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

ANNEX

Standing Committee on the Law of Patents

27th Session

(WIPO, Geneva, 11–15 December 2017)

General / Opening Statement

Mr Chair,

1. I am speaking on behalf of the EU and its Member States. First, we wish to congratulate you, Mr Pardo, on your election as the Chair of this important Committee. We would also like to welcome the new Vice-Chairs and thank the WIPO Secretariat for its work in preparing for this meeting.

2. We are pleased to note the success of the previous session of the Committee in constructively discussing and advancing the five main topics on the agenda of the SCP and in deciding on the future work of the Committee. The EU and its Member States are committed to constructively engage in our discussions on the basis of the agreed work programme for this week.

3. We note that it was decided that the current session of the SCP would further elaborate and discuss the non-exhaustive list of issues which have been discussed in the Committee during its past meetings. Without prejudice to the mandate of the SCP, the Committee agreed that its work for this session be confined to fact-finding and not lead to harmonisation at this stage. However, as the EU and its Member States have repeatedly emphasised, harmonisation of substantive patent law should be seen as the mid and long term aim of this Committee. Our present fact-finding work and discussions are of course highly relevant for this future work.

4. The programme for the coming days should provide opportunities for all of us to make steps forward on important issues. In particular, the EU and its Member States attach considerable importance to advancing work on the "Quality of Patents", as we believe that work on this topic would be of interest to member states across the spectrum of development. We are also 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.

5. On patents and health, 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. At the same time we would like to recall that we cannot go beyond the mandate of the SCP and WIPO, and discussions about other factors of access to medicines than patent protection should be left to other more appropriate fora.

6. The EU and its Member States express hope that, similarly to SCP 26, the Committee will manage to agree during this session on a work programme for its future sessions. We reiterate the importance of retaining the delicate balance between the topics discussed in the Committee.

7. 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.

8. Mr Chair, we remain committed to the work of this Committee and look forward to a constructive session.

Thank you.

Standing Committee on the Law of Patents

27th Session

(WIPO, Geneva, 11–15 December 2017)

Report on the international patent system:

Certain aspects of national/regional patent laws

(SCP/27/2)

Chair,

1. I am speaking on behalf of the European Union and its Member States. The EU and its Member States would like to thank the WIPO secretariat for preparing the document SCP/27/2.

2. We would also like to thank Bhutan, Germany, Jordan and Montenegro for their input based on which the SCP electronic forum website has been updated. The SCP website serves as a useful reference in our discussions and a good basis for better understanding certain aspects of national and regional patent laws. Thus, it is important to keep it up to date.

3. We would also like to thank Singapore for the interesting presentation. We remain interested in any information on recent developments of national/regional patent laws.

Thank you.

Standing Committee on the Law of Patents

27th Session

(WIPO, Geneva, 11–15 December 2017)

Exceptions and limitations to patent rights

(SCP/27/3)

(Related documents: SCP/14/7, SCP/19/6)

Mr Chair,

1. I am speaking on behalf of the EU and its Member States. The EU and its Member States would like to thank the WIPO Secretariat for preparing a draft reference document on the exception to patent rights regarding acts for obtaining regulatory approval from authorities in document SCP/27/3. We have read the document with great interest. We are also very grateful for today's presentation.

2. We wish to highlight the broad information and resource base from which the document has benefited. As noted in the introduction, the primary source of information for the preparation of the reference document was information collected through the SCP activities. As such, it is a good example of making use of this information and the work that has been conducted by the SCP in the past.

3. The reference document covers the list of issues which the Committee decided to address at its last session. In particular, it provides for a description of the regulatory review exception, an overview of its objectives and goals, national/regional implementation, challenges faced by member States in implementing the exception, and results of the national/regional implementation. However, we note that compared to the agreed list of issues, the element of "the multilateral legal framework of the regulatory review exception" has been added by the Secretariat. Considering its relevance to the topic at hand, we consider the overview provided of the WTO Dispute Settlement Panel Report regarding the *Canada – Patent Protection of Pharmaceutical Products* case justified.

4. It was interesting to learn that the exception is found in the applicable laws of more than 65 countries and that different approaches are taken in implementing this exception in the national level as regards to various important elements of its implementation, such as the source of law, beneficiaries, products and acts covered by the exception, as well as the conditions of taking advantage of the exception.

5. We are particularly interested in the part dealing with results of implementation of the exception in national/regional laws. On the one hand it appears that some Member States reported positive effects on the timeliness of regulatory registration and entry of generic versions of medicines into the market. On the other hand, the impact of the exception on competition between originator and generic products and reduction of price of the originator products remains unclear.

6. As to the challenges faced by Member States in implementation of the exception, it appears that these challenges are mostly related to uncertainty about the scope of the exception in the national laws and lack of awareness about this exception among potential users. We note that such challenges could be addressed by relevant and carefully targeted awareness raising and training activities.

7. Based on the draft reference document, there does not appear to be a specific need for normative work on the international level concerning the regulatory review exception at this stage.

8. At SCP 26 it was decided that preparation of the draft reference document covering the exception regarding acts for obtaining regulatory approval from authorities would be a first step of the work of the SCP in analysing the specific exceptions and limitations to patent rights in conjunction with patent protection. We are ready to further discuss the value of this exercise and whether it should be repeated for other exceptions and limitations. In general, the EU and its Member States are supportive of initiatives which truly contribute to our knowledge and understanding of the topic of exceptions and limitations, including those which have the potential of addressing development issues.

9. We would like to take this opportunity to emphasise again the utmost importance of striking an appropriate balance between work on exceptions and limitations to patent rights and on the legal standards used to determine whether an invention is patentable, such as novelty, inventive step, and industrial applicability. These two topics are closely interlinked, therefore, a holistic approach should be taken in order to find an appropriate balance between the interests of rights holders and the general public.

10. We look forward to hearing the views of other participants on the draft reference document and a constructive discussion on this agenda item.

Thank you.

Standing Committee on the Law of Patents

27th Session

(WIPO, Geneva, 11–15 December 2017)

Quality of patents, including opposition systems

(SCP/27/4 Rev., SCP/27/5 Rev.)

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

Chair,

1. I am speaking on behalf of the EU and its Member States. We continue to reiterate our strong support and commitment for advancing work on the topic of quality of patents. We are glad that at the last session of the SCP we managed to agree on an appropriate work programme on this topic for this session.

2. We thank the Secretariat for updating the summary of the responses to the Questionnaire on the term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination, taking into account the additional responses that were submitted by Member States after SCP 26. We are glad to note that it proved justified to give additional Member States and regional patent offices the possibility to submit responses to the questionnaire, as 20 new contributions were made. This increases the weight and value of the outcomes of the questionnaire even more.

3. As already stated at SCP 26, the EU and its Member States found the questionnaire and the compilation of answers prepared by the Secretariat helpful as we pursue work in the area of quality of patents. The results help us to gain a better understanding of how each Member State understands the term “quality of patents”. Although there are various approaches to which factors define the “quality of patents” and the meaning of the term may be different for each stakeholder in different contexts, there nevertheless appears to be a similar understanding of the main issues. We are confident that the findings of the questionnaire will prove useful in carrying out our work in the area of quality of patents and in engaging in harmonisation of substantive patent law in the future. The additional questions set out in the proposal by Canada and the UK in SCP/18/9 may provide a useful next step in this area and would allow the committee to learn more about how Member States evaluate and improve quality.

4. The updates made to the second part of the compilation of answers in document SCP/27/5 Rev. reinforce our earlier conclusion that there is extensive cooperation between IP offices and a wide and growing use of different collaboration methods at the bilateral, regional and international level. As expected, such cooperation has been found to facilitate the work of IP offices. It has also proven to have a positive impact on the efficiency of patent examination and the validity of granted patents.

5. Given the potential positive benefits of work-sharing, the EU and its Member States welcome the decision of SCP 26 to hold a half-day information exchange session on cooperation between patent offices in search and examination during this session. We look forward to hearing about the experiences and successful examples of WIPO Members, including the effects of such cooperation on patent granting procedures and capacity building. The EU and its Member States have continued to encourage more widespread use of work-sharing among patent offices of different sizes and from different levels of development. We trust that sharing sessions such as the one scheduled for this week will encourage more member states to learn about and participate in work sharing programmes.

6. In addition to facilitating the exchange of information and experiences, we continue to see merit in a study by the WIPO Secretariat on how different laws and practices may limit the potential for work-sharing and what voluntary measures could be put in place to address any problems at the international level. We thank the Secretariat for maintaining and updating a dedicated page on WIPO's website for existing work sharing activities that improves awareness of existing initiatives and enables patent offices to collaborate more efficiently. The WIPO CASE platform can be seen as a good example of cooperation between IP offices and dissemination of information about a particular method of work-sharing.

7. The EU and its Member States welcome the decision of the Committee to have a sharing session at this SCP on examples and cases relating to assessment of inventive step, giving particular attention to the topics suggested in the proposal by Spain contained in document SCP/24/3. Inventive step is a central concept in substantive patent law and its proper evaluation is key to guaranteeing a high quality patent system. Thus, we welcome the fact that this complex topic has continued to be discussed in the SCP. We believe that these discussions on the concept as well as methods of assessing the inventive step used in the WIPO Member States greatly benefit our work in this area. This is evidenced by the success and usefulness of a similar sharing session held during SCP 25. We are confident that this week's sharing session will also be useful for preparing a further study on inventive step to be submitted to SCP 28.

8. As for our future discussions on the topic of quality of patents, the EU and its Member States would like to reiterate support for advancing work in this Committee pursuant to the proposals made by the US (SCP/19/4 and SCP/23/4) and the Republic of Korea, the UK and US (SCP/20/11 Rev.), as well as earlier proposals concerning the quality of patents made by the Delegations of Canada and the UK (document SCP/17/8), the Delegation of Denmark (document SCP/17/7), and the Delegation of the US (document SCP/17/10). We are committed to contribute to advancing our work under a work program on Quality of Patents which reflects key elements of these contributions.

9. We look forward to a constructive discussion on this agenda item.

Thank you.

Standing Committee on the Law of Patents

27th Session

(WIPO, Geneva, 11–15 December 2017)

Patents and health

(SCP/27/6, SCP/27/8)

(Related documents: SCP/16/7, SCP/16/7 Corr., SCP/17/11 and SCP/24/4 and SCP/26/6)

Chair,

1. I am speaking 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. Access to safe, effective, quality and affordable essential medicines and vaccines for all is a major challenge and a key Sustainable Development Goal that we all must support. The European Union and its Member States remain committed to increasing access to affordable medicines and to find solutions to the world's pressing public health challenges and inequities.

2. As set out in the 2010 Communication and Council Conclusions on 'the EU role in Global Health', the EU pursues a human 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.

3. 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, from developed to 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.

4. We continue to believe that any further work in this area of patents and health 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.

5. We thank the Secretariat for the preparation of document SCP/27/6 on constraints faced by developing countries and LDCs in making full use of patent flexibilities and their impacts on access to affordable especially essential medicines for public health purposes in those countries, supplementing document SCP/26/5. We take note of this further work, which complements the study with input from members and observers of the SCP.

6. The EU and its Member States welcome the revised proposal by the delegation of Canada in document SCP/27/8. As already stated during SCP 26, we see merit in conducting an analysis of existing research on the topic of patent protection and access to medical products and health technologies. We are glad to note that several comments made by the EU and its Member States about the earlier version of the proposal have been taken on board in the revised version. In particular, the terms “medical products and health technologies” have been clarified, and the scope of the proposed paper has been better confined to the mandate of the SCP.

7. Considering the changes made to the initial proposal, the EU and its Member States are prepared to discuss the proposal further. We reiterate our past position that in order to ensure the highest quality of evidence relied on by the SCP, the report should include high quality, independent and evidence-based relevant studies, in particular studies prepared by UN organisations, such as WIPO and the WHO, as well as the WTO. We also wish to emphasise that we see the role of the potential report as a collection of information and a document supporting our future discussions in the SCP, and not an outline of different policy options for WIPO.

Thank you.

Standing Committee on the Law of Patents

27th Session

(WIPO, Geneva, 11–15 December 2017)

Confidentiality of communications between clients and their patent advisors

Chair,

1. I am speaking on behalf of the European Union and its Member States.

2. The EU and its Member States welcome the decision of SCP 26 to hold a sharing session on the experiences of Member States in implementing the confidentiality of communication between clients and their patent advisors through national legislation, including cross-border issues. We see this as an opportunity to get valuable insight into national practices, supplementing the compilation of court cases with respect to client-patent advisor privilege prepared by the Secretariat and presented in document SCP/25/4.

3. As stated on previous occasions, the EU and its Member States would like to see further action taken to address the recognition of foreign patent advisors' privilege. We believe that work on a non-legally binding instrument would be beneficial to all WIPO Member States. The potential soft law instrument should aim at conferring in Member States the same protection to communications between a client and its foreign patent adviser as that applicable under national law to communications between a client and its national patent adviser. This should be without prejudice to existing national legislation and should ensure optimal flexibility.

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

Thank you.

Standing Committee on the Law of Patents

27th Session

(WIPO, Geneva, 11–15 December 2017)

Transfer of technology

Chair,

1. I am speaking on behalf of the European Union and its Member States. The EU and its Member States are of the view that the transfer of technology is an important factor in fostering development. We therefore welcome the decision of SCP 26 to hold a sharing session this week on patent law provisions that contributed to effective transfer of technology.

2. However, considering that the CDIP has produced an excellent overview of the work that WIPO is performing in this area, our position is that the SCP should avoid duplicating the efforts of the CDIP in this respect.

3. We note that during the recent CDIP 20 the WIPO Secretariat introduced the compilation of technology exchange and licensing platforms contained in document CDIP/20/10 Rev. We consider this information extremely useful in obtaining an overview of the situation and informing WIPO's work in this area. We are glad to see the relatively big number of national, regional and international platforms covered in this non-exhaustive compilation. We draw attention to the fact that out of the five relevant regional networks and platforms covered in the compilation, two are located in Europe and hosted by the European Commission, indicating the importance attached by the EU to the issue of technology transfer. We take note of the various challenges related to technology transfer and licensing platforms identified in the document and acknowledge the need to keep in mind that these challenges pose particular difficulties in developing and least developed countries. We also welcomed the revamped match-making tool WIPO Match.

4. We continue to support updating the WIPO webpage on Technology Transfer regarding information on national, regional and international technology exchange and technology licensing platforms.

Thank you.