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Summary of the replies to the public consultation on Supplementary Protection Certificates and patent research exemption for sectors whose products are subject to regulated market authorisations

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products

{COM(2018) 317 final} - {SEC(2018) 246 final} - {SWD(2018) 240 final} - {SWD(2018) 241 final}

1. INTRODUCTION

The *Single Market Strategy*, adopted in October 2015, announced that the Commission would '*consult, consider and propose further measures, as appropriate, to improve the patent system in Europe, notably for pharmaceutical and other industries whose products are subject to regulated market authorisations*'.

In particular, the Strategy aimed to explore a recalibration of certain aspects of patent and supplementary protection certificate (SPC) protection, and announced that this recalibration could comprise the following three elements: (1) the creation of a European SPC title, (2) an update of the scope of EU patent research exemptions, and (3) the introduction of an SPC manufacturing waiver.

Accordingly, an online public consultation was conducted from 12 October 2017 to 4 January 2018. Its outcomes are summarised below. Comprehensive information on this public consultation can be found at https://ec.europa.eu/info/consultations/public-consultation-supplementary-protection-certificates-spcs-and-patent-research-exemptions_en.

2. PARTICIPATION

The consultation included a set of six specific sub-questionnaires for the following groups of stakeholders: (I) general public, (II) originators industry/associations, (III) generics and biosimilars industry/associations, (IV) health authorities/doctors/patients groups, (V) patent offices/practitioners, and (VI) industry/trade authorities.

A total of 231 replies were provided to the on-line consultation: 43 replies from the general public, 71 from originators industry/associations, 63 from generics and biosimilars industry/associations, 15 from health authorities/doctors/patients groups (mostly from national organisations dealing with health insurance/reimbursement/health technology assessment, from a doctors' organisation, and 2 from patients' associations), 34 from patent offices/practitioners, and 5 from industry/trade authorities.

Therefore, the largest category of respondents was innovative pharmaceutical companies ('originators', most of whom were SPC-holders), with 71 respondents, of whom 44 are based in the Union. The second largest category was generics/biosimilars organisations/companies, with 63 respondents, 51 of whom are based in the Union.

Amongst originators, it may be noted that 15 of the 71 respondents declared to also own a separate branch or business activity that develops or markets generics and/or biosimilars.

Most firm respondents have their headquarters in the Union, except for 16 firms that are based mainly in Switzerland, Asia and USA.

Both innovators and generics respondents are mostly global players. Regarding generics respondents, 33 respondents have a world-wide activity, 13 have EU- only activities and 4 are limited to their national domestic market. Regarding originators respondents, 31 respondents have world-wide activities, 8 have EU- only activities and 6 are limited to their national domestic market.

The statistics corresponding to respondents identified as SMEs or start-ups are the following:

- Among the 63 respondents defining themselves as mostly manufacturers of generics/biosimilars, 12 respondents identified themselves as an SME and one as a start-up;

- Among the 71 respondents defining themselves as mostly originators, 2 respondents identified themselves as an SME involved in medicines biotechnology and one as a start-up in the field of bio-pesticides.

In addition, several pharmaceutical associations (Medicines for Europe, EUCOPE, and EuropaBio) also represent pharmaceutical start-ups and SMEs and conveyed SME views both by responding to the public consultation and/or by sending position papers to the Commission services. The input of these position papers is taken into account in this summary of replies.

3. FIVE CLUSTERS OF QUESTIONS

The questions of the consultation can be clustered into the following seven headings (the question in the cluster (1) below was only addressed to the general public (group (I) of stakeholders):

(1) **Awareness** of the existence of the EU SPC system and its role in innovation, and awareness about the geographical origin of the production of the medicines consumed;

(2) **Profile** of the originators and generics respondents;

(3) **Effectiveness of the EU SPC regime**: the role of SPC in innovation, localisation of R&D and manufacturing;

(4) **Implementation** of the SPC system: the registration procedures, transparency of the system, associated cost and enforcement aspects;

(5) The SPC manufacturing **waiver**;

(6) The **unitary SPC**: need for it, the grant authority, language regime, etc.;

(7) The scope of the EU **Bolar** patent exemption: its role, national implementation, covering supply of active pharmaceutical ingredients, coverage of it by the Unified Patent Court Agreement, Bolar in the plant protection products market, availability for health technology assessment.

The following subsections summarise the replies submitted in relation to the groups of questions above.

3.1. General questions addressed to the general public: awareness of the existence of the EU SPC system

Of the 43 replies received from the general public, 36 respondents from the general public were aware of the SPC system (only 1 respondent stated not to be aware of). 34 respondents agree on the positive role of the SPC on pharmaceutical innovation (21 think that the SPC has been positive for the growth of the pharmaceutical industry in the EU), but 22 respondents think that the SPC is not enough to encourage certain categories of treatments (i.e. other incentives might be necessary). There is less awareness about the existence of SPCs for plant protection products (only 23 respondents were aware of them).

24 respondents are aware of the geographical location of the production of consumed medicines, and 23 care about where medicines are produced. Only 3 respondents do not care where medicines are produced.

3.2. Profile of the originators and generics respondents

Companies and organisations who participated in the consultation are mostly producers of human medicinal products (75% generic firms or associations and 61% for innovators) and veterinary medicinal products (21% generics and 20% innovators). There were very few

submissions from plant protection products stakeholders, but the main European originator generics associations in this field made submissions.

As highlighted in section 2 above, commercial activity of most firms is worldwide (not only specific for international firms but also for Union-based firms or associations). The commercial activity of more than 47% of innovators and 53% of generic firms is not limited to the EU market, but covers international markets. Only 17% of Union-based innovators who participated in the consultation and 24% of Union-based generic firms declare having a commercial activity restricted to the EU landscape.

Limited information is provided regarding their business structure. From those who provided information, more than half of generics firms declare having more than 90% of their manufacturing output (outsourced and not outsourced) located in the Union. The other big poles where generic firms concentrate a significant part of their manufacturing are China (16%), the USA (12%) and India (11%). On the other side, generic investments in clinical trials and R&D are reported to be mostly EU-based[1]. Innovators have reported little information on business structure, and their investment is spread worldwide, more than is the case with generics manufacturers. High investments are reported in almost all geographical markets, especially for investments in clinical trials and in R&D in Korea, Japan, the USA and Canada.

3.3. Effectiveness of the EU SPC regime: impact on innovation and indirect impact on generics and biosimilars

Most innovators consider the SPC, or the possibility of obtaining one, an important factor for investment decisions. However, as some companies indicate in the consultation, investment decisions are the result of having the right overall ecosystem of all the relevant policies that foster R&D. SPCs are considered to have a proportionate impact on investment along all steps of the value chain: R&D, clinical trials, manufacturing, distribution and commercialisation. Some innovators consider SPC availability as the main factor for investment decisions in manufacturing. However, the importance that the majority of innovators ascribe to SPCs is moderate, as they consider that SPCs are one factor in a package of elements: aside from the availability of SPCs, decisions on investments in research (excluding clinical trials and field trials) are driven by a combination of factors such as access to high skilled labour and recruitment of patients. With regard to the most important factors when investing in clinical trials, innovators consider health infrastructure and proximity of research universities.

Two thirds of originator respondents, and most practitioners, confirm that in the Union, SPCs are not available for certain types of innovation that require regulatory approval, such as medical devices; such innovations are however SPC-protected in the USA and Japan (as also confirmed by generics respondents). 8 innovators state that SPCs do not suffice to encourage them to invest in the development of antibiotics, orphan and neglected treatments.

According to the results of the public consultation, the three main drivers which lead generic firms to invest in the development of products outside the Union are the lack of SPC protection in other markets, the existence (or not) of a 'Bolar exemption' and the proximity of the export market to the manufacturing facilities. Most of them consider that Regulation (EC) No 469/2009 has forced them to relocate, or outsource (via licensing), their production outside the Union, to other countries where SPC protection does not exist or is weaker. They consider that supply sources of active pharmaceutical ingredients ('APIs') have also been affected by the SPC regime. The main factors that industry considers to be affecting API

[1] These findings should be considered as anecdotal, due to the few replies we have received in the public consultation.

supply sources are SPC protection, the scope of the Bolar exemption, indirect patent infringement rules in the country manufacturing the API, and compliance with regulatory standards. A secondary – but still relevant – driver is securing supply. Proximity to manufacturing does not seem to be of great significance for generics when choosing their API sources. However, most generics manufacturers claim that it is not always possible to find APIs supplied from within the Union. In contrast, they claim that, for biosimilars, R&D and manufacturing tends to take place at the same location. SPCs and the Bolar exemption are key elements for generics/biosimilars-related investments, over labour costs, including the way they can source APIs.

A few respondents (from the health professionals and patients group) claim that SPC protection has a negative effect on the development of medicines vis-à-vis added-value for patients.

3.4. Implementation of the SPC system

Respondents broadly support the way in which SPC issues are regulated at Union level, which is found to be globally effective. However, most respondents claim that there are different practices for registration and SPC enforcement across Member States (a few originators and generics manufacturers disagree).

However, EFPIA[2] suggests that guidance at Union level would improve the situation. This should not extend to amending the SPC *acquis*, as EFPIA considers that such an amendment process could lead to years of uncertainty; generics manufacturers seem to be split on whether to clarify aspects of the SPC Regulation implementation via legislative amendments.

IP practitioners (including patent offices) and generics manufacturers support this 'guidance' approach, especially since court proceedings in some Member States may take too long. Generics manufacturers mostly support SPC registration with substantive examination, but consider that transparency is not optimal (information published by public authorities is not always comprehensive or up-to-date, and private databases monitoring SPC status are expensive). Most respondents do not see problems with the level of registration fees or litigation costs for SPC holders, as they are already well compensated by the additional exclusive sales resulting from SPC protection.

3.5. SPC manufacturing waiver

Views expressed by generics/biosimilars manufacturers[3]

Most **generics/biosimilars ('G/B') manufacturers** support the introduction of a manufacturing waiver, considering that:

— SPCs disadvantage EU-based G/B manufacturers compared with those based in countries with no SPC when exporting G/Bs outside the Union. This problem is confirmed by 56 out of 62 G/B respondents (1 respondent denies this problem, and 2 do not know).

— SPCs disadvantage EU-based G/B manufacturers compared with those based in countries with no SPC when placing G/Bs on the market in the EU immediately after the SPC expires; this problem is confirmed by 53 out of 62 G/B respondents (3 respondents deny this problem, and 3 do not know).

[2] The European Federation of Pharmaceutical Industries and Associations.

[3] Questions 10, 11 and 34. Additional written information was provided by Medicines for Europe and certain national sister associations.

— The EU SPC, in its current form, increases reliance on imports of medicines and active pharmaceutical ingredients from outside the Union;

— The entry into force of the SPC Regulation in an EU country has triggered relocation to non-EU countries, or licensing of our manufacturing to a country with no or weaker SPC-type protection;

— Already today, it is not always possible to source active pharmaceutical ingredients ('APIs') from within the Union;

— The introduction of an SPC manufacturing waiver in the Union would increase G/B sales in countries outside the Union when protection in those countries expires; would lead them to increase their manufacturing in the EU; would not increase the risk of infringement of SPCs in the EU; and would not significantly reduce originators' sales in countries outside the Union when protection abroad expires.

The vast majority of **SMEs** manufacturing generics and biosimilars also share these views, and in general consider that the longer duration of SPCs in the Union compared to non-EU countries makes manufacturing in the Union less interesting for them.

Views expressed by originators[4]

Originators' submissions to the consultation reflect their broad – though not overwhelming – opposition to the introduction of an EU SPC manufacturing waiver: 54 out of 71 originators do not consider that EU-based manufacturers face export or EU day-1 entry-related problems vis-à-vis their competitors based in non-EU countries (with shorter or no SPC protection).

A majority of originators oppose the introduction of an SPC manufacturing waiver in the EU, considering that the current SPC framework does not put EU-based generics/biosimilars manufacturers at a particular disadvantage compared with foreign-based manufacturers (neither when exporting generics/biosimilars outside the Union nor when it comes to placing generics/biosimilars on the EU market after SPC protection expires), and that a waiver would:

— increase the risk of infringement of their SPCs in the Union;

— reduce protection to recoup their investments in R&D in the Union;

— reduce their sales in countries outside the EU when protection abroad expires;

— erode IPR protection, sending a negative message to those innovating and investing in the Union, or intending to do so;

— increase competition from EU-based generics/biosimilars in the EU market;

— provide EU-based generics/biosimilars manufacturers with limited benefits only (it is argued that EU-based generics companies are often the first to market in the EU, and that SPC(-like) protection is also available in the markets of EU's main export partners (USA, Japan, etc.).

Views expressed by other stakeholders

As indicated above, a large majority of the 43 citizens who answered the consultation state that they care about the origin of productions of the medicines they consume, while only 3 said they do not care.

[4] Questions 22, 23, 44. Additional written information was provided by EFPIA, EUCOPE, ECPA, EuropaBio and certain of their national sister associations.

10 out of 15 respondents in the group of patients/doctors/insurers agree that the EU SPC system puts EU-based manufacturers of generics and biosimilars at a disadvantage vis-à-vis competitors based in third countries when it comes to export. Only 1 respondent considers that this is not a problem. 6 respondents of this category see also an issue regarding timely EU day-1 entry for EU-based manufacturers of generics and biosimilars. 3 respondents do not consider that this is a problem.

11 Member States authorities or ministries took part in the public consultation and/or made written submissions. Some expressed support and none expressed explicit opposition to the idea.

One Member State strongly endorsed the introduction of an SPC manufacturing waiver in the EU for export and stockpiling purposes; in its view, it would also result in employment increase in the EU pharmaceutical industry and provide additional incentives for investments by generics/biosimilars companies in manufacturing and R&D in the Union. In particular, this Member State would like to see a legislative proposal as soon as possible introducing the manufacturing waiver, separately from the other issues considered for review.

Another Member State considered that before deciding to introduce the manufacturing waiver, a careful assessment should be made of all the impacts thereof, its proven importance, and the general impact of the waiver on the patent protection system as a whole.

A further Member State considered that the introduction of an SPC manufacturing waiver in the EU would not prevent originators from recouping their R&D investments, and that in the short term it would not significantly reduce their sales outside the Union when protection abroad expires.

Most respondents from national public authorities remained silent on the issue at this time.

3.6. Unitary SPC[5]

A very large majority of the respondents across all categories favour the creation of a unitary SPC, which would extend unitary patents when such patent rights expire.

Regarding the **benefits** of a unitary SPC, a great majority of originators consider that it could boost the value of investments, that it would reduce red tape relating to registration and to litigation, that it would provide uniform protection across the Union as well as legal certainty, that it would reduce maintenance costs, that it would offer a specialised court, and that it would make licensing easier. A large majority of generics/biosimilars ('G/B') manufacturers, including SMEs, share these views.

One Member State considered that it would also simplify and enhance the efficiency of the SPC application process.

Opinions diverge regarding the **practicalities** for implementing such a new title. While some respondents favour the grant of that title by a virtual office composed of national experts working on behalf of an EU agency, others prefer either to entrust the EPO with this task, or to set up a new EU agency to do so.

Amongst SMEs manufacturing G/Bs, half of them favour the grant of unitary SPCs by a new EU agency, while the other half favour the EPO for this purpose.

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[5] Questions 38, 39, 40, 43 as regards originators; questions 29, 30, 31, 32, 35 as regards generics/ biosimilars ('G/B') manufacturers as well as SMEs manufacturing G/Bs; questions 27, 28, 29, 30, 34 as regards IP practitioners; also questions 9, 10, 11, 12 as regards public authorities.

Concerning the **languages** to be used for a unitary SPC, a clear majority favoured the EPO language regime (English, French, German), which is the regime that is applicable to the EU unitary patent. However, SMEs manufacturing generics and biosimilars prefer the five language regime of the EUIPO (English, French, German, Italian and Spanish), whilst one of these favours the EPO regime.

Respondents also mostly considered that *national* **marketing authorisations** should be able to be used (in addition to *EU* marketing authorisations) as a basis for getting a unitary SPC, even though the latter would then not be enforceable in those Member States where no marketing authorisation would have been granted (through mutual recognition or decentralisation procedure).

In the absence of a unitary SPC, a majority of the respondents were of the opinion that National Patent Offices could grant – pursuant to the current legislation – national SPCs for products covered by future unitary patents.

3.7. Bolar exemption[6]

The questions of the consultation related to the Bolar patent exemption addressed a number of issues previously analysed by the the Commission services in the related inception impact assessment[7], and for which the Commission sought the views of stakeholders, including in relation to options to address them (e.g. via legislative amendments, guidelines, etc.). The issues relating to the Bolar exemption are:

- Effectiveness of the EU Bolar exemption;
- Whether the Bolar patent exemptions applies in all Member States to:
    - tests conducted by originator, generic and biosimilar manufacturers for the purpose of seeking marketing authorisations in non-EU countries;
    - tests conducted by pharmaceutical originators to meet new national regulatory requirements on pricing and reimbursement (e.g. health technology assessments, that compare a given medicine with others to show relative cost/efficacy effectiveness);
    - supply of patented active pharmaceutical ingredients (APIs) to EU-based generic manufacturers for the purpose of seeking marketing authorisations under the Bolar patent exemption;
    - plant protection product;
- Whether the future Unified Patent Court will apply the Bolar patent exemption in line with Member States' practice.

Respondents consider that several aspects of the implementation of the EU Bolar patent exemption are not clear in some Member States (e.g. a number of generics manufacturers claimed that courts in Member States have denied the Bolar exemption for foreign authorisation purposes). This provokes changes in their business models: a strong majority of the respondents in the generics group states that they would increase their orders for APIs from EU-based suppliers if the implementation of the Bolar exemption were clear in this regard.

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6 Questions 29, 34, 35, 36, 42 as regards originators; questions 17, 23, 26, 33, 36 as regards generics/ biosimilars ('G/B') manufacturers; questions 20, 23, 24, 31 as regards IP practitioners.

7 http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_grow_051_supplementary_protection_certificates_en.pdf

Originator submissions support the development of guidelines at Union level on the recalibration of Bolar aspects, such as exempting from patent infringement, on the one hand, tests and trials for the purpose of fulfilling health technology assessment ('HTA'[8]) requirements, registering generic medicines in third countries[9], and registering generic versions of pesticides in the EU; and on the other hand, supply of active pharmaceutical ingredients (APIs[10]) to generic companies.

Several originators favour the creation of a Commission-Member States expert group to follow Bolar developments. Respondents consider that the practice of the Unified Patent Court regarding the Bolar exemption should be compatible with the broader practices developed in many Member States (this is a major concern for a significant majority of the originators and generics manufacturers; almost half of IP practitioners also see this risk, and think it is undesirable).

It is uncertain whether the Bolar exemption is available for plant protection products. None of the respondents claim that this is the case[11]; a few state that it is not clear, and two state that it might be available in a few Member States. Only a minority of IP practitioners state that it is certainly available in their Member States.

[8] Only about half of the originators claim to have certainty on whether HTA activities are covered by Bolar in Member States. One claims that it moved clinical trials from a Member State due to uncertainty about Bolar covering HTA-related testing or not. About half of the practitioners cannot state either whether HTA-related testing is covered by Bolar.

[9] About a third of the practitioners cannot state whether testing for foreign registration of a medicine is covered by Bolar or not.

[10] Most generics manufacturers claim that it is not always possible to source APIs within the EU.

[11] Submission by ECCA (European Crop Care Association), the association representing the sector of generic plant protection products.