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Delegations will find attached, for information, the statements delivered on behalf of the European Union and its Member States at the above-mentioned WIPO meeting.

WIPO - Standing Committee on the Law of Patents

Twenty-Fifth Session

Geneva, 12-15 December 2016

Opening statement

Madam Chair**,**

The EU and its Member States would like to congratulate you and your vice-chairs on your election. We express our full support for your efforts to guide us through this weeks' agenda, as you have done during preceding SCP sessions.

The European Union and its Member States are pleased that progress was made at the previous session of the SCP, that positive conclusions were reached, and that delegations agreed to continue discussions on the basis of the work program on the topics: “Quality of Patents, including Opposition Systems”, “Client-Patent Attorney Privilege”, “Exceptions and Limitations to Patent Rights”, “Transfer of Technology”, and “Patents and Public Health”.

The programme for the coming days reflects the balance between different priorities and should provide opportunities for all of us to make steps forward. We have come here in a constructive spirit and with concrete proposals.

We are pleased to see four sharing sessions on the programme - on exceptions and limitations to patent rights, on quality of patents, including opposition systems, on patents and health and on transfer of technology. We would like to emphasize the importance of sharing sessions in general and we hope that these sessions will provide useful information in relation to challenges and opportunities faced.

Having said this, we would like to highlight our areas of interest.

In particular, we attach considerable importance to advancing work on the "quality of patents" along the lines proposed by delegations from Canada, the UK, Denmark, the US, and Spain as endorsed by all other Member States of the European Union, as we believe that work on this topic would be of interest to member states across the spectrum of development.

We are keen to continue discussions on the topic of “Client-Patent Attorney Privilege”, as convergence of differing provisions would be of benefit to users of the patent system, irrespective of the level of development of individual WIPO Member States. We believe that the sharing session on this particular topic at the next SCP could help, because it can provide valuable input in taking this work forward.

We also remain committed to discussing key aspects of substantive patent law.

Finally we would like to highlight that the European Union under its enhanced cooperation procedure has made significant advances on the European Patent with unitary effect. In that context, significant advances have also been made on the creation of the Unified Patent Court. The Unitary Patent will help to attract and retain innovation, talent and investment. It will come into effect once the necessary ratifications of the Unified Patent Court Agreement have taken place.

Madame Chair, we remain committed to the work of this Committee and look forward to a constructive session. We would also like to thank the WIPO Secretariat for its extensive work in preparing for this meeting.

Thank you.

WIPO - Standing Committee on the Law of Patents

Twenty-Fifth Session

Geneva, 12-15 December 2016

Exceptions & limitations to patents rights

Related documents: SCP/14/7, SCP/19/6 and SCP/25/3

Madam Chair**,**

The European Union and its Member States would like to thank the WIPO secretariat for preparing document SCP/25/3 on Member States' experience and case studies on the effectiveness of exceptions and limitations. However, we note that the document contains the information only from 2 member states and some observers. Nevertheless, the European Union and its Member States believe that this document, as well as the previous document (SCP/23/3), will serve as a useful reference.

We are pleased to see the sharing session on this topic. We are confident that it will provide useful insights as well as a valuable basis for achieving further progress in this area. Exchange of practical experiences on the effectiveness and challenges of E&L in addressing development issues is the main prerequisite for meaningful outcomes.

As regards exceptions and limitations in general, we would like to stress once again that exceptions and limitations to patent rights maintain an appropriate balance between the interests of rights holders and the general public. Taking this balance into account, it is important to address both sides at the same time, on the one hand exclusions from patentability or exceptions and limitations to patent rights, and on the other the corresponding legal standards used to determine whether an invention is patentable, such as novelty, inventive step, and industrial applicability.

Thank you Madam Chair.

WIPO - Standing Committee on the Law of Patents

Twenty-Fifth Session

Geneva, 12-15 December 2016

Quality of patents, including opposition systems.

Related documents: SCP/17/7, 8, 10, SCP/18/9, SCP/19/4, SCP/20/11 Rev., SCP/23/4 and SCP/24/3

Madam Chair,

This intervention is made on behalf of the EU and its Member States.

The EU & its Member States are convinced that the cornerstone of the efficiency and the effectiveness of patent offices daily work has been the international cooperation including work sharing. This working method plays an important role as a powerful tool for granting high quality patents.

Patent offices take the advantage of work sharing in order to reduce backlogs, to avoid duplication of work, and improve the overall efficiency of the patent granting process.

Being aware of the complexity of the assessment of the inventive step, we would like to see further studies on the assessment of this most difficult patentability requirement within this committee.

Last time, we saw examples not only from WIPO, such as the presentation of the webpage for work sharing WIPO CASE, but also from Member States that ensured us that examination and administration of patent applications can be facilitated. We believe that having more examples can help member states to collect information on existing work sharing programs and to educate themselves. In this respect we look forward to discussing the questionnaire which covers cooperation and collaboration between patent offices in search and examination of patent applications, as well as quality of patents. The sharing session and the proposed study on the assessment of inventive step could provide an additional useful information source.

We would like to reiterate our support for the proposals to that effect submitted by US – SCP/19/4 and SCP/23/4 -, the proposal made by the Republic of Korea, the UK and US – SCP/20/11, the proposal made by Spain and endorsed by all other Member States of the EU - SCP 19/5/rev and SCP 24/3, as well as earlier proposals concerning quality of patents made by Denmark, Canada, the UK and US under SCP/17/7, 8, 10, and SCP/18/9.

We believe that the presentations that some EU member states will deliver on this item, will contribute to the ongoing discussions.

We look forward to a constructive discussion and are ready to commence our work to the benefit of all WIPO member states.

Thank you.

WIPO - Standing Committee on the Law of Patents

Twenty-Fifth Session

Geneva, 12-15 December 2016

Patents and Health – Opening Statement

Madam Chair,

The European Union and its Member States are committed to increasing access to affordable medicines and to find solutions to the world's pressing public health challenges and inequities. In line with the 2010 Communication and Council Conclusions on 'the EU role in Global Health', the EU pursues a rights-based approach to health. Strengthening all areas of a health system, including the availability of qualified health workers, the provision of affordable medicines and the adequate financing of the sector, is central to moving towards universal health coverage with quality health services accessible and affordable for all. The quality and integrity of the pharmaceutical distribution chain is also essential to improving public health.

The current innovation model, including the role of trade related to IP, has delivered consistent progress in global public health, leading to key new and improved treatments as well as much extended life expectancy, both in developed and least developed countries. This model already integrates a variety of tools such as incentives for innovation based on intellectual property, on public and private financing and awards or on public research. Such variety is necessary to address situations, where there is a functioning market and those where there could be market failures.

The European Union and its Member States take note of the contribution provided by the Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, and of the subsequent message of the Secretary-General, which encourages all stakeholder to chart a way forward in appropriate fora to ensure access to medicines and health technologies for all who need them, wherever they are.

We would recall that the HLP is not a MS-driven process and that WIPO remains a MS-driven organisation. The HLP report has not been endorsed by any UN body or agency, nor did the members of the HLP reach consensus on the recommendations contained in the report. We would also like to recall the important and authoritative contribution of the tri-lateral WIPO-WTO-WHO study entitled “Promoting access to medical technologies” to discussions on this topic.

Thank you, Madam Chair.

WIPO - Standing Committee on the Law of Patents

Twenty-Fifth Session

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Patents and Health – High Level Panel Report

Madam Chair,

The European Union and its Member States take note of the contribution provided by the Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, and of the subsequent message of the Secretary-General, which encourages all stakeholder to chart a way forward in appropriate fora to ensure access to medicines and health technologies for all who need them, wherever they are.

The work conducted by the Panel started from an assumption that there was a "policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health". As the European Commission already indicated in its written contribution to the Panel, it does not share this assumption.

The European Union and its Member States share the Report's acknowledgement that there are many reasons "why people do not get the healthcare they need, ranging from: under-resourced health systems, a lack of sufficiently qualified and skilled healthcare workers, inequalities between and within countries, exclusion, stigma, discrimination and exclusive marketing rights". Another important problem are the global medicines shortages and stock-outs.

This is why in its written contribution to the Panel, the European Commission encouraged it to adopt a holistic approach to the problem of access to medicines that could result in a valuable contribution to the wider debate.

However, due to its limited mandate, the High-Level Panel has focused its proposals exclusively on addressing an alleged conflict between a research and development model that (partially) relies on intellectual property rights and the possibility of providing affordable medicines. In doing so, it has missed an opportunity to advance more balanced, comprehensive and workable solutions to the problem of access to health. The European Union and its Member States would also highlight that no conclusions could be reached with the support by all Members of the Panel, as demonstrated by the dissenting opinions attached to this report.

The European Union and its Member States are committed to increasing access to affordable medicines and to find solutions to the world's pressing public health challenges and inequities. In line with the 2010 Communication and Council Conclusions on 'the EU role in Global Health', the EU pursues a rights-based approach to health. Strengthening all areas of a health system, including the availability of qualified health workers, the provision of affordable medicines and the adequate financing of the sector, is central to moving towards universal health coverage with quality health services accessible and affordable for all. The quality and integrity of the pharmaceutical distribution chain is also essential to improving public health.

The challenge is to strike the right balance between the need to promote and finance the research of new and better medicines for all, ensuring that medicines are accessible and affordable to those in need, while guaranteeing the sustainability of health systems. We believe that these goals are not contradictory and must be pursued jointly.

The current innovation model, including the role of trade related to IP, has delivered consistent progress in global public health, leading to key new and improved treatments as well as much extended life expectancy, both in developed and least developed countries. This model already integrates a variety of tools such as incentives for innovation based on intellectual property, on public and private financing and awards or on public research. Such variety is necessary to address situations, where there is a functioning market and those where there could be market failures.

The Report underplays the fact that the development of new drugs requires significant investment and long-term research, coupled with clinical trials and regulatory approval procedures. The exclusive right conferred by a patent is an important incentive for innovator pharmaceutical companies to make the necessary investments into that research and development. Without incentivizing the innovator pharmaceutical companies to invest in research, the sustainable development goal of ensuring healthy lives and promoting well-being for all, including achieving universal health coverage, would be severely undermined.

Several of the issues covered in the report's recommendations are addressed in EU legislation, EU & Commission policies and actions, including at multilateral level. To name a few examples: the Commission is a major funder of research and innovation for poverty-related and neglected diseases and for new antibiotics. At the WHO, the EU and the Member States supports the implementation of the WHO global strategy and plan of action on public health, innovation and intellectual property, including the development of the Global Observatory on Health Research and Development. In the area of trade, the EU ensures that its free trade agreements are consistent with the Doha Declaration and it has supported the extension of the drug patent exemption for least-developed countries. As part of its health policy, the EU adopted new legislation to ensure that all clinical trials to be conducted in the EU will be registered in a publicly accessible EU database (Regulation EU No 536/2014).

However, several other recommendations are not in line with the EU rules and practices and thus cannot be supported. This is, in particular the case for the proposals to revise the paragraph 6 decision or the TRIPS Agreement on these matters, the recommendations in relation to INN and standard international common names for biological products, and the proposal to create additional structures at UN level on the issue of health technology innovation and access.

Any future activities at the UN level in this area should be conducted on the basis of a much broader understanding of the complex issues involved.

Thank you, Madam Chair.

WIPO - Standing Committee on the Law of Patents

Twenty-Fifth Session

Geneva, 12-15 December 2016

Patents & Health – INN disclosure

Related documents: SCP/16/7, SCP/16/7 Corr., SCP/17/11, SCP 21/9 and SCP/24/4.

Madam Chair,

This intervention is made on behalf of the EU and its Member States.

The EU and its Member States wish to reiterate their understanding of the challenges and constraints certain countries may face in handling public health problems. Availability of medicines to treat certain illnesses is a major challenge and a key Sustainable Development Goal that we all support.

In relation to the feasibility study on the disclosure of international non-proprietary names (INN) in patent applications and/or patents, contained in document SCP/21/9, we reiterate our position expressed at previous SCP sessions.

On the basis of the information assessed and provided by the study, the case for a disclosure requirement of INNs has not been made. The costs and benefits for such a disclosure requirement are unclear, and the study highlights other limitations.

First of all, it is impossible to disclose, at the time of filing, the future corresponding and yet to be published INN in patent applications filed before the publication of the Recommended INN. In this scenario, the preliminary findings point to the major challenge of how to retroactively link the corresponding INN information to such applications without unduly burdening applicants and patent offices.

The feasibility study also highlights limitations in cases where the INN is known. Here it should be noted that the mere indication of INN in patent applications is not sufficient to find out, with one click, what a patent searcher is looking for.

At the same time, the study points to the fact that patent searchers have developed methodologies to search patents for a medicine, primarily using publicly available databases, and that increasing sophistication of IT tools might significantly contribute to a simpler and more cost efficient patent search in the fields of chemistry and pharmacology.

We believe that any further work in this area should reflect a balanced approach, taking into account the various factors of relevance to patents and health as for example proposed by the United States of America in document SCP/17/11.

At the same time we still have to bear in mind not to go beyond the mandate of the SCP and the WIPO mandate and leave discussions about other factors than patent protection of access to medicines to other relevant UN organizations.

Thank you.

WIPO - Standing Committee on the Law of Patents

Twenty-Fifth Session

Geneva, 12-15 December 2016

Confidentiality of communications between clients and their patent advisors

Related documents: SCP/25/4

Madam Chair**,**

This intervention is made on behalf of the EU and its Member States.

The European Union and its Member States thank the WIPO secretariat for preparing a compilation of court cases with respect to client-patent advisor privilege based on the information provided by members, and presented in document SCP/25/4.
We also welcome the information submitted by Japan and Switzerland, and thank WIPO for making this information available on the dedicated WIPO website to this topic, namely Compilation of laws and practices regarding the scope of client attorney privilege and its applicability to patent advisors[1].

In relation to confidentiality of communications between clients and their patent advisors, time is ripe to consider a concrete mechanism to address the recognition of foreign patent advisors' privilege.
Without prejudice to existing national legislation and in order to ensure optimal flexibility, a soft law approach should be considered, aiming at conferring in Member States the same protection to communications between a client and its foreign patent adviser than that applicable under national law to communications between a client and its national patent adviser.

[1] http://www.wipo.int/scp/en/confidentiality_advisors_clients/national_laws_practices.html

The convergence of existing diverse systems in the area of confidentiality of communications between clients and patent advisors among WIPO Member States would be beneficial for users of the patent system, irrespective of the level of development of individual WIPO Member States.

Thank you.

WIPO - Standing Committee on the Law of Patents

Twenty-Fifth Session

Geneva, 12-15 December 2016

Transfer of technology

Madam Chair,

This intervention is made on behalf of the EU and its Member States.

The EU & its Member States are of the view that an excellent overview of work that WIPO performs in the area of Transfer of technology was produced by the CDIP where thorough discussion on the evaluation report on the '"Project on Intellectual Property and Technology Transfer: Common Challenges – Building Solutions" was held at its meeting in April 2016.

We would like to emphasize that the SCP should avoid duplicating the efforts of CDIP in this respect. Nevertheless, we are committed to consider proposals to deepen our understanding of the impact of patent disclosure on transfer of technology and as a concrete step we suggest to update the existing WIPO webpage on Technology Transfer.

Thank you.

WIPO - Standing Committee on the Law of Patents

Twenty-Fifth Session

Geneva, 12-15 December 2016

Proposal of the Group of Countries of Latin America and the Caribbean (GRULAC) on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions

Related document: SCP/22/5.

Madam Chair,

This intervention is made on behalf of the EU and its Member States.

The EU & its Member States would like to reiterate that in respect of the GRULAC proposal to revise the 1979 WIPO Model Law for Developing Countries on Inventions included in SCP/22/5, there is the tailor made and demand driven technical assistance by the WIPO Secretariat being provided along the lines of the Development Agenda Recommendations.

This technical assistance takes into account specific country needs and situations, in a way that is much more wide ranging than a simple application of the Model law would be. As yet, no convincing arguments for revision of the model law were presented in order to further consider the proposal.

If taken forward, a revision would lead to a substantive harmonization of the patent law. In which case we could use the opportunity and start with harmonization of other aspects of patent law, which could be beneficial to all.

We would like to emphasize once again that WIPO should not touch upon interpretation of the TRIPS provisions.

Thank you.

WIPO - Standing Committee on the Law of Patents

Twenty-Fifth Session

Geneva, 15 December 2016

Patents and Health – Closing Statement

Thank you Madam Chair,

Firstly, the EU would like to thank you and your Vice-Chairs for your work in chairing this Committee.
The EU would like to join other delegations in their regret that no consensus was reached on future work at this Committee. In particular, the EU would have wished to see an item on the contribution of innovation to the improvement of global public health.

As the distinguished delegate from Nigeria touched upon Anti-Microbial Resistance in her closing statement, allow me to briefly comment on this matter. In the EU, 25.000 people die each year from an infection due to antibiotic-resistant bacteria, and infections due to these selected multidrug-resistant bacteria in the EU result in extra healthcare costs and productivity losses of at least €1.5 billion each year. More importantly than the monetary losses, however, 300 million people worldwide are expected to die prematurely because of drug resistance over the next 35 years.

It is an important global economic and a societal challenge that can't be tackled by countries or public administrations alone. Therefore, the problem needs a comprehensive "One Health" approach to it. That means that a holistic, multi-sectorial approach, involving many different sectors – public health, food safety, bio-safety, environment, research and innovation, international cooperation, animal health and welfare as well as non-therapeutic use of antimicrobial substances. These are all needed to tackle this complex problem.

The EU backs up its statements with actions. In recent years alone – in the period 2007-2013 – 150 million Euros have been invested by the EU in research and development programs to combat AMR.
Thank you Chair.