forward that would warrant in-depth analysis in the framework of this sector inquiry.
- (1518) Some respondents representing the interests of the originator industry submit that the assumption that generic products could enter the market on the first day after loss of exclusivity of the originator medicine is implausible due to several factors including regulatory issues. They point inter alia to the introduction of the Bolar provision in 2005 allowing generic companies to carry out research on the originator medicine in the EU, necessary to prepare for a marketing authorisation application. Whilst this argument is addressed in detail in the specific chapters of the report, the sector inquiry confirmed that generic companies had found legal ways to carry out the research elsewhere. The European association EFPIA that represents the interests of originator companies confirmed that the application for marketing authorisation is not a patent violation.

3. Comments on Topics Raised in Specific Chapters of the Preliminary Report

Main Market Features

- (1519) An association of biotech companies and an originator company voice their concern about the approach by which the Preliminary Report covered generic medicines and biosimilar medicines. They point out that both science and the EU regulatory framework make a difference between the two categories. According to the glossary of

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the report, however, the term generic was supposed to also include biosimilar medicines, unless otherwise specified.

- (1520) The Preliminary Report did acknowledge throughout the text that there are specific differences between generic versions of molecule-based medicines and biosimilars. For instance, it was clearly explained that the production of biosimilars is more complex and costly due to the fact that the active ingredient is based on live tissue. The Preliminary Report also highlighted that there are special requirements for the approval of biosimilars by EMEA, and the EU legislative framework was reviewed. This distinction has been further reinforced in the Final Report. At the same time it should not be forgotten that biosimilar medicines, like generic versions of molecule-based medicines, are lower-priced versions of an originator medicine and their market entry can be affected by the deployment of the tool-box-instruments. A respondent from the health insurance sector, for instance, is concerned with the allegedly alarmist discourse - aimed at creating a climate of suspicion - that certain originator companies foster in relation to the safety of biosimilar medicines.
- (1521) A number of submissions show that there are conflicting views of the pharmaceutical industry's role in providing information to medical doctors. Associations representing the originator industry consider that providing information to doctors is also a regulatory requirement. Moreover, with regard to the promotion of prescription-only medicines, they point to the code of conduct of an originators' association.
- (1522) By contrast, a European consumer association and a respondent from the health insurance sector emphasise that such promotion activities involve providing doctors with biased information. In their view, promotion of prescription drugs to doctors is another strategy in the toolbox of originators to block generics. They consider that information on medicines should exclusively be provided by independent public bodies. As pointed out in the report, these conflicting submissions highlight that the relationship between the industry and doctors is strongly debated. The same holds true, however to a different degree, for the relationship between the industry (including generic companies) and pharmacies.
- (1523) As regards the funding of basic research, differing views have been submitted: one respondent points to studies suggesting that as much as 84% of all funds for basic research come from public sources. On the other hand, a contribution from an originator company puts emphasis on the fact that the investments into pharmaceutical research are paid by the sales of originator medicines. As outlined in the Preliminary Report, approximately 1.5% of the turnover of pharmaceutical companies were spent on basic research, the remainder of R&D expenditures mainly concern clinical trials and tests. The biggest cost blocks for originator companies were marketing and manufacturing.

Main Issues Investigated

Competition between Originator and Generic Companies

- (1524) Respondents from the originator industry submit that the Preliminary Report uses inflated patent numbers that would have to be divided by 27 Member States as they

concern the same invention in those Member States. It is acknowledged that, from a patent law perspective, counting each Member State separately in the case of an EPO patent appears unusual. The EPO also highlighted this issue during the public consultation. The amendments made in the specific chapter of the Final Report respond to the issues raised and introduce the concept of patent families. At the same time in order to analyse the competitive process it is important to be aware of the commercial implications that the multitude of separate national patents, even if based on the same EPO patent, can have for a potential market entrant. Each patent can constitute a barrier to enter the national market concerned and needs to be tackled individually before national courts, if the challenger believes it to be invalid or seeks to establish a lack of patent infringement. Accordingly, the challenger needs to confront the sum of all national patents in all Member States where a product launch is foreseen. As set out in the Preliminary Report, this can mean up to 1,300 patents. In practice, this also means additional litigation costs and a risk of conflicting judgments. Some stakeholders drew particular attention to the deterring effect of litigation for small and medium-sized companies.

- (1525) Respondents from the originator industry furthermore submit that it is not clear how divisional applications can delay generic entry as they neither extend the term of patent protection nor its scope. They pointed out that divisionals are often requested by the EPO and that no causality between applications for divisionals and delay of generic entry has been proven. In this context it has to be clarified that more and more divisional applications are filed within the pharmaceutical sector and that the vast majority of these divisional applications are not requested by the EPO but made on a voluntary basis. Furthermore it has never been stated that divisionals extend scope or term of protection of the parent patent but rather that they create legal uncertainty by extending the period where applications are still pending.
- (1526) The EPO comments that the Preliminary Report provides further insight into certain patterns of applicant behaviour which may increase legal uncertainty, some of which are already under careful scrutiny within the EPO. Furthermore, the EPO fully agrees that certain types of applicant patenting strategies, e.g. defensive patenting or the filing of multiple divisional applications, may not be in line with the policy objectives of the patent system. Indeed, on 25 March 2009, the EPO took measures that limit possibilities and time periods during which voluntary divisional patent applications can be filed.⁷¹² This measure will help to reduce legal uncertainty for competitors.
- (1527) Generally, patent settlements are a useful and efficient way of dealing with disputes, which is acknowledged in the report. A number of stakeholders comment on the issue of the legality of settlement agreements, and, in some cases, present their views on what kind of approach the Commission should adopt in this regard. Several companies and associations express concern that settlement agreements entailing a limitation on generic entry and a value transfer from the originator to the generic company could automatically be deemed anticompetitive. They state that a competition assessment of

⁷¹² See the Decision of the Administrative Council of the European Patent Organisation of 25 March 2009 amending the Implementing Regulations to the European Patent Convention (CA/D 2/09) at: <http://www.epo.org/patents/law/legal-texts/decisions/archive/20090325.html>.

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settlement agreements should be done on a case by case basis taking into account the factual circumstances of each individual settlement. An association of IP law practitioners, an originator company and an association of originator companies state that the sector inquiry unduly puts into question the legality of settlement agreements which include a licence agreement (including the launch of an authorised generic), and that this is not in line with the Technology Transfer Block Exemption Regulation⁷¹³.

- (1528) Some parties submit that the legal test for assessing the legality of a settlement agreement should be whether the agreement restricts competition beyond the exclusionary zone of the patent. An association representing the interests of the generics industry demands that patent settlements should be looked at under Article 82 of the EC Treaty. Furthermore, several companies and associations would like the Commission to provide legal guidance on this issue.
- (1529) Originator companies and their associations as well as associations representing practitioners in the field of IP law submit that settlements should generally be encouraged in order to avoid time, energy and money being wasted in unnecessary litigation. They also point out that settlements are sometimes encouraged by courts. This was, however, already acknowledged in the Preliminary Report.
- (1530) The classification of settlement agreements set out in the Preliminary Report is based on structural features of the agreements and not on a competition law assessment. As stated in the report, it is important to underline, that any assessment of whether a certain settlement could be deemed compatible or incompatible with EC competition law would require an in-depth analysis of the individual agreement, taking into account the factual, economic and legal background.
- (1531) However, stakeholders submit that the lack of transparency of patent settlements concluded constitutes a problem. In this context it is submitted that patent settlements should be supervised. As explained in Chapter C.2.4, in the USA, pharmaceutical companies are required to file patent settlement agreements with the Federal Trade Commission (FTC) and the Department of Justice (DoJ). Furthermore, in the USA, a new legislative proposal has been made which, if approved, would make certain patent settlements including a value transfer to the generic company unlawful.
- (1532) Different views are expressed as regards the interventions by originator companies before national authorities other than patent offices when it comes to the evaluation of generic medicines by authorities. While originator companies reaffirm their claimed rights to raise concerns when necessary, generic companies report about their experience on allegedly inaccurate information provided by originator companies to national agencies. Associations of originator companies state that the overall number of interventions of originator companies in regulatory proceedings concerning generic products is low compared to the overall number of applications. However, the sector inquiry confirms that intervention on the best-selling substances does take place. Moreover, the inquiry also documented hundreds of intervention and litigation cases

⁷¹³ Commission Regulation (EC) No 772/2004 of 27 April 2004 of the application of the Article 81(3) of the Treaty to categories of technology transfer agreements, Official Journal L 123, 27.4.2004, p. 11-17.

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only based on the 219 substances investigated over the period 2000 – 2007. Also it is considered that the number of interventions reported is likely to be a conservative estimate, as neither originator companies nor Marketing Authorisation bodies had readily available and fully reliable information on interventions.

- (1533) A European association of originator companies also argues that interventions regarding safety issues have to be made in each and every Member State for the purposes of safeguarding patients. By counting each of these interventions separately, the report would be inflating the figures. It should be noted, however, that the documents provided during the sector inquiry do not confirm this hypothesis. It appears that originator companies conduct selective interventions and do not systematically raise their arguments in all Member States. The statement of the European association is also contrasted by the submission of a Spanish association representing originator companies which points to the fact that it is difficult to obtain interim injunctions in Spain and explains that therefore companies would rely more on interventions, constituting the underlying reason why the figure for Spain would be particularly high.
- (1534) Several associations of originator companies commented that some interventions/litigation cases regarding data exclusivity could be a consequence of legal uncertainty. According to these submissions, clarification was needed and there were referrals to the ECJ.

Competition between Originator Companies

- (1535) Some stakeholders representing the originator industry contend that there is no evidence of "defensive patenting" blocking innovation.
- (1536) It has to be pointed out that in a number of cases, documents quoted in the Preliminary Report clearly highlight the intentions of originator companies, whose internal documents obtained by the Commission show instances where the main or even sole purpose of (defensive) patenting was blocking competitors. Moreover, as set out in the report, in the vast majority of litigation cases between originator companies, available information suggests that the originator companies concerned by the litigation were actual or potential competitors as the patent-holders had an INN or R&D pole in the same ATC3 class as the INNs and R&D programmes of the other originator. Interestingly, it appears that in more than one third of these cases the patent invoked in litigation did not cover any of the patent-holders INNs or R&D programmes, suggesting that an originator company entered into litigation against a competitor over patents which did not protect any of its activity in the market.
- (1537) Several stakeholders submit that pharmaceutical companies tend to concentrate their research efforts in the most promising therapeutic areas. Consequently, the number of more than 1,100 overlaps established in the sector inquiry, where patents of one originator company may be infringed by the INNs, R&D programmes and/or patents of another originator company, is not considered surprising. Similarly, an association of originator companies and several other stakeholders submit that in their opinion the number of litigation cases and disputes between originator companies and of INNs concerned, as well as the number of contacts between originator companies is small. Furthermore, respondents point out that in most cases licences were granted if

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requested, which is perceived to be contradictory to the Preliminary Report which outlines that there could be a "blocking effect" induced by this practice of originator companies.

- (1538) It should be noted that the number of overlaps indicated in the Preliminary Report is very conservative given that only around 40% of companies provided concrete data on overlaps while others stated that they do not conduct regular searches. Moreover, the universe of 219 INNs is based on late life cycle methodology and geared towards originator-generic competition. With regard to licences, requests to obtain a licence were unsuccessful in about 20% of cases, which could lead to delays or blocking of innovation. The Preliminary Report does not endeavour to establish competitive harm; anti-competitive effects can only be assessed on a case-by-case basis, which goes beyond what a sector inquiry can do.

Regulatory Framework

- (1539) The Preliminary Report summarised stakeholder's comments on the regulatory framework. Stakeholders generally agree with the description provided in the Preliminary Report and acknowledge the essential role of the regulatory framework governing patents, marketing authorisation and pricing and reimbursement. Some commentators, mostly originator companies, are of the opinion that the Preliminary Report does not fully recognise the role of the regulatory framework and the impact of EU and national regulation as regards company practices. However, it is important to point out that the Preliminary Report described the regulatory framework, summarized comments by stakeholders on this framework and outlined the interaction between the regulatory framework and company practices. Further analysis is provided in the Final Report.

Patents

- (1540) There is strong support from most stakeholders, including generic and originator companies, for the creation of a single Community patent to amend the current costly and burdensome system consisting of a bundle of national patents. Stakeholders also strongly favour the creation of a centralised, specialised European patent judiciary replacing the existing fragmented patent litigation system for European and Community patents. In that respect, several respondents highlight that it is essential that the rulings of the unified judiciary should be of high quality, cost-effective and obtained in a timely manner.
- (1541) Stakeholders, including the European Patent Office (EPO), generally agree that there is considerable scope to reduce the duration of EPO opposition and appeal procedures. The EPO also supports the findings of the Preliminary Report insofar as it bolsters some of the EPO's current initiatives intending to increase the quality of European patents, such as "Raising the Bar" - which focus on, inter alia, the consistent application by the EPO of patentability criteria. The EPO also highlights that the Preliminary Report provides relevant insight into certain patterns of applicant

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behaviours which may increase legal uncertainty, some of which were already under careful scrutiny within the EPO, such as the rules governing the filing of divisional applications. It should be noted that in the meantime the EPO has adopted stricter rules against potential abuses of voluntary divisional applications.⁷¹⁴ At the same time, the EPO draws attention to the line between IP law and competition law drawn by the ECJ. In particular, it argues against a scrutiny of the intent of applicants applying for patent rights for purposes of competition law.

- (1542) Several originator companies state that there is or should be a legal presumption of validity if patents have been granted. In this respect, the Commission, draws attention to the fact that each court asked to rule upon the (in)validity or (non-)infringement of a patent will have to assess every case in the specific circumstances. In this respect it is important to note that a high proportion of the patents investigated in the sector inquiry were revoked or annulled.⁷¹⁵ The same applies to opposition procedures.
- (1543) Stakeholders also submit certain additional ideas that were not part of the Preliminary Report but that deserve to be mentioned in the Final Report. One of these ideas is to provide better opportunities for generic companies to obtain legal certainty regarding the patent situation before launching their generic product, thereby avoiding the risk of interim injunctions and damage claims. Another idea is to ensure that the interests of patients, who ultimately pay the bill for the medicines they receive, be taken into account in court proceedings regarding patents and in patent settlements. A third idea, inspired by legislative developments in the US, is that legislation could be adopted at Community level to prohibit patent settlements that include a transfer of value from the originator company to the generic company. These ideas were analysed by the Commission services, but no policy proposals were deemed appropriate at this stage.

Marketing Authorisation

- (1544) Several interested parties submit that delays at marketing authorisation level may constitute important bottlenecks when bringing medicines on the market. Originator and generic companies and their associations highlight uncertainties arising from the timing of evaluation procedures, the restricted number of agencies willing to act as reference Member State and the accessibility of slots in several national agencies. Some parties also provide possible explanations for these delays such as the increasing workload in certain national agencies and limited resources. Some contributors suggest that the Final Report should propose ways forward to address the identified bottlenecks and a rethinking of the network of EU medicines authorities or a call for action for national agencies.

⁷¹⁴ See the Decision of the Administrative Council of the European Patent Organisation of 25 March 2009 amending the Implementing Regulations to the European Patent Convention (CA/D 2/09 at: <http://www.epo.org/patents/law/legal-texts/decisions/archive/20090325.html>).

⁷¹⁵ Moreover, in a number of cases patents were reduced in scope (reported by respondents to the sector inquiry as amended). In the context of the public consultation, the EPO and other stakeholders pointed out that final outcomes resulting in amendments cannot clearly be identified as a success or defeat for either side involved in opposition and appeal procedures, therefore amendments are not allocated to either side.

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- (1545) A number of comments were made with regard to the evolution of the regulatory requirements requested by authorities. On the one hand, platforms of health insurers and public health organisations call for reinforcement of the requirements for granting marketing authorisation, either suggesting the introduction of new criteria of assessment, added therapeutic value, or by expressing concerns on the increase of exemptions to standard procedures (accelerated procedures and conditional authorisation). On the other hand, originator companies suggest that a potential decrease in new innovative medicines coming on the market could result from an increase of regulatory requirements for enhanced patient safety. Some originator companies also voice concern about the diverging use of Health Technology Assessments (HTA) in the EU, which a majority of Member States have started to rely on to measure the value of innovative medicines and to support their pricing policies. Their concerns relate to the absence of EU generally accepted HTA standards and requirements, and the variation in evaluation processes across countries and regions, to allegedly unrealistic standards of proof for innovative products or to HTA methodologies allegedly not being advanced and mature enough to fully capture the dynamic aspects of medicines.
- (1546) A number of generic companies reported about the challenge they face with secondary medical use patents and the absence of possibilities to have a differentiation of dossiers for generics when different patent situations exist in Europe. Moreover, representatives of generic companies confirm the findings of the Preliminary Report that patent linkage at the level of marketing authorisation bodies, i.e. the practice of linking the granting of a marketing authorisation for a medicine to the patent status, appear to delay the market entry of generic medicines. They call upon the Commission to act against patent linkage. An association of originator companies, on the other hand, defends the right of originator companies to take legal action against an administrative act, which would allegedly enable patent infringement.
- (1547) Some originator companies reiterate their calls for further international harmonisation of marketing authorisation procedures. Health insurers support this call as long as it would not lead to a lowering of existing quality standards in the EU.

Pricing and Reimbursement

- (1548) Many stakeholders make comments on the regulatory framework governing pricing and reimbursement while recalling that pricing and reimbursement policies are the competence of Member States. They express the need for less complex and more transparent pricing and reimbursement procedures and decisions. According to these stakeholders, this would help reduce delays in price and reimbursement approvals (and hence market access) as well as administrative burden (in particular for SMEs). Streamlined procedures and decisions would clarify expectations from society and payers, and hence allow steering the research agenda of pharmaceutical companies. Stakeholders support the idea that national systems should evolve further towards transparent, swift and predictable pricing and reimbursement processes that are as

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close to a free market as possible. They call for a better implementation of the Transparency Directive⁷¹⁶.

- (1549) Originator companies and their associations mention that, in their view, a highly regulated pricing and reimbursement landscape may lead to an uncompetitive generic market and lower savings from generic competition. According to these stakeholders, the experience with the "preference policy"⁷¹⁷ in the Netherlands and the variation in savings/price-reductions between Member States both demonstrate this lack of savings. They call upon the Commission to identify these saving potentials and help Member States realise it. Generic companies express concern about the use of "tendering" procedures, such as implemented by certain Dutch health insurers as part of the above-mentioned "preference policy". According to them, although this can bring significant savings in the short-term, the reduction of the number of generic players may lead to an oligopolistic generics landscape in the mid-term with consequent price increases.
- (1550) For some respondents, the issue of patent linkage at pricing and reimbursement level is a particular concern, as claims of alleged patent infringements can delay the pricing and reimbursement decision-making process for generic products and consequently patients' access to generic medicines. Several respondents call upon the Commission to clarify that authorities should not take into account third parties' submissions when assessing the granting of pricing or reimbursement status of a generic medicine.
- (1551) Generic companies and representatives of health insurers mention several ideas/practices to promote generic uptake and savings such as automatic pricing and reimbursement procedures for generic medicines, better shared knowledge on the proof of bio-equivalence of generic medicines (facilitating substitution), a Bolar-like provision in national and European pricing and reimbursement legislations, the promotion of therapeutic reference pricing, and the prescription of INNs instead of specific products. According to these stakeholders, the Commission should assess these ideas, together with Member States.
- (1552) Stakeholders representing generic companies also argue that the balance of litigation risks, where interim injunctions are concerned, should be more equally spread by introducing European legislation that would allow the award of damages to national health care systems and insurers. This idea is based on their perception that the balance of risk in the area of interim injunctions is overwhelmingly in favour of originator companies which are able to easily compensate generic companies if the case is eventually lost (and the granted injunctions revoked) through the additional revenues gained during the injunction period.

⁷¹⁶ Directive 89/105/EEC of 21 December 1989, OJ L 40, 11.2.1989, pp.8-11.

⁷¹⁷ See Chapter B.2.3.5.

Conclusion on the Public Consultation

In the framework of the public consultation on the report, more than 70 submissions from interested parties were received. Stakeholder responses in summary are:

Consumer representatives, the generic industry and the health insurance sector underline the uniqueness of the report and submit that the findings confirm their concerns that generic entry is not occurring as quickly as it should and that less novel medicines reach the market addressing unmet patients' needs. They call for urgent action to remedy the problems highlighted in the preliminary report.

Originator industry representatives, partly supported by representatives of law firms and patent attorneys, by numbers the largest amount of submissions, argue that the Preliminary Report does not provide evidence that companies' practices hinder innovation, which leads to a decline in innovation. They also suggest that delays to generic entry cannot be attributed to the behaviour of originator companies, but consider factors related to the regulatory framework to be most important for delays. They finally suggest that the Commission should investigate other shortcomings in the market, e.g. the alleged lack of competition between generic companies.

The European Patent Office provides input on the functioning of the European patent system and draws attention to the line between IP law and competition law as drawn by the ECJ. In particular, it argues against a scrutiny of the intent of applicants in applying for patent rights for purposes of competition law.

Despite the differences in views on some of the findings set out in the Preliminary Report, there is broad consensus among stakeholders on the need to establish a Community patent and for a unified specialised patent litigation system in Europe.

F. CONCLUSIONS

1. Findings

- (1553) The pharmaceutical sector is vital to the health of Europe's citizens. Europe's patients need access to safe, innovative and affordable medicines. The market for prescription and non-prescription medicines is worth over € 138 billion ex factory and € 214 billion at retail prices. This translates into a retail expenditure of approximately € 430 for each EU citizen in 2007.
- (1554) In January 2008 the European Commission launched a sector inquiry into EU pharmaceuticals markets under the EC competition rules (Articles 81 and 82 of the EC Treaty) because information relating to innovative and generic medicines suggested that competition may be restricted or distorted. This was indicated by a decline in innovation measured by the number of novel medicines reaching the market, and instances of delayed market entry of generic medicines, as compared to what might be expected. This report confirms the decline of new chemical entities reaching the market and the delays of generic market entry and highlights some of the possible causes. In this respect, it points to company practices contributing to the phenomena described.
- (1555) The sector inquiry has provided the Commission with reliable data on how competition functions in the pharmaceutical sector as regards the competitive relationship between originator and generic companies and amongst originator companies, quantifying industry practices and pointing to certain areas of concern. The report clarifies in particular how industry operates in the existing legal framework. The acquired knowledge will also benefit all other interested parties in their understanding of the competitive relationships in the sector. A reliable factual basis is indispensable for the Commission to identify specific needs for action and to set priorities. Furthermore, national policy makers and public authorities may decide to take further action based on the analysis, for instance in relation to pricing and reimbursement policies. The inquiry relates to the period 2000 – 2007 and involves investigation of a sample of 219 medicines. The main findings set out in this report relate to:

Competition between Originator Companies and Generic Companies

- (1556) The report emphasises that patents are key in the pharmaceutical sector, as they allow companies to recoup their often very considerable investments and to be rewarded for their innovative efforts. The report also underlines the need to keep public health budgets under control.
- (1557) The report finds that originator companies use a variety of instruments to extend the commercial life of their medicines. The results of the sector inquiry suggest that the behaviour of companies contributes to the generic delay.

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- (1558) The strategies observed include filing for a large number of patents in relation to a single medicine (so-called "patent clusters"⁷¹⁸, up to nearly 100 product-specific patent families, which can lead to up to 1,300 patents and/or pending patent applications across the Member States⁷¹⁹), engaging in disputes with generic companies leading to nearly 700 cases of reported patent litigation, concluding more than 200 settlement agreements with generic companies which partly restrict generic entry and lead in certain instances to value transfers from the originator to the generic company and intervening in national procedures for the approval of generic medicines. The additional costs caused by delays to generic entry can be very significant for the public health budgets and ultimately the consumer.
- (1559) The sector inquiry confirms that generic entry does not always take place as early as it potentially could. For a sample of medicines under investigation which had lost exclusivity in 2000 to 2007 the average time to enter after loss of exclusivity was more than seven months on a weighted average basis, whereas also for the highest selling medicines, for which rapid entry matters most, it took about four months.
- (1560) These delays are important as the price of generic medicines during the first year after loss of exclusivity was, on average, 25% lower than the price of the originator medicines prior to the loss of exclusivity. Two years after entry, prices of generic medicines were on average 40% below the former originator price. Also the prices of originator products appear to drop following generic entry. The market share (in volume terms) of the generic companies was about 30% at the end of the first year and 45% after two years. In other words, any delay will have a significant cost / revenue impact.
- (1561) In relation to a sample of medicines analysed, the report estimates that savings due to generic entry could have been 20% higher than they actually were, if entry had taken place immediately following loss of exclusivity. According to the analysis the expenditure amounting to about € 50 billion would have been about € 15 billion higher without generic entry. However, additional savings of some € 3 billion could have been attained, had entry taken place immediately. As indicated, the findings of the inquiry suggest that the behaviour of originator companies contributes to the delay of generic market entry.

Competition between Originator Companies

- (1562) The preliminary findings of the inquiry also suggest that originator companies apply patent strategies, which may interfere with the development of a competing medicine. When such strategies mainly focus on excluding competitors without pursuing

⁷¹⁸ This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying interventions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

⁷¹⁹ The inquiry confirmed that the average number of patents and patent applications for the top selling medicines is 140% higher (i.e. 237) than the average of the overall sample (98.5).

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innovative efforts, they are called by some originator companies "defensive patent strategies"⁷²⁰.

2. Remedies

(1563) Any action by public authorities in the pharmaceutical sector should aim at creating a competitive environment that ensures that Europe's citizens have access to innovative, safe and affordable medicines without undue delays. In this respect both competition law enforcement and regulatory measures can and are to be considered to improve the functioning of the market to the benefit of consumers.

2.1. Intensify Competition Law Scrutiny

(1564) Where appropriate, the Commission will make full use of its powers under antitrust rules (Articles 81, 82 and 86 of the EC-Treaty), merger control (Regulation (EC) No 139/2004)⁷²¹ and State aid control (Articles 87 and 88 of the EC-Treaty). The Commission, in close cooperation with the National Competition Authorities, will pursue any antitrust infringement in the sector, wherever required by the Community interest. Action can also be taken at national level and in areas which were not the primary focus of the inquiry or are outside its scope.

Market Concentration

(1565) As described in the Final Report, the pharmaceutical industry is currently going through a significant phase of consolidation. This includes, on the one hand, an increasing concentration among (large) originator companies as well as the acquisition of biotech companies.

(1566) On the other hand, the generic landscape is undergoing substantial changes also, in the form of acquisitions of generic companies by originator companies and through merger & acquisition activities within the generic industry.

(1567) The trend towards increased market concentration is followed with attention by the Commission and analysis of these merger cases will benefit from the insights gained through the sector inquiry so as to preserve a competitive structure and process in the market.

Company Practices

⁷²⁰ This term is being used by the report, as it constitutes part of the terminology employed by stakeholders in this sector and thus is key to understanding the stakeholders' behaviour and practices. It is important to underline that from a patent law perspective each patent has to fulfil the criteria: (1) novelty, (2) inventive step and (3) industrial application. The underlying interventions of the applicant are irrelevant under patent law. For further details see also Chapter A, explaining the use of terminology.

⁷²¹ Council Regulation (EC) No 139/2004 of 20 January 2004, OJ L 24 of 29.1.2004, p. 1–22.

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- (1568) Promotion of innovation and driving economic growth are common goals of industrial property law and competition law. Innovation constitutes an essential and dynamic component of an open and competitive market economy. Intellectual property rights promote dynamic competition by encouraging undertakings to invest in developing new or improved products and processes. So does competition by putting pressure on undertakings to innovate. Therefore, both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof.⁷²² If the existence and exercise of an industrial property right are not of themselves incompatible with competition law, they are not immune from competition law intervention.⁷²³ However, certain practices can only be an infringement in exceptional circumstances.⁷²⁴
- (1569) The Commission and national authorities have already taken action in a number of cases in the past for specific violation of competition law in the pharmaceutical sector. The decisions taken include⁷²⁵: fines imposed on a pharmaceutical company by the UK competition authority for selling its products to hospitals at very low prices, whilst selling the same products via pharmacies at very high prices to patients, a strategy that could be sustained as doctors were found to be strongly influenced by the brands used in hospitals (NAPP case);⁷²⁶ interim measures granted by the French competition authority to a generic company whose products were systematically criticised by a competing originator company's sales staff even after marketing authorisation (Arrow Génériques case);⁷²⁷ the decision by the Italian competition authority, in which it was found that the refusal of an originator company to grant a licence for the production of an active ingredient, needed by producers of generic medicines to access national markets where the originator did not have any exclusive rights, constituted an infringement of Article 82 of the Treaty (GSK case);⁷²⁸ and fines imposed by the

⁷²² Commission Notice – Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements, OJ C 101 of 27 April 2004, p. 2-42.

⁷²³ See Commission Notice – Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements, OJ C 101 of 27 April 2004, p. 2-42. See also Judgment of the Court of 27 September 1988, Case 65/86 (Bayer v. Süllhöfer), [1988] ECR, p. 05249.

⁷²⁴ See, for instance: Joined cases C-241/91 P and C-242/91 Radio Telefis Eireann (RTE) and Independents Television Publications (ITP) v Commission (Magill) [1995] ECR I-743, para. 50; case C-418/01 IMS Health v NDC Health [2004] ECR I-5039; case T-201/04 Microsoft v Commission [2007] ECR II-3601, in particular paras. 688 et seq. Commission Communication of 16 July 2008 on an Industrial Property Rights Strategy for Europe, COM(2008)465 final.

⁷²⁵ A number of other cases were concluded or are ongoing.

⁷²⁶ See decision of the director general of faire trading No CA98/2/2001 of 30 MARCH 2001, NAPP pharmaceutical holdings and subsidiaries (NAPP), (available at: http://www.ofc.gov.uk/shared_ofc/ca98_public_register/decisions/napp.pdf).

⁷²⁷ See Judgment of the Cour de Cassation of 13 January 2009, Pourvoi no. P 08-12.510 (press release available at: http://www.conseil-concurrence.fr/user/standard.php?id_rub=211&id_article=865).

⁷²⁸ See Decision of Autorità Garante della Concorrenza e del Mercato of 8 February 2006, No 15175 (Case A363 - Glaxo-PRINCIPI ATTIVI), available at: <http://www.agcm.it/>.

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Commission for the abuse of a dominant position consisting in the misuse of regulatory procedures (AstraZeneca case).⁷²⁹

- (1570) The sector inquiry has identified a number of issues that warrant further scrutiny under the competition rules. The Commission in cooperation with the national authorities will not hesitate to make use of its enforcement powers under competition law, where there are indications of practices that have the potential to restrict or distort competition in the market. The Commission also invites market participants who suffer from anticompetitive practices or otherwise have information about such practices to inform the Commission or the relevant national authorities thereof.
- (1571) With regard to competition between originator companies in particular, defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts and/or the refusal to grant a license on unused patents will remain under scrutiny in particular in situations where innovation was effectively blocked.
- (1572) As regards competition between originator companies and generic companies, delays to generic market entry are a particular point of concern. The possible use of specific instruments by originator companies in order to delay generic entry will be subject to competition scrutiny if used in an anti-competitive way, which may constitute an infringement under Article 81 or 82 of the EC Treaty. In the case of clear indications that a submission by a stakeholder intervening before a marketing authorisation body was primarily made to delay the market entry of a competitor/applicant, injured parties and stakeholders are invited to bring relevant evidence of practices to the attention of the relevant competition authorities.
- (1573) Agreements that are designed to keep competitors out of the market may also run afoul of EC competition law. Settlement agreements that limit generic entry and include a value transfer from an originator company to one or more generic companies are an example of such potentially anticompetitive agreements, in particular where the motive of the agreement is the sharing of profits via payments from originator to generic companies to the detriment of patients and public health budgets.
- (1574) To reduce the risk that settlements are concluded at the expense of consumers, it would seem useful for the Commission to consider further focused monitoring, within the context of the existing legal framework, of those settlements with a potential to adversely affect European consumers. This monitoring would have to take duly into account the administrative burden imposed on stakeholders and will be limited in time until the Commission has gathered sufficient information on the subject matter to decide whether further action is needed.
- (1575) Any enforcement actions will be initiated on a case-by-case basis and will include a thorough examination of the specifics of each case taking into account the legitimate objectives to protect innovation and the regulatory framework.

⁷²⁹ See Commission Decision of 15 June 2005 (Case COMP/A. 37.507/F3 - AstraZeneca); currently under appeal before the Court of First Instance (T-321/05).

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(1576) Specific enforcement action is already underway in a number of cases. For example, in November 2008 – outside the sector inquiry – the Commission carried out surprise inspections at several companies in different Member States. At the time of the publication of this report no final conclusion was reached.

Other Initiatives

(1577) Competition law enforcement by itself will be an important component for the creation of a more pro-competitive environment; however it will not be able to address all main issues identified. Stakeholders made a significant number of comments on the regulatory framework, which they consider decisive for the pharmaceutical sector. The report summarises these comments and proposes possible policy options as to how the regulatory framework should evolve with a view to improving its functioning and minimising the risk of anti-competitive behaviour in the future. The most important areas are patent law, marketing authorisation rules and pricing and reimbursement provisions.

2.2. Rapid Establishment of the Community Patent and Creation of a Unified Litigation System

(1578) All stakeholders expressed strong support for the urgent creation of a single Community patent⁷³⁰ and a unified and specialised patent litigation system⁷³¹ in Europe which are currently under discussion. Rulings by the unified litigation system should be swift, of high quality and cost-effective. The results of the inquiry confirm that the Community patent and unified litigation system would create significant cost and efficiency improvements, in particular by reducing the costs associated with multiple filings, by eliminating essentially parallel court cases between the same parties in different Member States and by enhancing legal certainty through the avoidance of conflicting rulings. The Commission continues to make all efforts leading to the rapid adoption of these instruments.

(1579) Stakeholders agree on the importance that European - and in the future Community - patents granted by the EPO should respond to a high quality standard. Strong support was further received by all stakeholders that the EPO should be enabled to accelerate procedures whenever possible. Based on its findings of the sector inquiry, the Commission supports the recent initiatives by the EPO to "raise the bar". In this respect the Commission welcomes the recent decision to limit the time period during which the voluntary divisional patent applications can be filed. The Commission also supports the EPO in its efforts to shorten the opposition and appeal procedures.

⁷³⁰ The latest draft text of the proposal for a Council Regulation on the Community patent can be found in Council Working Document 8588/09 of 7 April 2009, at <http://register.consilium.europa.eu/pdf/en/09/st08/st08588.en09.pdf>.

⁷³¹ The latest text of the Draft Agreement on the European and Community Patents Court and Draft Statute can be found in Council Working Document 7928/09 of 23 March 2009, at <http://register.consilium.europa.eu/pdf/en/09/st07/st07928.en09.pdf>.

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(1580) Regarding the request by the originator industry to introduce so-called "clearing the way" mechanisms to solve patent issues before generic market entry, it is not clear that such new mechanisms would bring a positive added value at this stage when there are still significant discrepancies between national legal systems (e.g. on duration of court proceedings or the conditions/likelihood to obtain interim injunctions). In this light, generic companies should remain able to maintain the first mover advantage in relation to other generic competitors, unless an effective national system to clear the way exists. In any event the conditions, under which such a mechanism could be introduced, would need to be studied carefully.

2.3. Streamlining the Marketing Authorisation Process

(1581) The sector inquiry does not include within its scope the in-depth analysis of the Community regulatory framework for pharmaceuticals, which harmonises requirements for the placing on the market of medicinal products with the main objective of protection public health. However, it acknowledges the role played by the regulatory environment as regards the market access of both originator and generic medicines. In the replies to the consultation, various stakeholders have also commented on this legal framework.

(1582) The Community rules on the authorisation of generic medicines and on data exclusivity were substantially reviewed in 2004, and new provisions apply from 2005, although some will only show their full effects in some years' time.

(1583) Overall, most stakeholders called for strict implementation and enforcement of both the old and new regulatory framework. The comments of stakeholders received during the inquiry will constitute an additional valuable information basis to be taken into account by the Commission in the further implementation of its policies in the sector. Moreover, the Commission wishes to make the following observations.

(1584) Whilst there is broad consensus amongst stakeholders that – overall – the European framework governing marketing authorisation works well, stakeholders report what they perceive to be shortcomings in implementation that lead to delays and unnecessary administrative burdens for companies.

(1585) The Commission will provide full support to the European Medicines Agency (EMA) and the national agencies to assess how resources and capacity problems may be solved within the network of national authorities and invites Member States to actively contribute to the efforts for speeding up and streamlining administrative procedures to reduce bottlenecks and delays. Moreover, as outlined in the Communication of 10 December 2008 on the future of the pharmaceutical sector, the Commission considers that the network of EU medicines authorities requires optimisation to improve its efficiency, minimise the regulatory burden it generates and thus speed up market access for medicines. The ongoing EMA review provides a first opportunity for this analysis.

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- (1586) Stakeholders also complained about perceived discrepancies with regard to the national implementation of the EU regulatory framework. Effective enforcement as well as several actions by the Community institutions to remedy this situation are underway such as the implementation of the new Regulation on variations⁷³² and the ongoing efforts in the network of national marketing authorisation bodies. Where necessary, infringement actions will need to be considered.
- (1587) The Commission calls upon Member States and national agencies to make better use of the possibility of mutual recognition of marketing authorisations by enhancing procedures and reducing administrative burdens on companies, enabling full mutual recognition without additional requirements imposed on companies. The Commission also underlines the need for stronger coordination between agencies in order to avoid as far as possible discrepancies in the application of the legal framework, making full use of the existing instruments such as the coordination group for mutual recognition established by Directive 2001/83/EC⁷³³ or the various Community databases on medicinal products run by the EMEA. Marketing authorisation bodies are encouraged to transfer upon request and without delay all information needed by pricing and reimbursement bodies to avoid or at least limit duplication of efforts.
- (1588) Industry, most prominently generic companies, complained about the possibilities of originator companies to intervene in regulatory proceedings before marketing authorisation bodies and reported about diverging approaches to the disclosure of confidential information taken by different national authorities. The Commission recalls that marketing authorisation procedures are bilateral proceedings between the applicant and the administration.⁷³⁴ Third party submissions and even less so formal interventions during the assessment of an application for a marketing authorisation are not foreseen in Community pharmaceutical legislation. However given the duty of the competent authorities to consider any information which may impact on the product's assessment (safety, efficacy, quality), marketing authorisation bodies might not be able to simply disregard information submitted by third parties during the marketing authorisation procedure. In this light and irrespective of the reason for which a submission is made, Member States and agencies should ensure that the submission by the third party is well documented, made transparent towards the applicant and should make all necessary efforts that the intervention does not necessarily lead to delays for the applicant. Depending on the national legal framework, companies or health

⁷³² Changes subsequent to the placing of medicines on the EU market (e.g. change in the production process, change in the packaging, change in the address of the manufacturer etc.) are called 'variations'. Variations to the terms of a marketing authorisation are subject to the requirements of EU law, currently codified in Commission Regulations (EC) No 1084/2003 and No 1085/2003. From 1 January 2010 Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products will be applicable (Official Journal L 334 of 12.12.2008, p. 7-24).

⁷³³ Directive 2001/83/EC of 6.11.2001, OJ L 311 of 28.11.2001, p. 67–128, last amended by Directive 2008/29/EC of 11.3.2008, OJ L 81 of 20.3.2008, p. 51–52.

⁷³⁴ Judgment of the Court of First Instance, Case T-326/99 (Olivieri) of 18 December 2003, ECR 2003 p. II-06053.

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insurers may also pursue damage claims under national legislation in case of proven foregone revenues or savings due to unfounded interventions.

- (1589) The Commission will continue to strictly enforce the applicable Community law and, for instance, act against patent linkage, as according to Community legislation, marketing authorisation bodies cannot take the patent status of the originator medicine into account when deciding on marketing authorisations of generic medicines. The Commission is also committed to ensuring that the new data exclusivity rules introduced in Community legislation in 2004 are fully implemented in all Member States.
- (1590) The Commission equally notes the comments from stakeholders that the data exclusivity framework should be used to improve access to medicines. The Commission is committed to the development of an EU pharmaceutical framework for the 21st century which promotes innovation in particular in areas with unmet medical needs. In its Communication of 10 December 2008 on a Renewed Vision of the Pharmaceutical Sector, the Commission announces that it will adopt a report on the use of personalised medicines and ‘-omics’ technologies in pharmaceutical research and development and on the possible need for new Community instruments to support them, by 2010.⁷³⁵ This report will provide an opportunity to consider the current data exclusivity system, and its ability to contribute to innovation and improve access to medicines.
- (1591) Companies also call for further international harmonisation in the area of marketing authorisation, mostly between Europe and the United States, to reduce unnecessary regulatory divergences. The Commission fully supports further international harmonisation as this has the potential to considerably reduce the costs of market access and innovation by reducing unnecessary regulatory divergences and points to the strategy for this area outlined in its Communication on a Renewed Vision of the Pharmaceutical Sector of 10 December 2008.
- (1592) In the course of the sector inquiry generic companies also complained about information campaigns organised by the originator industry questioning the quality of generic medicines. The Commission would like to recall that all medicinal products (whether originator or generic) authorised for placing on the Community market are subject to the same requirements of quality, safety and efficacy. Any campaigns which put this fact in question ignore the key principles for marketing authorisation in the EU and may mislead the public. The Commission urges Member States to take action, in particular on the basis of Article 97 of Directive 2001/83/EC, if any such campaigns are detected in their territory.

⁷³⁵ With the emergence of new technologies like pharmacogenomics and patient-specific modelling and disease simulators, personalised medicine is now on the horizon. In the long term, doctors may be able to use genetic information to determine the right medicines, at the right dose and time. This field is already affecting companies' business strategies, the design of clinical trials and the way medicines are prescribed. Although it is too early to say whether ‘-omics’ technologies will indeed revolutionize the sector, the Commission closely monitors the area and will reflect on how it can support its development.

2.4. Improving Pricing and Reimbursement Systems and Developing a Pro-Competitive Environment for Generic Uptake

- (1593) During the sector inquiry, many stakeholders expressed concerns as regards the delays and uncertainties faced in procedures regarding the pricing and reimbursement status of medicines. Originator companies argued that this would deny patients access to innovative medicines and shorten the period during which the companies enjoy exclusivity. Generic companies argued that such delays limit savings for health bodies.
- (1594) Key elements of the relevant context for the Commission's strategy in this area are based on the Recommendations of the Pharmaceutical Forum, the Commission Communication of 10 December 2008 on a Renewed Vision of the Pharmaceutical Sector and the in-depth monitoring of the functioning of markets in the pharmaceutical sector.⁷³⁶ Depending on the final outcome of all these initiatives, the Commission will examine the potential need for a review of the existing EU rules in the area of pricing and reimbursement (Transparency Directive 89/105/EEC).
- (1595) The Commission urges all stakeholders to ensure that the time-limits of three or six months established by the Transparency Directive 89/105/EEC⁷³⁷ are respected and will continue to investigate all complaints pointing to an incorrect transposition or systematic disrespect of the Directive. The Commission also draws the attention of stakeholders to the possibility to challenge the alleged failure of national authorities to respect the requirements of the Directive before the national courts and encourages affected parties to consider this possibility – including damage claims – when deemed necessary.
- (1596) The Transparency Directive 89/105/EEC lays down maximum time-limits for pricing and reimbursement decisions, which do not preclude Member States from establishing quicker decision-making procedures where deemed appropriate. In order to speed up pricing and reimbursement decisions for generic products, the Commission invites Member States to consider the introduction of national provisions granting automatic/immediate pricing and reimbursement status to generic products (i.e. without detailed assessment) where the corresponding originator product already benefits from reimbursement based on a higher price. This would considerably alleviate the administrative burden for all concerned and lead to faster access of generic products.
- (1597) According to generic companies, delays with respect to pricing and reimbursement decisions are sometimes the result of additional requirements, e.g. information on the

⁷³⁶ For details see recommendations of the Pharmaceutical Forum (adopted in October 2008, see <http://ec.europa.eu/pharmaforum/>), the Commission Communication of 10 December 2008 (COM(2008) 666 of 10.12.2008: Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector) and the in-depth monitoring of the functioning of markets in the pharmaceutical sector (as announced in Objective 7 of the above referred Communication).

⁷³⁷ The specific time limits laid down in Directive 89/105/EEC are 90 days for pricing decisions, 90 days for reimbursement decisions or 180 days in case of joint procedures.

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patent status or an additional evaluation of the bio-equivalence between the originator and the generic product. These additional requirements, requested by the pricing and reimbursement bodies, seem to provide a tool to originator companies to intervene and hence to prolong a given procedure.

- (1598) The Commission notes that the Transparency Directive requires Member States to set out objective and verifiable criteria for granting pricing and reimbursement status to medicines, so that the competent national authorities must not add criteria or assessments which are not foreseen by national law. It also considers that assessments of the patent status and of bio-equivalence should fall outside the competence of pricing and reimbursement bodies, as they are neither equipped nor competent to deal with these issues. The entry of generics is also affected where authorities in Member States consider that pricing and reimbursement applications constitute a patent violation. In this respect it is underlined that EFPIA, the European association representing originator companies, submitted in the context of the public consultation on the Preliminary Report that applications for marketing authorisations by generic companies would not amount to a violation of patent law. The same logic should apply to applications for pricing and reimbursement status.
- (1599) In this context, originator companies should not intervene before the pricing and reimbursement authorities in order to raise bioequivalence issues or a potential patent violation by the generic applicant. The Commission considers the pricing and reimbursement procedures as bilateral proceedings between the applicant and the administration. Since the pricing and reimbursement authorities are not competent to assess patent, bioequivalence or safety issues, Member States should disregard third party submissions raising such issues. They should also ensure that interventions by third parties are in general well documented, made transparent towards the applicant and do not lead to delays in processing the price and reimbursement decisions.
- (1600) Originator companies attribute amongst others part of the delays for originator medicines to cross-border referencing systems used in a number of Member States, and part to the trend towards fragmented decision-making at a more regional/local level. The Commission – whilst fully acknowledging national choices – points to the findings of the sector inquiry that cross-border referencing can lead to delays and creates sometimes room for misuse (hidden discounts on published price lists used for reference pricing). Regarding the fragmented decision-making, the Commission underlines that this is an issue to be dealt with by Member States.
- (1601) Stakeholders and in particular originator companies, also complained about the uncertainty of prices/reward when developing new medicines. The duplication of national assessments that try to establish the "added value" of the new medicine over and above existing medicines was specifically mentioned. There is general interest in cross-border collaboration on scientific aspects of added value assessments. In this respect the Commission points to the fact that the duplication of the scientific assessments in the Member States results in additional costs, which are ultimately borne by the consumers/tax payers. Also there is a risk of contradicting decisions on essentially the same questions. Moreover, at this stage smaller Member States do not always have the means for the scientific assessments and thus do not benefit from the possibilities available to larger Member States. Thus a Joint Action on Health Technology Assessment has just been submitted for funding under the Health Programme 2009. In addition, the Commission's proposal on the implementation of

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patients' rights in cross border healthcare contains a provision for further cooperation on health technology assessment. However cost effectiveness analysis is rather dependent on the budgetary situation and health priorities of each Member State.

- (1602) Finally, comments were received on national mechanisms that could foster competition forces in the pharmaceutical sector, in particular in the generic sector.
- (1603) Econometric analysis on the impact of generic entry carried out in the context of the sector inquiry tend to indicate that national regimes with compulsory generic substitution for pharmacists and encouraging doctors to prescribe the substance (as opposed to a particular brand) appear to be favourable to price competition and the level of generic penetration. The same holds for policies involving reimbursement of medicines at the level of the lowest priced product and a frequent adjustment of reimbursement levels to take account of price developments in the market. Likewise, differential co-payment for patients further appears to favour price competition. By contrast, the use of price caps for generic medicines appears not favourable to price competition or generic penetration.
- (1604) In this light the Commission invites Member States, to the extent not yet done, to consider policies facilitating rapid generic uptake and/or generic competition. Different possible policies to achieve this goal are currently being discussed in the context of the Transparency Committee established by Directive 89/105/EEC.
- (1605) Certain Member States have achieved significant savings to the benefit of consumers when health insurers carried out tender or similar processes for certain generic products. These systems can help ensure that price reductions offered by generic companies do not stay in the distribution system, but are passed on to consumers. Whilst tenders can be a very powerful tool to reduce costs for public health budgets, the medium and long term effects need also be considered when setting the tender conditions (e.g. duration of award period should not lead to market foreclosure). Compliance with European law (e.g. public procurement law) when carrying out such tenders is also essential.
- (1606) The Commission will facilitate cooperation between Member States and the exchange of best practices on generic policies in the framework of relevant discussion platforms, such as the Transparency Committee established by Directive 89/105/EEC.

3. The Way Forward

- (1607) The sector inquiry confirms that generic entry does not always take place as early as it potentially could under the current relevant legal framework. It shows that company practices are amongst the causes and suggests that a variety of other conditions might play also an important role. The sector inquiry also confirms a decline of novel medicines reaching the market and points to certain company practices that might, amongst other factors, contribute to this phenomenon. Further market monitoring is ongoing trying to identify the additional factors that are likely to play a role in this context.
- (1608) The Commission will address the issues identified in the course of the sector inquiry by applying increased scrutiny under EC competition law to the sector and by bringing

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specific cases, where appropriate. First enforcement action is already under way. To reduce the risk that settlements are concluded at the expense of consumers, the Commission will also consider further focused monitoring of settlements that limit generic entry and include a value transfer from an originator company to a generic company.

- (1609) As far as the regulatory framework is concerned, the Commission reaffirms on the basis of its findings in the context of the sector enquiry the urgent need for the establishment of a Community patent and of a unified specialised patent litigation system in Europe, which pursuant to the sector inquiry has received increased support from the pharmaceutical sector. With respect to patent law the sector inquiry also fully confirmed the relevance of the recent initiatives of the European Patent Office to ensure a high quality standard of patents granted and to accelerate procedures ("raising the bar").
- (1610) With respect to marketing authorisation the Commission will focus on the full implementation and effective enforcement of the regulatory framework, e.g. regarding patent linkage or the respect of deadlines in the approval procedures. The Commission recalls that third party submissions and even less so formal interventions during the assessment of an application for a marketing authorisation are not foreseen in Community pharmaceutical legislation. It calls upon marketing authorisation bodies to ensure that submissions by third parties that cannot be excluded are well documented and made transparent towards the applicant, and to make all necessary efforts that submissions do not necessarily lead to delays for the applicants.
- (1611) Concerning pricing and reimbursement the Commission invites Member States to consider (the introduction of) provisions that would grant pricing and reimbursement status to generic products automatically/immediately where the corresponding originator product already benefits from such a status. Moreover, Member States should disregard third party submissions raising patent, bioequivalence or safety issues. Member States should ensure that submissions by a third party at pricing and reimbursement bodies that cannot be disregarded are well documented, made transparent towards the applicant and should make all necessary efforts that the intervention does not lead to unnecessary delays for the applicant. Finally, the Commission invites Member States to the extent not yet done to consider policies facilitating rapid generic uptake and/or generic competition. It will facilitate cooperation between Member States and the exchange of best practices on generic policies. Depending on the outcome of the various initiatives⁷³⁸ the Commission will examine the potential need for a review of existing EU rules in the area of pricing and reimbursement (Transparency Directive 89/105/EEC).
- (1612) Based on the objectives outlined in this Communication, the Commission will continue to pursue a constructive dialogue with all stakeholders to ensure that the innovative

⁷³⁸ Recommendations of the Pharmaceutical Forum, Commission Communication of 10 December 2008 on a Renewed Vision of the Pharmaceutical Sector and the in-depth monitoring of the functioning of markets in the pharmaceutical sector.

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potential of the Community's pharmaceutical industry can fully develop and that patients benefit from better access to safe and innovative medicines at affordable prices without undue delays.