

## **Standing Committee on the Law of Patents**

**Twenty-Ninth Session**  
**Geneva, December 3 to 6, 2018**

### **DRAFT REPORT**

*prepared by the Secretariat*

1. The Standing Committee on the Law of Patents (the “Committee” or the “SCP”) held its twenty-ninth session in Geneva from December 3 to 6, 2018.
2. The following Member States of WIPO and/or the Paris Union for the Protection of Industrial Property were represented: Albania, Algeria, Argentina, Australia, Austria, Azerbaijan, Bahamas, Barbados, Belarus, Bhutan, Bolivia (Plurinational State of), Bosnia and Herzegovina, Brazil, Burkina Faso, Canada, Chile, China, Colombia, Costa Rica, Côte d’Ivoire, Croatia, Czech Republic, Democratic People’s Republic of Korea, Denmark, Djibouti, Ecuador, Egypt, El Salvador, Estonia, Finland, France, Gabon, Germany, Ghana, Greece, Guatemala, Honduras, Hungary, India, Indonesia, Iran (Islamic Republic of), Ireland, Israel, Italy, Japan, Kazakhstan, Kenya, Kuwait, Kyrgyzstan, Latvia, Lithuania, Madagascar, Malaysia, Malta, Mexico, Mongolia, Morocco, Nepal, Nicaragua, Nigeria, Norway, Oman, Pakistan, Paraguay, Philippines, Poland, Portugal, Qatar, Republic of Korea, Romania, Russian Federation, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sudan, Sri Lanka, Sweden, Switzerland, Tajikistan, Thailand, The Former Yugoslav Republic of Macedonia, Tunisia, Turkey, Uganda, United Arab Emirates, United Kingdom, United States of America, Uruguay, Zimbabwe (92).
3. Palestine was represented in an observer capacity. Representatives of the following intergovernmental organizations took part in the meeting in an observer capacity: European Patent Organization (EPO), Eurasian Patent Organization (EAPO), European Union (EU), Patent Office of the Cooperation Council for the Arab States of the Gulf (GCC Patent Office), South Centre (SC), United Nations (UN), World Health Organization (WHO), World Trade Organization (WTO) (9).

4. Representatives of the following non-governmental organizations took part in the meeting in an observer capacity: Asian Patent Attorneys Association (APAA), Centre for International Intellectual Property Studies (CEIPI), Civil Society Coalition (CSC), CropLife International (CROPLIFE), Drugs for Neglected Diseases initiative (DNDi), European Law Students' Association (ELSA International), Innovation Insights, Institute of Professional Representatives Before the European Patent Office (EPI), International Association for the Protection of Intellectual Property (AIPPI), International Center for Trade and Sustainable Development (ICTSD), International Chamber of Commerce (ICC), International Federation of Intellectual Property Attorneys (FICPI), International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Japan Intellectual Property Association (JIPA), Japan Patent Attorneys Association (JPAA), Knowledge Ecology International, Inc. (KEI), Médecins Sans Frontières (MSF), Medicines Patent Pool Foundation (MPP), Third World Network Berhad (TWN), Union of European Practitioners in Industrial Property (UNION) (20).
5. A list of participants is contained in the Annex to this report.
6. The following documents prepared by the Secretariat were submitted to the SCP prior to the session: "Draft Report" (SCP/28/12 Prov.2.); "Draft Agenda" (SCP/29/1 Prov.); "Report on the International Patent System: Certain Aspects of National/Regional Patent Laws" (SCP/29/2); "Reference Document on Research Exception (SCP/29/3); "Further Study on Inventive Step (Part I)" (SCP/29/4); "Confidentiality of Communications between Clients and their Patent Advisors: Compilation of Laws, Practices and other Information (SCP/29/5); "Summary of Document SCP/29/5: Confidentiality of Communications between Clients and their Patent Advisors: Compilation of Laws, Practices and other Information" (SCP/29/5 Summary); "Patent Law Provisions that Contribute to Effective Transfer of Technology, Including Sufficiency of Disclosure" (SCP/29/6); "Corrigendum to Document SCP/29/6" (SCP/29/6 Corr.).
7. In addition, the following documents prepared by the Secretariat were also considered by the Committee: "Proposal from Brazil" (SCP/14/7); "Proposal Submitted by the Delegation of South Africa on Behalf of the African Group and the Development Agenda Group" (SCP/16/7); "Corrigendum: Proposal Submitted by the Delegation of South Africa on Behalf of the African Group and the Development Agenda Group" (SCP/16/7 Corr.); "Proposal by the Delegation of Denmark" (SCP/17/7); "Revised Proposal from the Delegations of Canada and the United Kingdom" (SCP/17/8); "Proposal by the Delegation of the United States of America" (SCP/17/10); "Patents and Health: Proposal by the Delegation of the United States of America" (SCP/17/11); "Questionnaire on Quality of Patents: Proposal by the Delegations of Canada and the United Kingdom" (SCP/18/9); "Proposal by the Delegation of the United States of America regarding Efficiencies of the Patent System" (SCP/19/4); "Proposal by the Delegation of Brazil regarding Exceptions and Limitations to Patent Rights" (SCP/19/6); "Proposal by the Delegations of the Republic of Korea, the United Kingdom and the United States of America regarding Work Sharing between Offices in order to Improve Efficiencies of the Patent System" (SCP/20/11 Rev.); "Proposal by the Delegation of the United States of America on the Study of Worksharing" (SCP/23/4); "Proposal by the Delegation of Spain" (SCP/24/3); "Proposal by the African Group for a WIPO Work Program on Patents and Health" (SCP/24/4); "Proposal by the Delegation of Spain" (SCP/28/7); "Proposal by the Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom (SCP/28/8); "Revised Proposal by the Delegations of Argentina, Brazil, Canada and Switzerland" (SCP/28/9 Rev.); and "Revised Proposal by the Delegations of Argentina, Brazil, Chile and Switzerland" (SCP/28/10 Rev.).
8. The Secretariat noted the interventions made and recorded them. This report summarizes the discussions on the basis of all observations made.

## **AGENDA ITEM 1: OPENING OF THE SESSION**

9. Mr. Dámaso Pardo, elected Chair of the SCP, opened the twenty-ninth session of the Standing Committee on the Law of Patents.

10. Mr. Francis Gurry, Director General of the World Intellectual Property Organization (WIPO), welcomed the participants. Mr. Marco Alemán, (WIPO) acted as Secretary to the SCP.

## **AGENDA ITEM 2: ADOPTION OF THE AGENDA**

11. The SCP adopted the draft agenda (document SCP/29/1 Prov.), with inclusion of documents SCP/28/10 Add. and SCP/29/6 Corr.

## **AGENDA ITEM 3: ADOPTION OF THE DRAFT REPORT OF THE TWENTY-EIGHTH SESSION**

12. The Committee adopted the draft report of its twenty-eighth session (document SCP/28/12 Prov.2), as proposed.

## **GENERAL STATEMENTS**

13. The Delegation of Switzerland, speaking on behalf of Group B, expressed its appreciation to the Chair for its guidance in the Committee. Further, the Delegation thanked the Secretariat and the WIPO Conference Section for the preparation of the twenty-ninth session of the SCP, including the two half-day conferences and sharing sessions. The Delegation expressed its appreciation for the efforts and willingness of all Member States during the previous session that had led to a balanced work program. The Delegation hoped that such constructive spirit would prevail during the twenty-ninth session. Further, the Delegation stressed the importance of the SCP, which was the only multilateral forum on patents. With that regard, the Delegation believed that discussions during the Committee including those on the future work, should be beneficial to the real world, including IP offices, innovators, practitioners and other users of the patent system. The Delegation thanked the Member States that had provided the Secretariat with updated information for the SCP Electronic Forum. The Delegation pointed out that the Committee's work on the quality of patents continued to be a priority issue. The Delegation therefore welcomed the sharing session on opposition and administrative revocation mechanisms as well as the sharing of experiences on cooperation between patent offices in search and examination. Further, the Delegation supported further discussions on the subject of inventive steps and thanked the Secretariat for further study on inventive step (document SCP/29/4). The Delegation attached considerable importance to advancing work on the topic of confidentiality of communications between clients and their patent advisors. In its opinion, the protection of confidentiality might impact the quality of the patent protection process and the quality of the patent to be issued. Further, the Delegation pointed out that the users of the patent system had expressed their need to work in a trustful environment throughout the entire patent prosecution process, including cross-border situations. Taking into account the differences in patent protection provisions, the Delegation believed that the convergence of approaches in the form of a soft law would contribute to a predictable, more qualitative patent framework. In that regard, the Delegation stated that Group B was ready to engage in the discussions and to work on other issues related to exceptions and limitation to patent rights, patents and health as well as technology transfer. Further, the Delegation highlighted that during the discussions, the interests of all relevant stakeholders, including the broader public

and right holders, should be taken into account and the discussions should be balanced. The Delegation also added that the discussions and the work of the Committee should not duplicate the efforts of other WIPO Committees or international fora. In conclusion, the Delegation looked forward to constructive discussions.

14. The Delegation of Morocco, speaking on behalf of the African Group, expressed its confidence in the experience and leadership skills of the Chair and also expressed its appreciation to the Chair for its guidance in the Committee. Further, the Delegation thanked the Secretariat for the preparation of the twenty-ninth session of the SCP. In addition, the Delegation underlined the importance and significance of the SCP's role as a multilateral forum which enabled Member States to discuss fundamental issues. The Delegation pointed out that the work of the SCP was essential for the development and balanced use of the patent system and that it could play a significant role in the achievement of socio-economic development of Member States. In that regard, the Delegation was of the view that the SCP should provide a well-balanced response to the needs and interests of the different stakeholders in the international patent world. The Delegation thanked the Secretariat for updating the SCP Electronic Forum. The African Group looked forward to the information exchange sessions under items 6 and 7 of the agenda as well as to the related sharing sessions. The Delegation expressed its hope that those sessions would help to improve the effectiveness of the patent system, taking into account, in particular, the interests of developing countries and least developed countries (LDCs). The Delegation took note of document SCP/29/3 on exceptions and limitations to patent rights, and thanked the Secretariat for the preparation of the study. The Delegation was of the view that exceptions and limitations were an integral part of a solid patent system, especially since they established a balance between general interest and the rights of patent holders. In particular, the Delegation pointed out that document SCP/29/3 enabled Member States to have a clearer understanding of those exceptions and limitations as well as a better understanding and explanation of those exceptions and limitations to patent rights. Further, the Delegation noted that the discussions on patents and health remained crucial in order to promote a more balanced patent system. Therefore, the Delegation pointed out that that issue became a priority for the African Group. In that regard, the Delegation recalled the Sustainable Development Goals (SDG Agenda 2030). Specifically, SDG Goal 3 aimed at ensuring healthy lives and promoting wellbeing for all. In that regard, the Delegation recalled the proposal contained in document SCP/24/4. In particular, the Delegation was of the view that that document was an excellent basis for discussion on policy priorities of public authorities in the area of public health, and that it gave a solution for international challenges in terms of access to affordable medicines. Further, the Delegation supported discussions on the opposition systems which was an important issue in Agenda Item 6. The Delegation further emphasized that the Committee should give equal prominence to that issue in the work of the SCP as it did to the issue of quality of patents. Further, the Delegation stressed the importance of the contribution of all the competent bodies of WIPO to the implementation of the WIPO Development Agenda Recommendations. In that regard, the Delegation recalled the decision of the General Assembly of WIPO in 2010, which had requested the WIPO competent committees to include in their annual reports contributions to the implementation of the Development Agenda Recommendations. The Delegation pointed out that the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore was the only committee that had submitted its contribution to the WIPO Development Agenda Recommendations. The Delegation stressed the importance of that contribution, and invited the other committees to accomplish that task.

15. The Delegation of El Salvador, speaking on behalf of the Group of Latin American and Caribbean Countries (GRULAC), expressed its appreciation to the Chair and Vice-Chairs for their guidance in the Committee. Additionally, the Delegation thanked the Secretariat for its excellent work in preparing the meeting and the published documentation. The Delegation stated that the activities of the Committee were highly important, as they dealt with issues

having substantial impact on the development of all Member States. Further, the Delegation pointed out that substantive issues such as exceptions and limitations to patent rights, patents and health and the transfer of technology, were matters of special importance for its Group. The Delegation stressed the importance of advancing work on the quality of patents, because it believed that the work on that topic was crucial for access to new technologies. Therefore, the Delegation looked forward to the discussions under Agenda Item 6. With regard to Agenda Item 5 on exceptions and limitations to patent rights, the Delegation thanked the Secretariat for document SCP/29/3 which contained valuable information. With regard to Agenda Item 7, the Delegation thanked the Secretariat for organizing the half day conference on publicly accessible databases on patent information status and data, on medicines and vaccines. In that regard, the Delegation expressed its hope that the half-day conference would have a positive and concrete impact on the Committee's work. With regard to transfer of technology, the Delegation reiterated the importance of that topic for developing countries and LDCs. In that regard, the Delegation thanked the Secretariat for document SCP/29/6. Finally, the Delegation expressed its confidence in the productive and fruitful work of the Committee.

16. The Delegation of China noted that it had always attached a high importance to the role of intellectual property in stimulating innovation, technology and economic development. In that regard, the Delegation reaffirmed its firm position to protect intellectual property. The Delegation stressed a high importance of the exchange and cooperation among Member States in order to carry out comprehensive, in depth exchange within the framework of intellectual property. Underlying the importance of the SCP, the Delegation stated that the Committee remained a very important platform for discussions in relation to the international patent system. The Delegation remained committed to make progress in the discussions and information sharing sessions, particularly in relation to exceptions and limitations, patents and health and technology transfer. In its opinion, those topics were of vital importance for striking appropriate balance between the interests of right holders and the general public. Finally, the Delegation stressed that due to differences among Member States, it was necessary to show more flexibility in order for the Committee to move forward, taking into account the interests and the needs of all different parties on those topics. In conclusion, the Delegation expressed its hope to have fruitful discussions in order to advance the work of the SCP.

17. The Delegation of Lithuania, speaking on behalf of the Group of Central European and Baltic States (CEBS Group), thanked the Secretariat for preparing the session. The Delegation stressed the importance of the sharing sessions organized by the Secretariat. It also expressed its hope that further discussions would allow Member States to prepare the ground for the harmonization of substantive patent laws. As regards the discussions on exceptions and limitations to patent rights, the Delegation thanked the Secretariat for document SCP/29/3. The Delegation looked forward to continue discussions on quality of patents, and thanked the Secretariat for document SCP/29/4. With regard to the sharing sessions, the Delegation noted that two members of the CEBS Group, the Delegations of the Czech Republic and Hungary, would make presentations in the sharing sessions. The Delegation took note of document SCP/29/5 on confidentiality between clients and their patent advisors. As it had been underlined in previous sessions, the CEBS Group supported the soft-law approach in the area of the client-attorney privilege. With regard to future work, the Delegation stressed the importance of keeping the right balance between the interests of different stakeholders. In conclusion, the Delegation expressed its readiness to engage in the discussions in a constructive manner.

18. The Delegation of Austria, speaking on behalf of the EU and its Member States, thanked the Secretariat for preparing the meeting. Further, the Delegation stressed the importance of a sound and reliable international patent system. In that regard, the Delegation noted that patents served as a sound pillar of global economy in a multilateral world by being useful for countries on all stages of development. In addition, the Delegation stressed the role of the Committee in

promoting the global patent system for the benefit of all Member States. The Delegation expressed its willingness to contribute to that process and expressed its hope that the further study of similarities and differences among Member States would help to remove trade obstacles and get a vision regarding a more harmonized global patent regime. The Delegation felt that the Committee would be able to make considerable steps forward on important issues, such as quality of patents and confidentiality of communications between clients and their patent advisors. The Delegation looked forward to interesting and fruitful discussions with respect to publicly accessible databases on patent information status and data on medicines and vaccines, as well as to the sharing sessions on patents and health. With regard to discussions on the future work of the Committee, the Delegation expressed its hope that the Committee would agree on a balanced work program for future sessions. The Delegation reiterated the importance of retaining the delicate balance between the topics discussed in the SCP. In particular, the Delegation pointed out that mutual understanding would enable Member States to create a beneficial work program for future sessions. The Delegation remained committed to the work of the Committee and looked forward to a constructive session.

19. The Delegation of Indonesia, speaking on behalf of the Asia and the Pacific Group, expressed its confidence in the experience and leadership skills of the Chair, and also expressed its appreciation for the hard work done by the Secretariat towards the preparation for the meeting. The Delegation noted that, even if the Paris Convention and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) had set minimum international standards of patent protection, the patent law remained essentially territorial and governments had flexibility to formulate their domestic patent laws. The Delegation continued that the TRIPS flexibilities allowed governments, and especially in countries with limited resources, the necessary policy space to meet their health needs and, at the same time, to foster innovation. The Delegation further stated that the SCP played important role in creating a balance between the rights of patent owners and the larger public interest, particularly in the area of public health, technology transfer and patent flexibilities. The Delegation stated that its Group would constructively participate and contribute towards a productive discussion on those issues. The Delegation looked forward to the half-day conference on cooperation between patent offices in search and examination and information exchange on opposition systems. The Delegation hoped that the information exchange sessions and the sharing sessions of the SCP would provide guidance for improving and further enhancing the efficiency of the patent system in a manner sensitive to the diverse needs of members of the Committee. The Delegation thanked the Secretariat for preparing document SCP/29/4, and looked forward to the presentation of that document. Further, the Delegation supported the idea that the SCP should have discussions on the opposition systems. The Delegation further emphasized that the Committee should give equal prominence to that issue in the work of the SCP as it did to the issue of quality of patents. In particular, the Delegation was of the view that there should be a work program on opposition systems that would comprise a questionnaire on different kinds of opposition mechanisms available in various countries, the procedures and modalities for their use, constraints in their use, and how such systems could be strengthened and constraints could be removed. The Delegation was of the opinion that the SCP should agree on a common understanding of the term "quality of patents". Specifically, the Delegation questioned whether the term meant efficiency of patent offices in processing patent applications, or the quality of patents granted, ensuring that the offices did not grant patents of questionable validity. In that regard, the Delegation requested the Secretariat to provide regular information to Member States on the outcome of patent applications in different jurisdictions and on the outcome of opposition procedures. Further, the Delegation took note of the proposal made by the Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom (document SCP/28/8) and looked forward to the discussions on that proposal. In addition, the Delegation looked forward to the discussions on documents SCP/29/3, SCP/29/5 and SCP/29/6. With regard to patents and health, the Delegation wished to take the opportunity to draw the attention of the Committee to the report of the United Nations Secretary-General's

High-Level Panel on Access to Medicines (UNHLP Report). The Delegation noted that the Report had specifically explored the policy incoherence between intellectual property, trade and human rights, and made a number of recommendations in that regard. The Delegation continued that some of those recommendations were specifically addressed to WIPO, and were directly relevant to the subject of the sharing session on patents and health. The Delegation stated therefore that the Asia and the Pacific Group wished to request the SCP to initiate those exploratory discussions based on that important Report. Further, the Delegation took note of the Proposal by the Delegations of Brazil, Canada and Switzerland (document SCP/28/9), and stressed the importance of considering the role of the patent system in promoting the development of new medical products and advancement of health technologies. The Delegation therefore looked forward to the discussion on that proposal. In addition, the Delegation drew the attention of the Committee to the fact that the Protocol amending the TRIPS Agreement would enable developing countries with insufficient or no manufacturing capacities in the pharmaceutical sector to import cheaper generic medicines produced under compulsory licensing. Referring further to paragraph 6 of the Doha Declaration, the Delegation noted that that amendment gave legal certainty that medicines could be exported at reasonable prices to satisfy the needs of the countries with limited pharmaceutical production capacity. The Delegation hoped that the Committee would also consider a work program to support the Members' commitment and bring that important measure into force in accordance with the mandate of the Committee and WIPO. In that regard, the Delegation looked forward to a half-day conference on publicly accessible databases on patent information status and data, on medicines and vaccines and sharing of experiences by practitioners on negotiating licensing agreements. The Delegation hoped that sharing of experience would provide better understanding on the connection between the patent system and medicines.

20. The Delegation of Tunisia supported the African Group's statement delivered by the Delegation of Morocco. The Delegation congratulated the Chair and the Secretariat for preparing the session and Director General for opening the meeting. The Delegation thanked the Secretariat for the update of the SCP Electronic Forum in relation to certain aspects of national and regional patent laws. Further, the Delegation thanked the Secretariat for document SCP/29/3, and reiterated the importance of exceptions and limitations to patent rights. The Delegation was of the view that exceptions and limitations contributed effectively to striking the right balance between public interest and private rights. As regards the implementation of exceptions and limitations to patent rights into national laws, the Delegation reiterated constraints faced by developing countries and LDCs in making full use of patent flexibilities. The Delegation expressed its willingness in applying those exceptions and limitations in order to access affordable and essential medicines for public health purposes. The Delegation therefore supported the African Group's statement that had underlined the use of patent flexibilities in the field of health by developing countries and LDCs. Further, the Delegation noted that access to medicines should not be a privilege but the right for everybody. Finally, the Delegation stressed the important role of the SCP in that regard.

21. The Delegation of India noted that WIPO should ensure a right balance between innovations and socio-economic development. The Delegation thanked the Secretariat for preparing the session. It noted that discussions during the Committee should be limited to fact-finding work, and pointed out that it was not in a position to support the process of harmonization of patent law. The Delegation welcomed further studies on exceptions and limitations to patent rights, including compulsory licensing. The Delegation was of the view that those studies were extremely important in view of the accessibility and affordability of medicines. Further, the Delegation thanked the Secretariat for document SCP/29/4. The Delegation was of the view that a well-defined opposition system added value to the process of the patent examinations and helped to ensure quality in patent claims. With respect to patents and health, the Delegation supported proposal of the African Group (document SCP/16/7). It also expressed its appreciation for the UNHLP Report on access to medicines. The Delegation

reiterated the importance of the inclusion of International Nonproprietary Names in patents. On the subject of confidentiality of communications between clients and their patent advisors, the Delegation believed that that question was not a substantive patent law issue and should be governed by the law of evidence. As regards the sufficiency of disclosure, the Delegation noted the importance of that criterion. Finally, the Delegation looked forward to the sharing sessions and information exchange sessions on the various agenda items. The Delegation remained committed to a constructive and participative discussion on those issues in the twenty-ninth session of the SCP.

22. The Delegation of South Africa aligned itself with the statement made by the Delegation of Morocco on behalf of the African Group. Further, the Delegation welcomed the balanced work program of the SCP. In addition, the Delegation underlined the importance and significance of the SCP's role as a multilateral forum which enabled Member States to discuss fundamental issues. The Delegation pointed out that the work of the SCP was essential for providing access to knowledge, technology transfer, and safe, affordable medicines for the benefit of all. The Delegation looked forward to the discussion on document SCP/29/3 and noted the importance of that issue for developing countries and LDCs. In that regard, the Delegation expressed its willingness to have a document on the challenges experienced by Member States in implementing exceptions and limitations. Further, the Delegation noted that the discussions on patents and health became a priority for the Delegation. In that regard, the Delegation welcomed the discussions on Agenda Item 7. The Delegation stated that it would constructively participate and contribute towards a productive discussion on those issues.

23. The Delegation of Bolivia supported the statement made by the Delegation of El Salvador on behalf of GRULAC. The Delegation thanked the Secretariat for preparing the session. The Delegation looked forward to discussion on exceptions and limitations to patent rights, patents and health and transfer of technology. The Delegation was of the view that those issues would help to find a balance between the patent system and access to medicines. In that regard, the Delegation supported the African Group proposal on the work program of the Committee.

24. The Delegation of the Republic of Korea expressed its appreciation for the Chairs' excellent leadership and expertise. Further, the Delegation thanked the Secretariat for preparing the session of the SCP. The Delegation stated that the SCP was one of the important committees for Member States to engage in substantive and fruitful discussions on technical issues in relation to patent law and international cooperation. In particular, the Delegation noted that the SCP provided the opportunity to discuss important issues. Further, noting that patent offices should provide high quality examination of patent applicants, the Delegation expressed its view that quality of patents should remain a main topic of the SCP. The Delegation hoped that Member States would show more flexibility and cooperative spirit during the discussions. Further, the Delegation expressed its hope for a balanced patent system in order to effectively recognize and protect intellectual creations of inventors. In particular, the Delegation noted that so-called social innovation would positively influence the lives of people. Finally, expressing its hope for fruitful discussions, within the SCP, the Delegation stated that it was ready to engage in those discussions in a constructive manner.

25. The Delegation of Egypt supported the statement made by the Delegation of Morocco on behalf of the African Group. It welcomed the Chair's presidency and thanked the Secretariat for its preparation of the session, including sharing sessions and conferences. The Delegation stressed the importance of the SCP for patent offices, especially in examining and registering patents. The Delegation also pointed out the importance of cooperation between WIPO and its Member States, especially in enhancing skills in developing countries in the field of transfer of technology, which would encourage innovation, creativity and social and economic development. In that regard, the Delegation welcomed the Secretariat's efforts in preparing the document on exceptions and limitations to patent rights, as they encouraged creativity. The



Delegation also welcomed the conference on cooperation between patent offices and exchange of experiences in that field, to be held during SCP/29. In addition, the Delegation highlighted the importance of patents in the field of public health and the role played by WIPO in meeting a country's needs, especially in small LDCs. The Delegation therefore looked forward to the sharing session and conference that would be held under the agenda item on patents and health, and supported the proposal made by the African Group. The Delegation expressed its willingness to contribute to the Committee's work, and looked forward to discussions that would lead to positive outcomes.

26. The Representative of KEI welcomed the conclusions of SCP/28 which had called upon the Secretariat to prepare a draft reference document on compulsory licensing for SCP/30, which was tentatively scheduled in June 2019. The Representative recommend that that reference document analyze cases where non-voluntary use had been allowed as a limitation on remedies, including, for example, recent limitations on remedies for infringement of patents on medical diagnostic tests and medical devices in the United States of America. In addition, the Representative urged the SCP to schedule a presentation by experts on the legal basis and experience of states in permitting the non-voluntary use of patents on medical inventions as a limitation on the remedies available in Part 3 of the TRIPS Agreement, including specifically cases of running royalties for infringement of medical devices and diagnostic tests, and the export of those products outside of the WTO Article 31bis framework. Furthermore, the Representative welcomed the Committee's decision to convene a half-day conference on publicly available databases on patent information status and data on medicines and vaccines and a sharing session by practitioners of voluntary licensing at SCP/29. In addition, the Representative thanked the Delegations of Argentina, Brazil, Switzerland and Chile for their initiative as documented in SCP/28/10. As part of the Committee's ongoing work on patents and health, the Representative proposed that the SCP investigate the extent to which patent exceptions for the treatment of humans apply to new cell and gene therapies, such as CART treatments for cancer.

27. The Representative of TWN stressed the importance for the SCP to look at the realities and to base its discussions on the empirical data. Further, the Representative noted the high number of issued patents which would increase the cost of monitoring patent rights and decrease economic freedom and consumer welfare.

28. The Representative of JIPA had the pleasure to provide a statement on behalf of their association, comprising about 900 major Japanese companies as members. The Delegation made the statement in collaboration with the Japan Pharmaceutical Manufacturer's Association (JPMA), which counted 71 leading R&D oriented pharmaceutical companies, and with the support of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). The Representative specified that developing a new medicine implied significant costs and a long R&D period. The Representative highlighted that intellectual property rights were able to provide companies invested in launching a new medicine with an opportunity to keep creating more innovative drugs or more variable therapies for patients. The Representative stated that, although the effectiveness of using a compulsory license had been proactively discussed, he did not believe that the problem of access to medicines could be solved by limiting patent rights, including issuing a compulsory license. The Representative pointed out that, as mentioned in document SCP/26/5, 95% of the medicines contained in the 2013 WHO model list of essential medicines were not under patent protection in the majority of lower income countries. The Representative concluded that such fact meant that there should be factors other than patent protection which were restricting access to medicine. The Representative stated that Japanese pharmaceutical companies strongly recognized the issue of access to medicines and were proactive in finding a solution to it. In particular, the Japanese pharmaceutical companies were participating in the Neglected Tropical Diseases programs and had concluded joint research agreements with the Broad Institute, Colorado State University

and University of Chicago on the development of a potential new treatment for tuberculosis. The Representative recalled that the joint research had been awarded funding from the Global Health Innovative Technology Fund (GHIT). The Representative believed that those activities were contributing to improving access to medicines. Considering that there were factors other than patent protection which were restricting access to medicines, the Representative believed that promoting R&D of medicines and the use of the patent systems could accelerate the launching of new drugs. The Representative was convinced that the patent system promoted public health in developed countries as well as in the developing countries.

29. The Representative of FICPI thanked the Chair and the Secretariat for a well-prepared and well-run meeting. The Representative stressed the importance of the confidentiality of communication between clients and their patent advisors, and hoped for further discussions in that regard.

#### **AGENDA ITEM 4: REPORT ON THE INTERNATIONAL PATENT SYSTEM: CERTAIN ASPECTS OF NATIONAL/REGIONAL PATENT LAWS**

30. The Secretariat presented document SCP/29/2.

31. The Delegation of Japan thanked the Secretariat for its great effort in preparing for the meeting. It informed the Committee that through the revision of the Japanese patent law, the grace period had been extended from six months to one year. The Delegation noted that the grace period provided an important role in appropriately protecting inventions and encouraging inventive activities, especially by research individuals, individual inventors, and SMEs who were often unfamiliar with the intellectual property system. It further observed that due to the fourth Industrial Revolution underpinned by emerging technologies, research projects based on open innovation and industry-academia collaborations had been significantly increased. As a result, the Delegation noted, the risk of losing the novelty of inventions had been increased through disclosure of the inventions by persons other than the inventors themselves. In the opinion of the Delegation, such risks should certainly be reduced by providing appropriate relief measures. The Delegation explained that those circumstances formed the basis for its decision to revise the patent law and extend the grace period from six months to one year. The Delegation stated that the new provision had come into effect in June 2018. The Delegation was convinced that extending the grace period would contribute to protecting inventions more appropriately and promoting innovations in Japan.

32. The Delegation of Austria, speaking on behalf of the EU and its Member States, thanked the Secretariat for preparing document SCP/29/2 and updating the SCP Electronic Forum. The Delegation thanked the Delegations of Argentina, Japan, Morocco, the Republic of Moldova, Singapore, and Uganda for their input, based on which the SCP Electronic Forum website had been updated. The Delegation thanked the Secretariat for updating the SCP Electronic Forum website and encouraged all Member States to continue sharing the updates.

33. The Delegation of Switzerland, speaking on behalf of Group B, thanked the Secretariat for the preparation of document SCP/29/2. In addition, the Delegation also thanked Member States that provided input on changes in their national patent laws. The Delegation pointed out that the regularly updated SCP Electronic Forum website was an important source of information.

34. The Delegation of Lithuania, speaking on behalf of the CEBS Group, thanked the Secretariat for preparing document SCP/29/2. In particular, the Delegation expressed its appreciation for hard work, done by the Secretariat, that allowed to keep the SCP Electronic Forum up-to-date. The Delegation pointed out that the SCP Electronic Forum was an important source of information and served as a good basis for further discussions.

35. The Delegation of France thanked the Secretariat for preparing the meeting and the documents. As regards the French legislation on intellectual property, particularly on patents, the Delegation noted that a large number of changes would be introduced with respect to the procedure for processing patent applications. It noted that the law on the growth of enterprises was being examined and would be adopted soon. The Delegation explained that that law placed its emphasis on innovation by SMEs, in particular, and contained proposals to facilitate and strengthen the protection of innovation. The Delegation stated that one of the means for doing so was to reform intellectual property. The Delegation informed the Committee that, first, the law provided for strengthening the utility model certificates by extending its term of protection from 6 to 10 years and by including the possibility of converting the application into an application for patent, so as to facilitate access to intellectual property. Second, the Delegation noted, the law provided for a provisional patent application of 12 months in length to attain a priority date with a minimum of formalities, i.e., submission of a description would be enough without the requirement for a claim. Third, the Delegation stated that an opposition procedure would be set up in its intellectual property office to eliminate the economic barriers to SMEs. Accordingly, any third party would thus have an opportunity of opposing a granted patent within a period of nine months from the grant. The Delegation noted that reasons for opposition would be similar to the reasons for revocation before the EPO. Lastly, the Delegation explained that the office would be able to examine inventive step when examining patent applications. In its view, examination of novelty and inventive step by its patent office during the examination procedure would lead to better quality of patents issued by the French office. The Delegation stated that in light of the small patent revolution in France, it would be keeping a very close eye on the discussions on quality of patents in the SCP, in particular with regard to inventive step and sharing of experience on that requirement. Once that new legislation was adopted, the Delegation would send the relevant information to the Secretariat so as to update the SCP Electronic Forum.

36. The Delegation of Argentina wished the Chair every success in its work, and thanked the Secretariat for the organization of the meeting. The Delegation associated itself with the statement made by the Delegation of El Salvador on behalf of GRULAC. As regards document SCP/29/2, the Delegation thanked the Secretariat for having updated the data available on the SCP Electronic Forum. In relation to the information supplied by Argentina, the Delegation pointed out that the definition of inventive step had been replaced by the following: there would be inventive step when the creative process or its results are not deduced from prior art directly by a person skilled in the art. The Delegation noted that in addition, it had requested the Secretariat to make a number of changes with respect to the exceptions and limitations to rights.

37. The Delegation of India thanked the Secretariat for preparing document SCP/29/2. Further, the Delegation noted that the Indian Patent Office had taken initiatives to process patent applications in strict adherence of time and in a manner that ensured better quality.

38. The Delegation of Turkey thanked the Secretariat for preparing document SCP/29/2. Further, the Delegation stressed the importance of the SCP. The Delegation hoped that with common efforts of all Member States, the patent system would play a better role in leading innovation, economic social and technological development. In that regard, the Delegation welcomed the updated SCP Electronic Forum in relation to the certain aspects of national and regional patent laws. The Delegation of Turkey shared experiences of its country in implementing the new IP Code which had entered into force in 2017. In particular, the Delegation reported that the patent granting period had become shorter through streamlining and simplification of procedures. The Delegation noted that the patent granting procedure with substantive examination had been established to prevent misuse by users. Consequently, search and examination reports had been prepared to make the system stronger. In addition, a post-grant opposition system had been introduced to make the patent system more reliable.

Furthermore, ownership of inventions originating from universities had been given to the universities themselves rather than the academician inventors – they would receive at least 30% of the income generated from the commercialization of the invention. Public institutions had the right to use the state-funded inventions to meet their own needs without paying any royalties. Moreover, the Delegation noted that the concept of reestablishment of rights had been introduced into the new law to facilitate users, and that when the annual fees had not been paid in due time, the restoration fee might be paid.

39. The Delegation of Switzerland informed the Committee on some changes in Swiss Patent Law, which would enter into force in January 2019. The Delegation stated that Switzerland had introduced in its patent law a pediatric extension system in order to encourage the development and availability of medicines for children by extending the term of protection of a patent or supplementary protection certificate by six months. Noting that there were not enough safe and high quality medicine products that had been especially developed or adapted for children, the Delegation observed that the extensions would remedy that problem and contribute to the development of new medicines for children in Switzerland. According to the Delegation, that amendment to the patent law was part of the ordinary revision of the Therapeutic Products Act, and the revised Patents Act and implementing provisions would come into force with a revision of the Therapeutic Products Act on January 1, 2019. The extensions were available by extending granted supplementary protection certificates by six months or through a new patent supplemental protection certificate, which was linked directly to the term of the patent and was also valid for six months. The Delegation further noted that whoever applied for a pediatric extension must conduct clinical studies that complied with the pediatric plan for the authorization of a medicine. In addition, the study results must be publicly available in the information on the medicine or product. Furthermore, the application for authorization in Switzerland must be submitted no longer than six months after the application for authorization to Europe Economic Area.

40. The Representative of EPI sought clarification from the Delegation of Japan regarding the calculation of the 12-month grace period. He asked whether that period was calculated from the filing date or the priority date.

41. The Delegation of Japan stated that the starting date of the grace period was the filing date.

## **AGENDA ITEM 5: EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS**

42. Discussions were based on documents SCP/14/7, SCP/19/6, SCP/28/3, SCP/28/3 Add and SCP/29/3.

43. The Secretariat made a presentation on document SCP/29/3 (SCP/29/A). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_a\\_reference\\_document\\_wipo.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_a_reference_document_wipo.pdf).

44. The Delegation of Brazil thanked the Secretariat for preparing document SCP/29/3, which in its view was balanced and reasonable. The Delegation noted that exceptions and limitations were an integral and necessary part of a strong and healthy patent system and reminded Member States that a basic tenet of the patent system was that legislation should provide incentives that led to new discoveries and inventions, while ensuring that those incentives were not overly restrictive and did not create barriers to innovation and dissemination of knowledge. The Delegation believed that it was under such framework that the role of exceptions and limitations should be addressed. The Delegation stated that all Member States had the legal and moral obligation to pursue the best balance between the interests of the IP right holders

and the interests of society as a whole. The Delegation was of the opinion that preserving such balance was the best way to safeguard the legitimate interests of IP right holders. The Delegation was of the view that the regulatory review exception, also known as the Bolar exception, played an important role in ensuring the realization of that balance, especially by ensuring that the market power granted by a patent did not create anti-competitive externalities.

45. The Delegation of Lithuania, speaking on behalf of the CEBS Group, thanked the Secretariat for preparing the reference document SCP/29/3 on research exception in accordance with the agreement reached at 27<sup>th</sup> Session of the SCP. In the Delegation's view, the document provided a good basis for further discussion on exceptions and limitations to patent rights. The Delegation then noted that with regard to the challenges faced by Member States in using the research exception, a majority of Member States reported that no particular challenges had been encountered. Therefore, while taking good note of the fact that the analysis of laws and jurisprudence indicated variations in national provisions, in the opinion of the CEBS group, there was no need for normative work on the international level concerning the research exception. Further, the Delegation noted the lack of data regarding economic impact of the research exception on research and innovation, as indicated in Chapter 7 of the document. Therefore, the Delegation supported that the Secretariat carry out further analysis to ascertain the effect of the research exceptions on scientific inquiry.

46. The Delegation of Chile thanked the Secretariat for preparing the reference document on the research exceptions, which was extremely useful from a practical point of view. It noted that the research exception was particularly relevant in their national situation as discussions were taking place for drafting an amendment law, which is considering incorporating a research exception. The Delegation considered that including exceptions in the patent law would make it possible to have a balanced patent system, allowing for the development of knowledge without infringing the exclusive rights of the patent holder. The Delegation noted that the research exception was especially useful as it could be seen from the database prepared by the Secretariat, which showed that at least 76 out of 90 countries had included such exception in their legislations. The Delegation looked forward to further developments and work by the Committee with regard to the topic.

47. The Delegation of Austria, speaking on behalf of the European Union and its Member States, thanked the Secretariat for preparing document SCP/29/3 on the research exception. The Delegation emphasized the broad information and resources presented in the document, namely, the international legal framework as well as inputs by Member States and regional patent offices. As the research exception was one of the most widely adopted exceptions in patent laws, the Delegation especially appreciated the compilation of concrete wordings of the provisions dealing with the research exception in more than 100 countries and regional patent organizations. In the Delegation's opinion, such compilation was very helpful for knowing and understanding the different legal practices. It noted that the document illustrated that although there was a broad common understanding on the exception itself, and there were common components in the exception among national laws, the differences in wordings among national provisions could result in different interpretations and coverages of the exception. The Delegation further noted that the document revealed that in some countries, the applicability of the research exception depended on the commercial intent of the third party, and that, as regards the challenges, the document mentioned that most Member States had encountered no particular challenges with regard to the practical implementation of the exception, while others noted there had been uncertainty over the scope of the exception, which in some countries had resulted in legislative changes. Further, the Delegation pointed out that the document showed that clarity in the scope of the exception would ensure legal certainty and predictability for patentees and third parties. Thus, the Delegation was highly interested in learning more about the economic dimension of the research exception as well as on the impact of the exception in general. Finally, the Delegation expressed that, in its view, although it did not seem that there

was a need for normative work to be carried out on the issue, the European Union and its Member States were always prepared to support initiatives which would lead to a better understanding and more legal certainty, that was beneficial for our economies. In conclusion, the Delegation expressed its hope to have fruitful discussions in order to advance the discussions of the SCP.

48. The Delegation of China thanked the Secretariat for its work. As regards document SCP/29/3, the Delegation noted that the document provided a very useful and comprehensive guideline which could help Member States to understand provisions of other countries and improve their own national patent legislations and systems. Further, the Delegation stated that the work of the Secretariat in that regard was very important in order to improve national and regional patent laws. The Delegation believed that, in most countries, exceptions and limitations represented very important legal provisions, since they struck a balance between the public interest and the rights of patent holders. The Delegation therefore supported discussions on the topic so that Member States could learn more about the practices of other countries.

49. The Delegation of Canada, speaking on behalf of Group B, thanked the Secretariat for preparing document SCP/29/3 as well as those Member States that had provided input. The Delegation recognized that innovation in all technological fields was fostered by an effective patent system where a delicate balance between the interests of the right holders and that of the wider public was maintained. The Delegation pointed out that exceptions and limitations were part of national and international patent systems. The Delegation recognized that the use of exceptions and limitations was at times appropriate in specific circumstances. It noted that WIPO and the SCP had already undertaken substantive work in the area of exceptions and limitations, which included expert studies, questionnaires, seminars, and Member States contributions, including practical experiences and case studies. The Delegation referred to the extensive documentation found on WIPO's website. It observed that such valuable references were available to any country that considered its domestic legislative arrangements and sought to adjust them according to its special needs and priorities. Therefore, the Delegation believed that the discussions and work under Agenda Item 5 had produced sufficient information for reflections on the implementation of exceptions and limitations.

50. The Delegation of India thanked the Secretariat for preparing document SCP/29/3, which contained detailed information on the international legal framework, regional instruments, national implementations and challenges faced by the Member States in implementing the research exception. The Delegation reaffirmed its views on the issue of exceptions and limitations to patent rights and expressed its full support to the work program as proposed by the Delegation of Brazil in document SCP/14/7 on exceptions and limitations to patent rights. Further, the Delegation stated that the SCP should focus on the use of some exceptions, such as compulsory licensing, parallel imports, government use and the Bolar exception, which were extremely important from the perspective of accessibility and affordability of medicines. In the Delegation's view, those substantive provisions on exceptions and limitations were highly important in the pharmaceutical field in developing and LDCs and also for the benefit of the public at large. In addition, the Delegation noted that the patent system should meet the objective of providing protection for the moral and material interests of inventors, and at the same time, should meet the objective of promoting the enjoyment of human rights of other members of the society.

51. The Delegation of the Russian Federation thanked the Secretariat for preparing document SCP/29/3. The Delegation was of the view that the document was very useful because it contained legal provisions that had been adopted in the legislation of different countries. The Delegation noted that the research exception was applied in the Russian Federation in accordance with the civil code. It stated that, in practice, the most problematic

issue was determining the scope of the exception. In that regard, the Delegation interpreted the research exception in view of a balanced approach that allowed free scientific research and technological innovation, but not for making commercial profit. Thus, the patented product or process could be the subject of research but should not be used as a means or as an instrument for research. The Delegation stated that in the Russian Federation, the interpretation of the exception was that the patented invention could only be used for purely experimental ends. As regards future work, the Delegation expressed its willingness that the SCP would continue to work on that issue. In particular, it noted the importance of the provisions on compulsory licensing and suggested that another reference document on the use of compulsory licenses would be useful.

52. The Delegation of Canada announced that Canada had begun the process of implementing a national IP strategy, which was announced by the Government in April 2018 and which included updates to Canada's provisions on exceptions and limitations. It noted that the IP strategy included new legislation intended to encourage creation and innovation by clarifying acceptable behaviors in the patent system. In that regard, the IP strategy bill proposed changes to Canada's patent system, such as including updates to two of Canada's exceptions and limitations. In particular, the research exception would be codified in legislation in order to clarify that infringement does not arise from research on a patented invention, and thus promote balance between rights holders and users of patented inventions. The Delegation stated that the exception would nonetheless retain important safeguards, notably, the exception applied to experimentation only. Further, the provisions on the prior use exception would also be amended so that a business is not required to cease its operations because of a subsequent patent covering its existing activities. In conclusion, the Delegation believed that those legislative amendments would further enhance clarity in the IP regime by ensuring a more balanced playing field for all market participants.

53. The Delegation of Japan expressed its appreciation to the Secretariat for its great efforts in preparing the working document SCP/29/3, draft reference document on research exception. As for the draft reference document on the compulsory licensing which would be prepared for SCP/30, the Delegation expressed its belief that the work should be factual, and should not be conducted in a way to prejudge the outcome. In addition, it pointed out that the discussions under item 5 of the agenda should be conducted in a well-balanced manner, giving careful consideration not only to the interests of general public, but also to the interests of the right holders, as well as to the benefits that the patent system, as incentives for innovation, provided to the society as a whole.

54. The Delegation of the United States of America thanked the Secretariat for the preparation of document SCP/29/3 and for its presentation. The Delegation was of the view that the document was a useful reference on how countries around the world utilized the provisions related to the research exception. The Delegation expressed its support to the statement made by the Delegation of Canada, speaking on behalf of Group B, that while the use of certain exceptions or limitations may at times be appropriate, those constraints on the patent right should never undermine the incentives necessary to promote cutting edge innovation and a proper prosperous society. In the Delegation's view, a notable point of distinction in the application of the research exception was whether the otherwise patent infringing research or experimental activity had a commercial or noncommercial purpose. With respect to the practice in the United States of America, the Delegation stated that SCP/29/3 correctly noted the very narrow parameters of the exception in the United States legal system which was limited to activities solely for amusement, to satisfy idle curiosity; and for strictly philosophical inquiry. The Delegation stressed that the application of the research exception like any other patent exceptions should strike a delicate balance and should ensure that it did not unreasonably conflict with the normal exploitation of a patent or prejudice the legitimate interest of the patent owner. Finally, the Delegation supported that the Secretariat would

prepare similar documents with respect to the other agreed exceptions and limitations from the questionnaire presented in document SCP/16/3. In that respect, the Delegation suggested that a further reference document be provided either on the prior use exception or the exception for the use of articles on foreign vessels, aircrafts and land vehicles.

55. The Representative from DNDi noted that whereas DNDi regularly concluded research and collaboration agreements with patent owners to undertake medical research activities, such agreements were not always possible, and hence DNDi had made use of patent research exceptions on various occasions based on legal advice from local patent attorneys to seek an improvement to a patented invention, to invent around a patented invention, or to investigate a non-effect on users of patented inventions. She stated that, in practice, use of the research exceptions had enabled DNDi to test patented compounds to treat neglected diseases, to develop alternative and affordable formulation adapted to patient needs, to undertake clinical trials with patented molecules for the purposes of regulatory approval. The Representative thanked the Secretariat for having produced document SCP/29/3 on the research exception, which was a crucial patent exception for organizations involved in medical research.

## **AGENDA ITEM 6: QUALITY OF PATENTS, INCLUDING OPPOSITION SYSTEMS**

56. The Delegation of Lithuania, speaking on behalf of the CEBS Group, reiterated its strong support to the advancement of work on the topic of quality of patents and thanked the Secretariat for the preparation of a study on inventive step based on the proposal by the Delegation of Spain. The Delegation expressed its interest in receiving further documents that would elaborate more extensively on the inventive step in the chemical sector, reflecting other topic suggested in paragraph 8 of document SCP/24/3. The Delegation also noted that it would be useful to have a conference on cooperation between patent offices and a sharing session on that issue. Further, the Delegation stated that since third party interventions and opposition procedures could affect the granting of high quality patents, the CEBS Group supported the second part of the joint proposal in document SCP/28/8, that was a study on approaches to the quality of the patent grant process to be prepared by the Secretariat. Finally, the Delegation noted that since technological advances directly affected the patent grant procedure, it would be useful to clarify how artificial intelligence solutions could affect patent prosecution.

57. The Delegation of Austria, speaking on behalf of the European Union and its Member States, thanked the Delegation of Spain for its proposal under paragraph 8 in document SCP/24/3 as well as the Secretariat for the compilation of document SCP/29/4. The Delegation also appreciated the great amount of work undertaken by the Secretariat towards illustrating the situation in different Member States and offices in a Further Study on Inventive Step regarding the issues of “secondary indicators”, “selection inventions” and the concept of “problem inventions”. The Delegation also thanked all Member States and offices for providing information and explanation regarding their relevant approaches, which made the work done by the Committee even more valuable and practice-oriented and helped to better comprehend the reason behind the decisions taken in different countries or offices, contributing to a converged understanding that could lead to a more stream-lined patent granting process. In the Delegation’s view, the Study provided an excellent representation of the issues in general and made available, where appropriate, a list of potential indicators that were used in more than one jurisdiction. It also elaborated further on some of those indicators and pointed out the difficulties or limits of some approaches. The compilation of the practice of some countries, be it important case law or examination guidelines, also gave particular insight and helped to gain better understanding of the different solutions. The Delegation also noted that, while the Further Study on Inventive Step as well as numerous similar studies in the past gave an excellent overview about the different patent law systems, the European Union and its Member States were also keen to learn about the practical relevance of such differences, for example, about



how often differences in inventive step practice led to different granting outcomes or whether it was possible to assess the economic impact of such differences. As answering questions like those might be a valuable input for further increasing the Delegations knowledge about the economic impact of the patent system, the European Union and its Member States encouraged the Secretariat to conduct studies to provide insight to those questions. The Delegation then expressed its interest in participating in the half-day conference on cooperation between offices as well as in the sharing session on approaches used to ensure the quality of patent grant processes. For a subsequent session of the Committee, the European Union and its Member States expressed their interest in getting more knowledge regarding the topic of inventive step and selection inventions in the chemical sector. The Delegation also expressed its support to the remaining aspects of the proposal set out in document SCP/28/8, specifically to the preparation of a study by the Secretariat on approaches to the quality of the patent grant process, as well as to continuing discussions on the use for examination and patentability of artificial intelligence.

58. The Delegation of Canada, speaking on behalf of Group B, thanked the Secretariat for the Further Study on Inventive Step contained in document SCP/29/4. The Delegation reiterated its views whereby the inventive step and its assessment was crucial to the patent system objectives. In its opinion, the Further Study on Inventive Step contributed to enhancing the Delegation's understanding of the concepts under discussion as well as corresponding practices of Member States. The Delegation noted that the sharing and use of work products was carried out through an area of intense daily exchanges and cooperation among patent offices, as evidenced by the numerous multilateral and regional initiatives that sought to facilitate collaboration, including those under the Patent Cooperation Treaty, the WIPO CASE platform and frameworks for cooperation among IP offices. The Delegation expressed the interest of Group B in learning about the experience of countries that had recently started to implement work-sharing programs and welcomed the sharing session on approaches used by IP offices to ensure the quality of the grant process.

59. The Representative of APAA thanked the Secretariat for its work. She shared the results of a comparative study on public review and challenge of the validity of patents, which showed that in Asian countries, the petition for review had been widely used and contributed significantly to enhancing quality of patents. The Representative expressed its view that the review by third parties was beneficial for all stakeholders as it was a measure for challenging patentability with less burden for patent offices. In its opinion, the availability of opposition complemented the examination process by offices and helped to improve the quality of patents. The Representative also noted that, even for patent holders, the opposition petition was a good opportunity to reinforce the patent by narrowing the scope of claims by amendment. The Representative therefore encouraged the Secretariat and the delegations to further share experiences on opposition and to improve such system in order to grant higher quality patents. The Representative also supported the proposal made by the Delegation of Spain in document SCP/28/7. She noted that, as professionals in the IP field, many members of the APAA were highly interested in how artificial intelligence would affect the IP field in various aspects. In that regard, the Representative pointed out that in 2018, one of the APAA's standing committees called "Emerging IP Rights Committee" had conducted a study on the impact of artificial intelligence on the creation of ownership of IP rights, and had circulated a questionnaire related to that question and the possible legal framework for dealing with artificial intelligence issues. The results of that questionnaire had shown that many of the participating countries were of the view that ownership should go to the user, the developer of the artificial intelligence or the public domain, but not to the artificial intelligence itself. Given the complexity of the topic, the Representative supported the proposal made by the Delegation of Spain and

suggested that a comprehensive study on the impact of artificial intelligence technology on the patent system could be prepared, including its patentability, how to protect inventions generated by artificial intelligence as well as the possible utilization of artificial intelligence in the patent system.

60. The Representative of TWN expressed its view that the TRIPS Agreement provided enough flexibility for each Member State to determine the threshold level of the inventive step, and thus each country should be free to determine the threshold of inventive step, depending on its socioeconomic conditions. In his opinion, developed countries especially had lowered the threshold level of patenting, which had resulted in a rush of granting patents that had created a backlog of patent applications in many patent offices. The Representative considered that the solutions such as patent prosecution highways (PPH) and work-sharing or burden sharing initiatives were increasing the problem by creating a kind of functional harmonization of substantive patent law.

61. The Representative of KEI made a comment in relation to Markush claims or other types of claims where the patent covered many possible implementations of the invention, and thus a company might protect a particular product with a patent that could be interpreted as to cover many other implementations or uses of the invention. The Representative posed the question as to how patent offices would deal with a patent claim that could cover, for example, a thousand different compounds whereas the applicant company only developed a single compound.

*Sharing session on approaches used by delegations to ensure the quality of the patent grant process within IP offices, including opposition systems, any challenges faced and how they have been overcome.*

62. The Delegation of Singapore made a presentation on the Quality of the Patent Grant Process (SCP/29/G). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_g\\_sharing\\_session\\_on\\_quality\\_singapore.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_g_sharing_session_on_quality_singapore.pdf).

63. The Delegation of the United Kingdom made a presentation on the UK's IPO Quality Management of Patents (SCP/29/H). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_h\\_sharing\\_session\\_on\\_quality\\_united\\_kingdom.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_h_sharing_session_on_quality_united_kingdom.pdf).

64. The Delegation of Japan made a presentation on the JPO's Initiatives on Enhancing the Quality of Patent Examination (SCP/29/I). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_i\\_sharing\\_session\\_on\\_quality\\_japan.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_i_sharing_session_on_quality_japan.pdf).

65. The Delegation of the Czech Republic made a presentation on the Patent Procedure and Quality Management Aspects (SCP/29/J). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_j\\_sharing\\_session\\_on\\_quality\\_czech\\_republic.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_j_sharing_session_on_quality_czech_republic.pdf).

66. The Delegation of Chile made a presentation on the Opposition Procedure (SCP/29/K). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/es/scp\\_29/scp\\_29\\_k\\_sharing\\_session\\_on\\_quality\\_chile.pdf](https://www.wipo.int/edocs/mdocs/scp/es/scp_29/scp_29_k_sharing_session_on_quality_chile.pdf).

67. The Delegation of Hungary made a presentation on the Quality of the Patent Granting Process at the Hungarian Intellectual Property Office (HIPO) (SCP/29/L). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_l\\_sharing\\_session\\_on\\_quality\\_hungary.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_l_sharing_session_on_quality_hungary.pdf).

68. The Delegation of the United States of America made a presentation on the Access to Relevant Prior Art Initiative Update (SCP/29/M). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_m\\_sharing\\_session\\_on\\_quality\\_united\\_states\\_of\\_america.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_m_sharing_session_on_quality_united_states_of_america.pdf).

*Half-day conference on cooperation between patent offices in search and examination, including sharing of information concerning the corresponding foreign applications and grants.*

69. The Secretariat made a presentation on the WIPO website and the information available under the webpage “International Worksharing and Collaborative Activities for Certain Examination of Patent Applications”.

70. The Delegation of Kenya made a presentation on Patent Application, Processing, Opposition, Search and Cooperation (SCP/29/C). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_c\\_conference\\_on\\_cooperation\\_kenya.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_c_conference_on_cooperation_kenya.pdf).

71. The Delegation of El Salvador made a presentation on Cooperation between Patent Offices in Search and Examination (SCP/29/D). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/es/scp\\_29/scp\\_29\\_d\\_cooperacion\\_el\\_salvador.pdf](https://www.wipo.int/edocs/mdocs/scp/es/scp_29/scp_29_d_cooperacion_el_salvador.pdf).

72. The Delegation of the United Kingdom made a presentation on the UK-Brazil Patent Prosecution Highway (SCP/29/E). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_e\\_conference\\_on\\_cooperation\\_united\\_kingdom.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_e_conference_on_cooperation_united_kingdom.pdf).

73. The Delegation of Brazil thanked the Delegation of the United Kingdom for its presentation. With regard to the cooperation between the Brazilian National Institute of Industrial Property and other patent offices in the search and examination procedures, especially with the UK IPO, the Delegation noted that as of 2018, the Brazilian National Institute of Industrial Property participated in seven pilot projects using PPH with the patent offices of China, Denmark, Japan, the United Kingdom and the United States of America as well as with the EPO and PROSUR. The Delegation explained that while the cooperation agreements with the seven offices mainly differed in relation to the field of technology, in all cases, it was possible to file a request in the partner patent office for accelerated examination under the PPH for the corresponding patent application in Brazil. For example, in relation to the PPH bilateral pilot program with the United Kingdom, which would be extended to July 31, 2020, the Delegation noted that the cooperation agreement covered the fields of biotechnology, electrical engineering and information technology, whereas it excluded the pharmaceutical field. The Delegation remarked that the PPH projects reduced the amount of examinations and facilitated the examiner’s work, contributing to the acceleration and improvement of the examination process.

74. The Representative of the EPO made a presentation on Cooperation Between Patent Offices in Search and Examination (SCP/29/F). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_f\\_conference\\_on\\_cooperation\\_epo.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_f_conference_on_cooperation_epo.pdf).

75. The Delegation of the United States of America expressed its support to the PPH and the Collaborative Search and Examination (CS&E) initiatives. With regard to the CS&E pilot project, the Delegation noted that, as opposed to the first two phases of the project where the patent offices had contacted the applicants of selected patent applications to ask them whether they had wanted to participate in the CS&E project, the third phase of the project consisted of an applicant-driven process. Thus, the applicants were free to select whether or not they wanted to participate and to choose the patent applications that they wished to be entered into the program. The Delegation pointed out the fact that, in the third phase of the CS&E, many applicants had indicated their intention to use the system. With regard to the language of the applications, the Delegation noted that as of 2018, only applications in English had been accepted for participation in the CS&E but that from January 2019, the EPO would start accepting applications in German and French and that the offices of the Republic of Korea and Japan were also considering to open the pilot project to applications filed in their native languages. In the Delegation's view, admitting applications only in English might be a reason why applicants from those countries had been more reluctant to participate in the CS&E project.

76. The Delegation of the Republic of Korea reiterated its support to the efforts by the patent offices towards providing high quality examination of patent applications. The Delegation noted the steady increase in the number of patent applications and patent applicants in the Republic of Korea in parallel to the growth of the country's trade volume. The Delegation remarked that currently the "super intelligence" and other technological developments had given rise to more complex technologies that made it more difficult to examine prior art and the patentability of patent applications. Thus, patent examination cooperation could be a stepping-stone for raising the effectiveness and the timeliness of the patent examination. In that perspective, the Delegation stated that the Korean Intellectual Property Office (KIPO) and the USPTO had held a conference in Seoul aimed at informing about the current status and the latest developments of international cooperation programs and the initiatives related to patent examinations among patent offices, as well as the necessities and the benefits of having multilateral cooperation platforms. More than 300 participants including industry users, stakeholders, and representatives from patent offices of Australia, Brazil, France, India, Japan, Singapore, the United Kingdom, etc. attended the conference. The Delegation remarked that there was consensus among the participants that patent offices should provide high quality examination services to user, as well as reduce duplicative works. Thus, in the Delegation's opinion, future cooperation programs should aim to achieve those goals.

77. The Delegation of China expressed its view that patent search and examination were a very important issue for patent quality in order to reduce duplication of work and improve the efficiency of patent offices. The Delegation stated its commitment to carrying out efforts to enhancing cooperation in the area of patent examination.

78. The Delegation of Japan noted that the JPO had been actively working to promote cooperation with other patent offices in the field of search and examination. It explained that Japan had been working on various cooperative initiatives, such as the PPH, the Global Dossier and the Japan-US Collaborative Search Pilot Program. Further, in July 2018, the JPO had launched the PCT Collaborative Search and Examination Pilot Program among the IP5 Offices. In the Delegation's opinion, Japan was one of the Member States that was very actively advancing the PPH program. In particular, Japan had set up the PPH with 42 offices, which had been accepted by many Member States as an effective work-sharing framework. As of 2018, 48 offices participated in the PPH. The Delegation noted that all of those cooperative initiatives aimed to enhance sharing of information among IP offices, so that they could utilize the information for their searches and examinations. The Delegation's view was that those cooperative activities would have positive effects on the quality and efficiency of examinations at each office, pointing out that while those initiatives could be quite useful to IP offices, none of the offices were forced to follow the examination results coming from other offices, so the

Delegation noted that independence of examinations at each office would not be undermined by the PPH. Finally, the Delegation expressed its commitment to further expanding collaborations with other offices, deepen cooperative relationships, sharing experiences and contributing to the discussions at the SCP.

79. The Representative of TWN stated that a statutory monopoly should be extended only to those inventions which satisfied the patentability criteria. In the Representative's view, there had been a gradual shift of balance in the patent regime by lowering the patent granting standards, expanding the scope of patentable subject matters, reducing fees, extending the rights of patent holders and the duration of patent rights and imposing harder sanctions for infringements. In the Representative's opinion, as a result of the lowering patent granting standards, leading patent offices had granted overly broad patents. Against that background, the Representative expressed TWN's concerns on work-sharing arrangements. In his view, such arrangements would result in the functional harmonization through the back door and in the elimination of the flexibilities relating to the scope of patentability. Further, in the Representative's view, such work arrangements could seriously undermine the territoriality of patents as they promoted that the sovereign examination of patent applications be carried out through the IP5 offices, being many of them known for their lower threshold of patentability.

80. The Representative of KEI noted that there were many different dimensions and areas where cooperation would be fruitful. With regard to the patent quality area, the Representative expressed its support to sharing information and databases about challenges to patents since the issues raised in the challenge in one jurisdiction could be very similar to issues raised in another jurisdiction. The Representative further noted that there was a problem of evergreening in the area of medical patents. The Representative mentioned the case of the drug "Humira®" for which around 247 patents had been filed. The Representative stressed that whereas compulsory licenses were available, some countries could not use them effectively as it was difficult to find a supplier of the drug under the compulsory license. In that regard, the Representative pointed out that it might be easier to find a supplier of a drug if there were compulsory license proceedings that involved multiple countries, because the combination of more than one country might make it more attractive for a generic supplier to enter into the market.

81. The Delegation of Chile stated that INAPI participated in the WIPO CASE system as a providing and accessing office, and used the ePCT platform. Further, since 2018, INAPI had been accessing the DASK platform, which allowed a secure transfer of documents among offices that were participating in that system. The Delegation noted that INAPI shared data from its databases with other offices and had renewed the cooperation with the Dominican Republic to exchange search and examination forms. The Delegation further noted that INAPI had also implemented a PPH program with the Pacific Alliance. The PPH program, which had been fully implemented with Argentina, Brazil, Colombia, Costa Rica, Peru and Uruguay, would soon start to be implemented with El Salvador, Ecuador and the Dominican Republic. Other PPH programs of INAPI were also operative with Canada, China, Japan and the United States of America.

*Discussion on a further study on inventive step (Part II)*

82. The Secretariat made a presentation on document SCP/29/4 "Further Study on Inventive Step (Part II)" (SCP/29/B). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_b\\_inventive\\_step\\_part\\_ii\\_wipo.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_b_inventive_step_part_ii_wipo.pdf).

83. The Delegation of Spain thanked the Secretariat for the preparation and presentation of document SCP/29/4 as well as all the Delegations for sharing their experiences and helping to improve their knowledge of the issue of inventive step. The Delegation remarked the

importance of continuing discussions on the issue and of sharing experiences in relation to the main aspects of inventive step, also in relation to specific areas such as secondary indications and chemical inventions. In the Delegation's view, the study on inventive step showed that some differences in practices needed to be harmonized worldwide, while taking into account the different particularities of each region. The Delegation expressed its interest in the preparation of the studies on inventive step in the areas of chemical inventions that were to be presented in the 30<sup>th</sup> session of the Committee. However, it regretted the fact that some delegations had not provided their input on the topics, especially regarding questions on chemical issues, which was a topic of much interest for many Delegations.

*Other discussions on this agenda item, including discussions on proposals by Member States.*

84. The Chair recalled that, at the previous session of the SCP, it was decided that the Committee would continue discussions on the proposal by the Delegation of Spain (document SCP/28/7). He further invited delegations to elaborate on their proposals in relation to quality of patents.

85. The Delegation of Spain referred to its proposal in document SCP/28/7, which contained an outline of work on various aspects of patent law relating to new technologies, particularly in relation to artificial intelligence (AI), Big Data and Blockchain. The Delegation announced that the proposal had been joined by the Delegation of France as a cosponsor, and invited the other Delegations to consider joining as well. The Delegation expressed its view that the technological developments mentioned in the proposal would sooner or later be reflected in patent law and thus, as the only multilateral forum in the field of patents, the SCP should not remain oblivious to a reality where the so-called AI, Blockchain, Big Data, etc., were playing an increasingly important role in many areas of life. The Delegation stated that WIPO had already shown that it was aware of that reality, as seen in the report published in February 2018, where 37 Intellectual Property Offices indicated how they used those new technologies in their management. Further, the Delegation referred to the Meeting of Intellectual Property Offices on ICT Strategies and AI for IP Administration on May 23-25, 2018, where it had been stated that efforts should be made to explore how to cooperate internationally in relation to that issue in order to avoid duplication of efforts. The Delegation also recalled that on the first day of the 29<sup>th</sup> session of the SCP, the Chair had referred to paragraph 9 of the Statement made after the G20 meeting in Argentina, stating that AI and other emerging technologies were very important and that works should continue in relation to those topics. The Delegation noted that offices like the EPO and the USPTO were also holding meetings to discuss those questions. In the Delegation's view, it was important to find answers to a number of questions such as those contained in document SCP/28/7 regarding AI and patents. Consequently, and in view of the novelty of the issue, the Delegation suggested that at the next session of the SCP, a document be prepared summarizing how those emerging technologies affect patent law and the work of patent offices. In its opinion, such a summary would serve as a basis for further consideration of the issue at future sessions of the Committee. Further, the Delegation proposed that a conference with experts and sessions for the exchange of experiences could be organized in the future.

86. The Delegation of France thanked the Delegation of Spain for the proposal in document SCP/28/7 and confirmed its support to the proposal and wish to cosponsor. In the Delegation's view, the patent community should look at technological advances such as AI, Blockchain, etc., and discuss how to best deal with those new technologies and with patents generated by AI. The Delegation expressed its view that it was essential that the Committee, which was the only multilateral forum dealing with patents, studied those issues in order to better understand related questions. With regard to the relation between AI, Blockchain and patents, as the Delegation of Spain, the Delegation of France supported the patentability of inventions based on AI. The Delegation suggested that the Secretariat prepare a document to

be discussed in future sessions explaining those new technologies and the challenges that they represented for patents and patent offices. Further, the Delegation supported the organization of conferences with experts that would focus particularly on AI issues, which could help to broaden the scope of a future study on AI and patents. The Delegation also expressed its interest in further discussing how AI could be a useful tool for offices and how it might have a positive impact on the work of an office or on the quality of patents by advancing the search and examination process. In the Delegation's opinion, it would be interesting to exchange the various experiences of different offices in using tools related to AI.

87. The Delegation of India thanked the Secretariat for preparing and presenting document SCP/29/4. The Delegation then reiterated its statement made in the 22<sup>nd</sup> session of the SCP with respect to the Study on Inventive Step (Part I) and Further Study on Inventive Step (Part II) that such documents should not be used as a tool for harmonization of the concept of inventive step. Further, the Delegation recalled the statement made on the Proposal by the Delegation of Spain (SCP/24/3) for additional studies on the assessment of inventive step. In the Delegation's view, inventive step was a feature of an invention that involved a technical advancement compared to the existing knowledge or having economic significance or both and that made the invention not obvious to a person skilled in the art. In that context, the Delegation reiterated its view that the TRIPS Agreement did not provide any definition of inventive step and novelty and gave freedom to Member States to define them considering their social, technical and economic conditions. It expressed its view that studying the interpretation on secondary indications by the courts of the different jurisdictions and the procedure followed in the various patent offices should only serve an academic purpose, but it could not be considered as a criteria for assessing the inventive step nor could it be used as a tool for the harmonization of the concept of inventive step. In addition, the Delegation noted that the opposition system played a vital role in ensuring the quality of patents and that, in the experience of India, the introduction of a product patent regime and of a pre-grant opposition system from 2005 had led to the refusal of many frivolous product patents applications during the prosecution stage. The Delegation stated that, on an average, one third of the granted patents had been revoked in post-grant opposition proceedings. In its opinion, having an effective opposition system ensured not only the quality of patents but also minimized drastically the cost and time involved in consuming litigations. Therefore, the Delegation proposed that a study be conducted on opposition matters in order to strengthen opposition systems. With regard to India's national experience, the Delegation noted that the Indian Patent Act provided an opportunity to the public to participate in the opposition (pre-grant) proceedings to challenge a patent application by raising objections on different grounds, which had helped to ensure transparency in the patent system and improve the quality of patents. Apart from the opposition system, the Delegation stated that the Indian Patent Office was also part of the PCT/MIA quality sub-group from 2013 and that the Indian Patent Office, operated as an ISA/IPEA, and had established its own internal quality management system.

88. The Delegation of the United Kingdom thanked the Delegations of Spain and France for their interventions regarding the Proposal by the Delegation of Spain. The Delegation then referred to the Proposal by the Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom contained in document SCP/28/8, which included a proposal for the preparation of a study by the Secretariat that included a compilation of responses from Member States on how they understood the term "quality of patents", the contributions by various delegations to the sharing session of the 29<sup>th</sup> session of the SCP on December 3, 2018, and any other information that the delegations wished to share. In the Delegation's view, such a study would also serve to highlight any common challenges faced or successful approaches used to address those challenges. The Delegation proposed that the study, which would not include any recommendations, could be discussed in the next session of the SCP as it might help to inform future work of the Committee.

89. The Delegation of Iran (Islamic Republic of) thanked the Delegations of Spain and France for their proposal. The Delegation expressed its view that any discussions or activities in relation to the impact of new technologies should be restricted to patent issues, as the SCP was a Committee related to patents and patent law. The Delegation then asked for clarification regarding when the proposed study would be prepared and by whom, the Secretariat or independent experts, and whether a sharing session or information session would also be organized.

90. The Delegation of the United Kingdom stated that, with regard to the proposal contained in document SCP/28/8, the intention was to limit any future work on the issue to the area of patents but that, in any case, the scope and practical aspects of future work depended on the agreement reached by the Committee. Nonetheless, the Delegation proposed that a preliminary study could be discussed at the next session of the Committee, which could serve as the basis for deciding which topics should be studied in more depth.

91. The Secretariat referred to point 9 of the proposal by the Delegation of Spain which stated that in order to address the questions raised in the proposal, the Delegation requested the Secretariat of the Committee, if possible with the assistance of renowned experts in the field, to carry out a study or studies addressing all or some of the aspects raised in points 6 to 8 of the proposal, which related mainly to the technological challenges that certain technologies had produced, and to certain challenges that the patent system faced because of developments in those technologies. Thus, in the Secretariat's view, what should be considered by the Committee was whether the request to undertake that study, if possible with the assistance of an expert in those fields, would be acceptable as an item for future work.

92. The Delegation of Mexico referred to the proposal by the Delegations of the Czech Republic, Kenya, Mexico, Singapore, and the United Kingdom, and expressed its hope that the Committee continue its work on quality of patents and the process of granting patents. In the Delegation's view, the topic of quality of patents was a substantive technical issue which had an impact on the improvement of the overall patent system. The Delegation also noted the importance of continuing sharing information on the different practices, experiences and legislations of the various Member States on the topic. It expressed its view that when a patent was granted in conformity with the law and the quality of the patent was ensured, such grant was beneficial for the patent system as a whole by promoting innovation and guaranteeing that innovators benefited from the protection they deserved. In that context, the Delegation supported that a study be undertaken by the Secretariat on the relevant approaches to ensuring the quality of patent and of the granting process, taking into account the answers to the questionnaire on the topic of quality of patents, any information provided by the Member States and any other additional information that Member States might wish to provide, including relevant aspects of their national legislation. In the Delegation's opinion, such a study would allow Member States to share and obtain information that could be taken into account for the improvement of their own patent system and quality of patents. Furthermore, the Delegation expressed its support to the proposal by the Delegation of Spain contained in document SCP/28/7 as, in the Delegation's view, it was necessary to know more about the challenges and opportunities that the use of new technologies raised in the context of intellectual property.

93. The Delegation of Singapore supported the statement made by the Delegation of the United Kingdom. In the Delegation's view, the sharing session at the 29<sup>th</sup> session of the SCP was beneficial for Member States since it offered the perspectives from offices of varying sizes and from various regions. The Delegation expressed its interest in positively contributing towards further discussions on the topic of quality of patents. Regarding the next steps, the



Delegation supported the proposal for undertaking a study by the Secretariat on the quality of patent and of the granting process based on the information presented at the sharing session, the responses to the questionnaire regarding the term “quality of patents” and any further information provided by Member States.

94. The Delegation of the Czech Republic stated that the sharing session had provided Member States with a wide range of information that could be used to conduct a study on the issue in line with paragraph 7B of the Joint Proposal in document SCP/28/8. In the Delegation’s view, such a study would also help small and medium size offices to better understand different approaches supporting the improvement of quality of patents. The Delegation reiterated its support for carrying out future work on the item of quality of patents.

95. The Representative of TWN expressed his views on the Further Study on Inventive Step. The Representative first stated that there was a lack of examples in the Study, which compromised the understanding of the concepts discussed. He noted that although there was enough policy space on the issue of inventive step, it was necessary that examples that allowed a robust understanding of how much each test would impact the flexibilities available to the Member States were also provided, so that Member States could assess those tests based on concrete examples on the commercial advantage of applying certain tests on inventive step. Second, he noted that in many cases, for example in the case of selection patents, meeting the inventive step criteria was not enough to obtain a patent but the requirement of novelty also needed to be met. Third, with regard to the courts’ experiences, the Representative noted that it should be considered that courts were different depending on the jurisdiction and that it was possible that the tests developed by some courts were not appropriate for application in other countries with different social and economic conditions. Thus, the Representative proposed that a caution or remark be included in the Study in that regard. Finally, the Representative stated that there were certain governance issues that also affected the quality of inventions and the quality of patents such as, for example, the fact that a patent office was funded by the filing and grant of patent applications, which would make such an office more prone to grant more patents, or the capacity building of examiners in developing countries, for which training according to their own national law and examination procedure should be provided. Thus, in the Representative’s opinion, the issue of quality of patents should be considered from a more holistic perspective rather than only limiting discussions to the patentability criteria.

## **AGENDA ITEM 7: PATENTS AND HEALTH**

### *Half-Day Conference on Publicly Accessible Databases on Patent Information Status and Data on Medicines and Vaccines*

96. The Representative of the MPP made a presentation on The Medicines Patents and Licences Database (MedsPaL) (SCP/29/N). The presentation is available at: [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_n\\_conference\\_on\\_databases\\_medicines\\_patent\\_pool\\_mpp.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_n_conference_on_databases_medicines_patent_pool_mpp.pdf).

97. The Secretariat as well as the Representative of the IFPMA made a presentation on Patent Information Initiative for Medicines (Pat-INFORMED) (SCP/29/O). The presentation is [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_o\\_conference\\_on\\_databases\\_wipo.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_o_conference_on_databases_wipo.pdf).

98. The Secretariat of the WHO made a presentation on databases on patent information status and data on medicines and vaccines.

99. Mr. Richard A. Jefferson, Chief Executive, Cambia, Professor of Biological Innovation, Queensland University of Technology, Canberra ACT, made a presentation on LENS.ORG (SCP/29/P). The presentation is available at: [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_p\\_conference\\_on\\_databases\\_richard\\_a\\_jefferson.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_p_conference_on_databases_richard_a_jefferson.pdf).

100. The Delegation of Brazil thanked all the speakers for their informative presentations and questioned what the main differences were between MedsPaL and Pat-INFORMED in terms of information provided by those respective databases.

101. The Representative of the MPP, responding to the question posed by the Delegation of Brazil, first stressed the similarities between those two databases. In particular, the Representative stated that both databases had a similar spirit and the objective, which was having better access to legal status of pharmaceutical patents. The Representative further explained that both MedsPaL and Pat-INFORMED were tools that procurement agencies could use to gather information on medicines they intended to purchase. The Representative explained further that one difference between the databases was the source of the data: the Pat-INFORMED database relied exclusively on patent information provided by participating companies, whereas MedsPaL gathered information primarily from national and regional patent offices. The Representative continued that another difference was country coverage: while the MedsPaL focused mainly on low- and middle-income countries, Pat-INFORMED had a global coverage. Further difference was related to disease areas covered by those databases: while MedsPaL provided information on the patent and licensing status of selected HIV, hepatitis C, tuberculosis and other patented essential medicines in low- and middle-income countries, Pat-INFORMED had certain disease areas that were not covered by the MedsPaL.

102. The Representative of TWN questioned whether those databases clearly indicated patents on the main molecule and secondary patents, such as formulations and compositions. He was of the view that such an indication would help the policy makers to take suitable actions, including use of the flexibilities. He also questioned whether a big amount of patents indicated in those databases might create a barrier for the procurement agencies to proceed with the procurement. He further referred to a recommendation of the United Nations Secretary-General's High-Level Panel on Access to Medicines (UNHLP) to WHO to establish an international database of prices of patented and generic medicines and biosimilars and asked the Representative of the WHO whether there was any progress in that regard.

103. The Representative of the MPP responded to the Representative of TWN that as regards the secondary patents, MedsPaL provided a brief description of what the specific patent was about and indicated the compound patents for a given molecule. The Representative noted that the MedsPaL did not get involved into question of patentability of the secondary patents in specific jurisdictions. As regards the question on whether the big amount of data might work as a barrier for the procurement agencies to proceed with the procurement, the Representative stated that having information on the patent status of the medicines to make informed decisions was important for such agencies. He added that having a good understanding of the patent system by the users and not just blindly relying on a database was also required in order to be able to interpret the data.

104. The Representative of the WHO, in response to the question posed by the Representative of TWN, stated that it was a challenging task to establish a pricing database as pricing was much more volatile compared to patent data. The Representative further stated that the WHO Vaccine Price Database (V3P) gathered price information on vaccines from more than 100 countries. The database as well as interactive graphs were available on the website of the WHO. The Representative further stated that another mechanism was the WHO Global Price Reporting Mechanism for HIV, tuberculosis and malaria, searchable by country and specific

product. He further informed the Committee that the Report of the Executive Board of the WHO would be published in December 2019 containing information on R&D cost and prices of cancer drugs.

105. The Representative of KEI questioned whether other countries should develop a workable mechanism for biologic drugs as was developed by the Food and Drug Administration (FDA) in the United States of America. He also asked the speakers whether there would be some benefits in developing the requirements for disclosure and sanctions for underdisclosure or over-listing the patents in the databases.

106. With regard to the question on biologics, Mr. Richard A. Jefferson stated that the essential issue for consideration in future patent policy in health related areas was microbiomics. He noted that that area was a massively growing discipline and that, in his view, the biologicals would be eclipsed by microbiomics within a short time.

107. The Representative of the MPP stated that few patents on biologics were included in the MedsPaL. He also noted that the area of biologics was much complex and that it was difficult to draw conclusions from the available data. With regard to the consequences of not listing certain patents in databases, the Representative stated that it did not apply to the MedsPaL, because it was not a mechanism of disclosure by the patent holders themselves. He also noted that the data in the MedsPal should not be interpreted as freedom to operate, and more thorough analysis was required by the users.

108. As regards the Pat-INFORMED, the Secretariat stated that pharmaceutical companies voluntarily and in good faith provided information on key patents for their approved pharmaceutical products in therapeutic categories covered by Pat-INFORMED, and that they were also committed to respond to *bona fide* inquiries from procurement agencies. The Secretariat further noted that information in Pat-INFORMED was meant to be adjunct to other information received on the specific pharmaceutical products and that with the appropriate context, such information would be useful.

109. The Secretariat made a presentation on the Patent Register Portal (SCP/29/Q). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_q\\_patent\\_register\\_portal\\_wipo.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_q_patent_register_portal_wipo.pdf).

110. The Secretariat made a presentation on the WIPO Standards for exchange of patent legal status data (SCP/29/R). The presentation is available at:  
[https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_r\\_wipo\\_standard\\_wipo.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_r_wipo_standard_wipo.pdf).

111. The Delegation of Lithuania, speaking on behalf of the CEBS Group, stated that the access to medicines was a major challenge, and that they were committed to participate in the initiatives that facilitated access to medicines. Nevertheless, the Delegation noted that any duplication with the work of other international organizations should be avoided. The Delegation continued that the SCP had a mandate to discuss that issue from the perspective of the patent system, and that it's Group was convinced that innovation, research and development of new life saving medicines and techniques would not be possible without respecting intellectual property rights where patent protection played a very important role. Further, the Delegation stated that the CEBS Group appreciated the half-day conference on publicly accessible databases on patent information status and data regarding medicines and vaccines. The Delegation further stated that, as in the previous SCP session, the CEBS Group was in favor of transparency in that area, and thus it supported the work program as proposed by the Delegations of Argentina, Brazil, Chile and Switzerland, contained in document SCP/28/10, and it also welcomed further updates from representatives of MPP and Pat-INFORMED on operation of those platforms as well as discussions on existing similar

initiatives. The Delegation also stated that, based on experiences of practitioners on negotiating licencing agreements, it looked forward to learn how to establish more transparent and efficient licencing process.

112. The Delegation of Austria, speaking on behalf of the EU and its Member States, wished to reiterate that access to safe, effective, qualitative and affordable medicines and vaccines for all was a major challenge and a key Sustainable Development Goal that all should support. The Delegation stated that many aspects of the health system played an important role in ensuring accessibility and affordability of medicines, such as incentives to research and innovation, but also the availability of qualified health workers, the provision of affordable medicines as well as the adequate financing of the sector and others. The Delegation continued that a number of exceptions and limitations had already eased access to patented inventions in the EU. Examples included the regulatory review exception and the Regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, that had been swiftly developed and adopted in 2006 by the EU, although the measure had only become binding in 2017. The Delegation further noted that that topic was appropriately addressed under the agenda item “Exceptions and limitations to patent rights”. As far as the mandate of the SCP and WIPO was concerned, the Delegation recalled that the SCP could not go beyond its mandate and that delegations needed to continue to reflect a balanced approach, taking into account the various factors of relevance to patents and health. The Delegation further stressed that intellectual property rights, such as patents, incentivized innovation, leading to new and improved treatments. Further, the Delegation thanked the Secretariat for organizing the half-day conference on publicly accessible databases on patent information status and data, on medicines and vaccines, as well as the sharing session of experiences by practitioners on negotiating licensing agreements. The Delegation noted that those were the topics that they found very promising, as they could lead to increased transparency, smoother licensing, and reduced costs – to the benefit of all. In conclusion, the Delegation welcomed interesting discussions of those highly important topics.

113. The Delegation of Switzerland, speaking on behalf of Group B, stated that continuing innovation was needed to face current and future health challenges. The Delegation continued that the protection of intellectual property rights, including patents, served as an incentive for medical innovation and thereby announced the availability of new medical products for all. The Delegation stated that it was in the interest of the public in all countries to have continuing research and development of safe and effective medical products. Reiterating that patents, as incentive for research and development, were part of the solution to the problem of availability of future medical products, the Delegation, therefore, believed that it was important to keep in mind the whole context of patents in health. The Delegation further stated that the availability of safe and effective medical products was a multi-faceted problem that included different dimensions and factors, as stated by many experts during various SCP sessions or by critical studies, such as the WIPO, WHO, and WTO Trilateral Study “Promoting Access to Medical Technologies and Innovation”. The Delegation stated that Group B supported work under the agenda item “Patents and Health” that would take into consideration the whole context of that field, was relevant to the SCP Mandate, and avoided duplication of work already being done by other Committees or by other multilateral organizations. The Delegation noted that they supported the holistic view in the area of patents and health. It further stated that different projects of collaborations showed how the patent system incentivized innovation and served to provide available and accessible key innovation about patents and inventions. Group B appreciated the half-day conference on publicly accessible databases on patent information status and data, on medicines and vaccines. Noting that there had recently been innovative work in that area by industry and other stakeholders, the Delegation was of the view that the conference helped outline those and other fruitful pragmatic approaches to enhance access to patent information that provided the global community and procurement professionals with valuable data. In that respect, the Delegation took note with interest of the proposal put forward

by the Delegations of Argentina, Brazil, Chile and Switzerland, contained in document SCP/28/10. The Delegation further stated that the issue of patents and health and in particular the issue of access to health technologies crossed into areas that were more in the realm of other specialized UN bodies, and that extensive work was already being done in that area by those organizations and other multilateral fora. The Delegation continued that its Group took note with interest of the proposal put forward by the Delegations of Argentina, Canada, Brazil and Switzerland, contained in document SCP/28/9 Rev., and thanked them for fostering discussions under that agenda item. The Delegation stated that it was open to work that would advance the common understanding of policies and initiatives that could enhance access to medical products. Group B also looked forward to the session for the sharing of experiences by practitioners regarding the negotiation of licensing agreements. The Delegation was of the view that such session would help shed light on concrete experiences in that area.

*Sharing of experiences by practitioners on negotiating licensing agreements*

114. Ms. Rosemary Wolson, Senior Intellectual Property Manager, Council for Scientific and Industrial Research (CSIR), Pretoria, made a presentation entitled “Challenges and Opportunities in Licensing Health Technologies: The Perspective of a practitioner from an African Research Organisation” (SCP/29/S). The presentation is available at: [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_s\\_sharing\\_session\\_on\\_licensing\\_rosemary\\_wolson.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_s_sharing_session_on_licensing_rosemary_wolson.pdf).

115. Mr. Oussama Ben Fadhel, Project Manager in Technology Transfer, Communication, Valuation and Technology Transfer Unit, Pasteur Institute, Tunis, made a presentation on sharing knowledge and experience on negotiating licensing agreements (SCP/29/T). The presentation is available at: [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_t\\_sharing\\_session\\_on\\_licensing\\_ous sama\\_ben\\_fadhel.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_t_sharing_session_on_licensing_ous sama_ben_fadhel.pdf).

116. Mr. Ernesto Cavelier, Partner, Posse Herrera Ruiz, Bogotá, made a presentation entitled “Voluntary License Agreements for Generic Manufacturers: Are They an Effective Path Towards Improving Access to Medicines in Developing Countries?” (SCP/29/U). The presentation is available at: [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_u\\_sharing\\_session\\_on\\_licensing\\_ern esto\\_cavelier.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_u_sharing_session_on_licensing_ern esto_cavelier.pdf).

117. Mr. Dorian Immler, Head of Patents Pharma, Animal Health and Consumer Health, Bayer, Leverkusen, made a presentation on licensing and health (SCP/29/V). The presentation is available at: [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_v\\_sharing\\_session\\_on\\_licensing\\_dori an\\_immler.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_v_sharing_session_on_licensing_dori an_immler.pdf).

118. Mr. Richard A. Jefferson, Chief Executive, Cambia, Professor of Biological Innovation, Queensland University of Technology, Canberra ACT, made a presentation entitled “Experiences with Open Licensing: the Biological Open Source (BiOS) Initiative” (SCP/29/W). The presentation is available at: [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_w\\_sharing\\_session\\_on\\_licensing\\_ric hard\\_a\\_jefferson.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_w_sharing_session_on_licensing_ric hard_a_jefferson.pdf).

119. Mr. Charles Gore, Executive Director, Medicines Patent Pool (MPP), Geneva, made a presentation entitled “The Medicines Patents Pool: Facilitating Access – Promoting Innovation” (SCP/29/X). The presentation is available at: [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_29/scp\\_29\\_x\\_sharing\\_session\\_on\\_licensing\\_cha rles\\_gore.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_x_sharing_session_on_licensing_cha rles_gore.pdf).

120. The Chair thanked the Representatives for their presentations and asked them what the sources of the R&D founding were in their respective countries.

121. Mr. Ernesto Cavelier, stated that, in Colombia, R&D was mostly financed by the government and private companies. He stated that universities also obtained funds from other sources, in particular, from licensing their own innovations.

122. Mr. Oussama Ben Fadhel, stated that 30 percent of its R&D financing came from the Ministry of Research of Tunisia, and that some other funding came from the Ministry of Health. He further stated that international funding agencies, such as the National Institutes of Health (NIH) also financed their R&D. He also noted that its institute had invested in R&D from the revenue of selling its own products, such as BCG vaccine. He stated that they were always in the search of finding new sources of funding for R&D.

123. Ms. Rosemary Wolson stated that in South Africa, the R&D funding came approximately equal from business and government, and with some smaller percentages from universities and other funding sources. She also mentioned that the targeted spending for R&D in South Africa was 1% of the gross domestic product (GDP).

124. Mr. Dorian Immler stated that he did not have exact numbers of R&D financing in Germany. Nevertheless, he assumed that the R&D sources would be similar to the financing of the R&D in the United States of America. He also added that the European Union as a multinational organization also invested into R&D, because there was a clear target by the European Union to make Europe more competitive and innovative. In that regard, he also mentioned Innovative Medicines Initiatives, which was EU public-private partnership funding health research and innovation.

125. The Representative of the TWN asked Mr. Ernesto Cavelier and Mr. Dorian Immler whether they were aware of the number of licenses issued to the Colombian companies and companies in other developing countries for production of generic medicines.

126. Mr. Ernesto Cavelier stated that in Colombia, the registration of licenses was not mandatory; therefore, it was difficult to know the actual number of licenses in place. He further stated that about 300 pharmaceutical companies were providing medicines to consumers in Colombia, and most of them obtained licenses for their products.

127. Mr. Dorian Immler stated that in order to ensure patient access, there was a whole panel of options available, and that Bayer had actually chosen a different approach through, for example, patient access programs and differential pricing program, on a more product and geography-specific way rather than going for a broad licensing program. Noting that each company should find the best solution so that, in the end, it would deliver the product to the patient, he noted that the choice of the option depended on various factors, such as the specificity of the product, the level of education and the number of patients per country.

128. The Representative of KEI asked Mr. Dorian Immler whether Bayer would be licensing to the MPP any of its cancer drugs that it had no intention of marketing at an affordable price in developing countries.

129. In response to the question posed by the Representative of KEI, Mr. Dorian Immler stated that there was much more to making sure that the right patients get the right drug than just to making such drugs available cheaply. Specifically, he noted the importance of good oncology treatment, including the diagnosis, care in the hospitals, and the treatment. He further stated that a compulsory license, which was in place in India for a cancer drug, was not the right way

to deal with the problem. He stated that, nevertheless, Bayer had expanded its patient access program so that a considerable number of patients could also be supplied the drugs directly from Bayer.

130. The Delegation of El Salvador, speaking on behalf of GRULAC, thanked the Secretariat for organizing a half-day conference on publicly accessible databases on patent information status and data on medicines and vaccines and the sharing of experiences on negotiating licensing agreements by practitioners. The Delegation stated that both activities had provided relevant information that could be very useful in facilitating access to medicines. The Delegation noted that the topic of access to medicines was a topic to which its Group attached a great importance. Further, the Delegation expressed its support to the proposals contained in documents SCP/28/9 and SCP/28/10.

131. The Delegation of China thanked all the speakers who had made presentations during the conference on publicly accessible databases on patent information status and data on medicines and vaccines, which provided useful information. The Delegation also thanked the Secretariat for organizing the sharing of experiences on negotiating licensing agreements by practitioners. The Delegation expressed its support for the organization of such sharing sessions to enable developing countries to have more patent-related information. As regards the topic of patents and health in general, the Delegation, on the one hand, stressed the importance of protection of innovation, and on the other hand, underlined the need for full consideration of the public health. Therefore, the Delegation stated that a study on patents and health would be very useful. The Delegation noted the need to increase the understanding of all countries, in particular of developing countries and LDCs, on the issue of flexibilities, including understanding on how to overcome barriers in order to use such flexibilities in practice. The Delegation further expressed its support to the proposal contained in document SCP/28/9.

132. The Delegation of India stated that scientific and technological developments should reach all the humankind irrespective of geographical boundaries. The Delegation stated that, at the same time, the innovator should also be benefitted from the effective patent administration. The Delegation continued that, therefore, the states had a responsibility for taking necessary efforts for the availability and affordability of medicines to all human beings. The Delegation further stated that the patent system should not be the barrier for outreach of medicines to the people in need. In its opinion, the system should balance the interests between the innovator and the society at large in terms of public health. The Delegation continued that, it was indeed one of the foremost responsibilities of the patent system and the innovator to ensure the accessibility of medicines at affordable prices in developing countries and LDCs. The Delegation stated that, even though many other factors influenced the availability and affordability of medicines, the patent protection was one which directly affecting access to medicines in those countries. The Delegation continued that all Member States shall come forward to work towards the access to medicine in developing countries and LDCs, while the patent protection should not be weakened. The Delegation further expressed its support to the proposal contained in document SCP/16/7. Further, as regards the proposal contained in document SCP/28/9 to conduct a review of pre-existing analysis and research on the topic of patent protection and access to medical products and health technologies, the Delegation proposed that such a review should identify specific constraints in relation to the flexibilities that could address public health needs and discuss the same with a view to identifying action oriented solutions. The Delegation also stated that the Committee should also consider the report of the UNHLP while conducting the review of research. The Delegation further noted that such a review should be restricted to patent law issues, such as a role of patentability criteria and the patent examination system in facilitating access to medicines and health technologies, which were key recommendations of the UNHLP. Further, the Delegation reiterated its stand on inclusion of International Nonproprietary Names (INN) in the patent specification, which would in turn facilitate the substantive examination in the grant of quality patents. In that regard, the

Delegation proposed that INN should be included in the patent specification when the applicant was fully aware of said INN so that the examiner could easily conclude on the issue of novelty, inventive step, unity of invention and therapeutic use of the substance. The Delegation continued that such inclusion of INN in the patent specification would not only ensure the easy access to the relevant medicines from databases by the society at a large, but would also enhance the trade in terms of negotiations of cross licensing and assignments by way of easy identification of the specifications related to specific class of drug molecules. The Delegation of India reiterated its stand that the Committee should initiate the work on a feasibility study on inclusion of INN in the patent specification. Further, as regards document SCP/21/9, the Delegation expressed its disagreement with respect to the burden on applicant for submitting the INN and the question of usefulness or advantage of mandatory disclosure of the INN in the patent specification when the applicant was fully aware of the said INN. The Delegation stated that inclusion of INN in the patent specification would not only reduce the search time in other countries for grant of quality patents, but would also ensure evading subsequent opposition proceedings and litigations in the courts. Further, the Delegation expressed its support to the proposal submitted by the Delegations of Argentina, Brazil and Switzerland asking for a regular update on publicly accessible databases of patent status information concerning medicines and vaccines. In its view, such a regular update would be beneficial for the public at large, especially in developing countries and LDCs. Noting that the national health care industries were growing at tremendous speed, the Delegation stated that it was important to maintain the obligation under the TRIPS Agreement and obligations of the States to consider the issues in a balanced manner. The Delegation continued that the national IPR policy of India was focused on enhancing access to health care, food security and environmental protection among other sectors of vital social, economic and technological importance. The Delegation concluded that it was also one of the objectives of India to fulfil the obligations under the TRIPS Agreement and to keep sufficient safeguards for public health by implementing the flexibilities contained in the TRIPS Agreement at the national level.

133. The Delegation of Ecuador thanked the Delegations of Argentina, Brazil, Canada and Switzerland for their proposal contained in document SCP/28/9. The Delegation expressed its support to the proposal because it would enable Member States to have a broad view on existing research on patents and access to medical products and health technologies. The Delegation also expressed its support to the proposal contained in document SCP/28/10 on a regular update on publicly accessible databases of patent status information concerning medicines and vaccines. The Delegation stressed the importance of encouraging any such initiative to make the patent system transparent to facilitate the access to patent status information.

134. The Representative of KEI announced the passing away of Dr. Amit Sengupta, a public health movement activist. The Representative further requested that, as part of the Committee's ongoing work on patents and health, the Secretariat schedule a presentation of document CDIP/14/INF/12 entitled "Alternatives to the Patent System that are used to Support R&D Efforts, Including both Push and Pull Mechanisms, with a Special Focus on Innovation-Inducement Prizes and Open Source Development Models" at the thirtieth session of the SCP.

135. The Representative of TWN stated that the compulsory product patent protection had resulted in a situation where the medicines were not available to the patients where they were required. The Representative stated that, as a result, patents in practice stood out to be a mechanism to protect profit at the cost of people's lives. The Representative continued that, for example, two important medicines for treatment of multidrug resistant tuberculosis, namely bedaquiline and delamanid were exorbitantly priced (bedaquiline around 900 US dollars and delamanid around 1,200 US dollars), and were therefore not affordable for either governments or individuals. The Representative stated that both drugs were included in the WHO list of essential medicines. He further stated that Sustainable Development Goals set a target to end



the tuberculosis epidemic by 2030. He continued that worldwide, nearly half a million people suffered from drug resistant tuberculosis each year which posed a serious public health challenge. In India alone, an estimated 130,000 multidrug-resistant tuberculosis patients emerged annually. The Representative continued that, in India, companies were donating those medicines to the government program but there was a huge gap between the demand and supply. The Representative stated that donation-based approach did not result in an adequate supply of medicines. In his view, the generic production and supply was the only way forward to ensure sustainable supply of those medicines. The Representative further stated that Member States, especially developing countries, should make use of flexibilities, such as compulsory license or government use, to facilitate sustainable generic production and supply. He noted that the current approach of depending on drug donation was insufficient to meet the growing demand and to combat the threat of multidrug-resistant tuberculosis. The Representative wished to take the opportunity to call upon Member States to desist from using political pressure against use of compulsory license and government use. He stated that such use of political pressure amounted to interference in the internal affairs of sovereign rights of states and violated the fundamental principles of public international law and also amounted to violations of obligations under the international human rights law. Finally, the Representative paid his tribute to Dr. Amid Sengupta, who had passed away the previous week. The Representative stated that Dr. Sengupta had been in the frontline of struggle for access to medicines and he would continue to inspire the followers.

#### **AGENDA ITEM 8: CONFIDENTIALITY OF COMMUNICATION BETWEEN CLIENTS AND THEIR PATENT ADVISORS**

136. The Secretariat presented document SCP/29/5.

137. The Delegation of Lithuania, speaking on behalf of the CEBS Group, stated that it attached great importance to continuation of the work under that agenda item. Therefore, it had received with great interest document SCP/29/5 on confidentiality between clients and their patent advisors as well as its summary, which provided an overview of compilation of laws and practices. The Delegation stated that the CEBS Group continued supporting a soft law approach on the issue of confidentiality of communications between clients and their patent advisors. The Delegation agreed with the statement in paragraph 14 of document SCP/29/5 SUMMARY, which stated that “[w]hile it was not realistic to seek a uniform rule involving fundamental changes in national judicial systems, the legal uncertainty surrounding the treatment of confidential communications between patent advisors and their clients could affect the quality of the patent system at the international level”. The Delegation stated that, however, there was no need for legally binding international instrument. The Delegation continued that the CEBS Group would be in a position to support further steps of the substantive nature in order to address that matter at the international level in a non-binding manner, aiming to provide patent applicants or owners of IP rights an opportunity to receive legal advice without risk of forcible disclosure of the communication received from their patent advisors. The Delegation expressed its view that the Committee could contribute to further elaborating the topic and providing more information on the problem as well as working on possible solutions.

138. The Delegation of Switzerland, speaking on behalf of Group B, stated that it continued to attach great importance to the topic of confidentiality of communications between patent advisors and their clients and welcomed the attention that the Committee continued to pay to that important issue. The Delegation also thanked the Secretariat for the preparation of document SCP/29/5 and its useful summary. The Delegation stated that patents were increasingly filed and granted in various jurisdictions. The Delegation noted that the issues surrounding the protection of the communication between patent advisors and their clients was truly related to patent application procedures, as well as patent prosecution and litigation. It

further stated that the issue had a significant impact on how the patents were filed and how communications under those procedures were handled. Noting that patent applicants or owners had to be able to receive cross-boarder legal advice without the risk of forcible disclosure of the communication received from their patent advisors, the Delegation stated that unclear regimes in that regard caused legal uncertainty and unpredictability and negatively affected the innovation environment. Therefore, the Delegation stressed that continued SCP work on that issue toward a mutually agreeable outcome was crucial. Noting that patent laws required that a patent application disclosed an invention in a manner sufficiently clear for the person skilled in the art to put the invention into practice, the Delegation stressed that the protection of confidentiality would not affect the disclosure of an invention in patent application. In particular, the Delegation reiterated that the patentability requirement was not compromised by a client/patent advisor privilege, and neither did the confidentiality of communication between clients and patent advisors affected the level of available prior art for patent examiners. The Delegation stated further that Group B continued to believe that the Committee should take substantive steps to address the matter at the international level in a manner that would provide Member States with the appropriate flexibilities to adapt a common, mutually agreeable approach to their specific legal systems. The Delegation was of the view that a non-binding soft law approach, which had been proposed during several SCP meetings, should be further pursued. Group B looked forward to further discussing the issue, including on the basis of the experiences of Member States so as to help inform the way ahead on that important topic.

139. The Delegation of Austria, speaking on behalf of the European Union and its Member States, thanked the Secretariat for the preparation of document SCP/29/5, as well as its summary. The Delegation noted that the document provided a very good overview of the current state of the discussion on the issue. The Delegation wished to emphasize that the topic deserved serious attention. The Delegation stated that patent applicants and owners should be able to receive legal cross-border advice without the risk of forcible disclosure of the communication received from their patent advisors. The Delegation stressed that the absence of national regulations and/or lack of clarity might seriously hamper the needed cooperation between the client and his/her patent advisor. The Delegation continued that companies and trade relations were becoming more and more globalised and that the same held true for inventors and the fate of their inventions. Thus, the Delegation stated, cross-border confidentiality in the communication of globally acting clients and patent advisors should be something stakeholders could rely on. The Delegation expressed its hope that the discussions with regard to the problem of how to ensure sufficient confidentiality in the litigation process would advance in the SCP. While the Delegation acknowledged the need of some flexibility in different legal systems, it was of the view that the SCP might contribute to increasing the awareness of that problem and the growing demand from practitioners to solve it. Finally, the Delegation stated that, while they were open to learn about alternatives to reach a solution, a soft law approach was a promising way to achieve the desired goal.

140. The Delegation of Canada was pleased to announce that as part of their IP Strategy, they had tabled an action in the Parliament that would establish a College of Patent Agents and Trademark Agents. The Delegation stated that those agents were key components of the innovation eco system as they helped inventors to secure IP rights. Following the granting of a statutory privilege to protect communications between IP agents and their clients in 2016, the new College would continue to ensure that businesses could have full and frank discussions with their IP agents and that they could trust the advice received from those important professionals. The Delegation continued that the new Act would require agents to comply with a Code of Professional Conduct, authorize the College to receive complaints and conduct

investigations into potential professional misconduct, and impose disciplinary measures, if necessary. The Delegation concluded that implementing the modern governance framework for IP agents would: (i) ensure that professional and ethical standards were maintained and that privilege communications would be protected; (ii) clarify client expectations; and (iii) support the provision of quality advice from IP professionals.

141. The Delegation of China thanked the Secretariat for the document prepared on the topic of confidentiality of communications between clients and their patent advisors, as well as for organization of a sharing session on the experiences and court cases of Member States in implementing the confidentiality of communication between clients and their patent advisors through national legislation, including cross-border issues, at the previous session of the SCP. The Delegation reiterated its view that the subject matter should be regulated by national laws and had to be left to each country's legislative models and traditions. The Delegation stressed that within the legislation of many Member States, and in particular, in patent law of China, there was no provision about confidentiality of communication between clients and their patent advisor. The Delegation reiterated that different legal traditions of countries should be respected and therefore national laws should decide whether it was necessary to establish a system to protect the confidentiality of communication between clients and their patent advisors. The Delegation was of the view that the current stage was not yet mature for the adoption of an international framework on that issue.

142. The Delegation of India reaffirmed its views that it had expressed in earlier SCP sessions that the confidentiality of communications between clients and their patent advisors imposed extra jurisdictional powers, which was a clear violation of the sovereign authority of a state, and that such protection was not recognized by either the TRIPS Agreement or the Paris Convention. The Delegation reiterated that in the Indian Patents Act, there was no provision for a client-attorney privilege. The Delegation also stated that citizens of India who were science graduates who had passed the patent agent examination could practice as a patent agent even without a law degree. The Delegation also reiterated that only Indian citizens were entitled to practice as patent agents in India, thus there was no question of extending any privilege to any foreign patent agents. The Delegation further stated that Section 126 of the Indian Evidence Act 1872 mandated that no barrister, attorney, pleader or vakil should be permitted to disclose communications made by his client or advice given by him in the course of his employment except if there was an illegal purpose or showing a crime or fraud after commencement of his employment. Further, the Delegation stated that Section 129 of the Evidence Act stated that no one should be compelled to disclose to a court any confidential communication between him and his legal professional advisor, except when he offered himself as a witness, to the extent necessary to explain evidence given. The Delegation further informed the Committee that the Supreme Court of India had pronounced a judgment restricting foreign law firms/lawyers from setting up offices in India and had only allowed them to come to India on temporary basis for advice on foreign law only and for participation in international commercial arbitrations. The Delegation was of the view that the important duty of the patent attorney was to promote dissemination of information about the patent application and, therefore, any effort of harmonization of the client-attorney privilege would ultimately lead to a defective and unenforceable grant of a patent. According to the view of the Delegation, any confidentiality of communication between a client and his or her attorney could be protected through a non-disclosure agreement.

143. The Delegation of Switzerland aligned itself with its statement made on behalf of Group B. The Delegation thanked the Secretariat for its excellent work in updating document on the confidentiality of communications between clients and their patent advisors (document SCP/29/5). The Delegation observed that document SCP/29/5 referred to the importance of a privileged communication, the purpose of which was to encourage clients to seek advice and the persons who provided the advice to be fully transparent, honest and open

in the process. The Delegation stated that the client should provide all the information that was relevant to receive the best advice, even if those elements that might be disadvantageous for his/her purposes. The Delegation continued that in order to ensure high quality of legal advice, the exchange between the client and his/her advisor should not be restricted because of the fear of the disclosure of their communication. The Delegation noted that document SCP/29/5 highlighted the difficulties that patent advisors and clients could face in cross-boarder situations. In particular, the Delegation stated that, as the study mentioned, confidential communication between the advisor and client might be protected by the rules and practices in the country of origin; however, such confidentiality relationship might not be recognized and protected in foreign countries in cases of litigation. The Delegation stressed that the issue concerned patent practitioners and clients in all Member States. The Delegation also observed that the study further highlighted that, in some countries, the communication between patent attorneys and clients was not protected, and that the scope of communications between overseas advisors and clients differed from country to country. The Delegation also noted that, in the relation to the cross-boarder aspects, the study summarized some of the issues relating to the loss of confidentiality in foreign countries due to nonrecognition of confidentiality of communications with non-lawyer patent advisors, or legal uncertainty as to the recognition of foreign privileges and secrecy obligations. Furthermore, the Delegation stated, the study discussed the lack of comprehensive legal and practical measures to avoid forcible disclosure of confidential communications in cross-boarder contexts. Noting that a further area of insecurity related to the treatment of the advice from in-house patent advisors, the Delegation stated that the legal uncertainty surrounding the treatment of confidential communication between patent advisors and the clients in various jurisdictions could affect the quality of the patent system at the international level, as was mentioned in document SCP/29/5. The Delegation further observed that the Document discussed several remedies to address the issues, for example, through national laws to provide the same effect for communications with national patent advisors and for those with certain foreign patent advisors, including patent advisors from both civil and common law countries. The Delegation agreed that while that approach would allow countries to maintain their flexibilities in terms of substantive law, it would not however solve the asymmetry of cross-boarder protection of confidential IP advice. The Delegation continued that another option would be to define a common minimum standard on international level that could be then implemented into national laws based on the domestic legal traditions and framework. The Delegation reminded the Committee that during the twenty-first session of the SCP, it had proposed to work on a non-binding soft law as a solution to the cross-boarder aspects of the issue. The Delegation noted that such framework might contain general definitions of key terms, such as patent advisor or privileged information, and a minimum protection standard. The Delegation explained that such a framework might serve as a template for national laws, it would have a great advantage, as it would provide a flexible approach that would allow national legislations according to a Member State's legal background, tradition and needs. In conclusion, the Delegation reiterated its proposal, and encouraged Member States to enter into discussions on the content of a non-binding framework.

144. The Delegation of Iran (Islamic Republic of) expressed its appreciation to the Secretariat for preparing document SCP/29/5 and the related presentation. Noting that there had been fundamentally divergent views among Member States on the issue of confidentiality of communication between clients and their patent advisors, the Delegation stated that, at that stage, it was too premature to discuss the norm-setting activities, including non-legally binding international instrument. The Delegation stressed the need to respect diversity of national approaches on the issue.

145. The Delegation of Japan stated that, in order to ensure that patent attorneys and their clients could maintain honest and frank communications, such communications should be properly protected in every country. The Delegation further stated that the creation of an improved system that would better protect confidentiality, would be quite helpful for all Member

States to understand and learn about the laws, regulations, court cases, and experiences in other jurisdictions. The Delegation stressed the importance of the SCP in providing a forum to discuss all those issues, to which it continued to put high value. In that regard, the Delegation wished to express its appreciation to the Secretariat for its great efforts in preparing document SCP29/5 which it considered useful. Noting the need to address the issue from a cross-border perspective, the Delegation stated that discussions to explore the possibility of creating an international framework, which could be accepted by a large number of countries, should be continued.

146. The Delegation of the Republic of Korea stated that it fully recognized the importance of the issue of confidentiality of communications between clients and their patent advisors, especially its cross-border aspects, since international disputes over patent rights had been globally increasing. The Delegation stated that what was most important to have an invention to be protected in the global market was a confidentiality-based communication between the patent advisor and the client. The Delegation expressed its belief that the topic could be effectively and desirably discussed at the SCP, even though each Member State operated under different legal systems. The Delegation emphasized that confidentiality of communications between patent applicants with good will and their patent advisors should neither be harmed nor be invaded due to different systems. The Delegation expressed its hope that Member States would make an effort to bring constructive results on the issue by involving in the discussions with open mind.

147. The Delegation of the United States of America thanked the Secretariat for preparing the collection of laws and practices relating to the confidentiality of communications between clients and their patent advisors, particularly in cross-boarder situations. The Delegation considered the topic to be of a great importance and it encouraged Member States to continue discussing their experiences relating to the issue at the SCP. The Delegation wished to stress that granting confidentiality/privilege to communications between clients and their patent advisors did not limit in any way the disclosure requirement provided by practically all patent laws as a condition of patentability.

148. The Delegation of Morocco, speaking on behalf of the African Group, thanked the Secretariat for the preparation of document SCP/29/5 and the related presentation. It recalled the position of its Group on that agenda item. In particular, the Delegation stated that, in their view, the different legal traditions should be respected and that it was the national legislation that should decide about the protection of confidentiality of communications between clients and their patent advisors, and extent of such protection.

149. The Representative of ICC stated that ICC was a global cross-sectoral business and industry organization. As stated at the earlier SCP meetings, ICC continued to consider confidentiality between clients and their patent advisors as a very important cross-boarder issue in the field of patents. Therefore, the Representative supported further work at the Committee on the topic.

150. The Representative of KEI noted the cross-boarder dimensions of confidentiality of communications between patent advisors and clients, including its implications on ascertaining patent validity.

151. The Representative of TWN stated that disclosure requirement was one of the fundamental requirements in patent law and therefore patent offices should make sure that the application meet the requirement. The Representative continued that, in his view, the extension of confidentiality or privilege to patent attorneys would compromise the ability of the patent offices to ensure that there was a complete disclosure of the invention in the application. The Representative stated that, in that regard, it was important to examine the role of a patent

attorney in the overall patent system. The Representative continued that patent attorney helped to draft the patent application, including the claims. Further, he stated that the art of patent drafting was that limited information disclosed in the application would result in broader scope of claims. Therefore, he stated, it was important that the patent offices had the ability to discover the documents to ensure that the requirement of the sufficiency of the disclosure was met. The Representative further noted that there was no concrete evidence that the court or the patent office had ordered the communication to be disclosed and therefore a patent, which should have been granted, had been denied. The Representative concluded that in the interest of transparency and accountability, it was not a good idea to extend the client-attorney privilege to patent professionals.

152. The Representative of FICPI thanked the Secretariat for preparing an updated document SCP/29/5, of which he was impressed, as well as its summary and the related presentation. The Representative stated that FICPI recognized the importance of the protection of IP advice to allow a client to have frank, full, honest and uninhibited communications with their qualified or otherwise suitably accredited IP advisors. The Representative further stated that confidential communications between a client and their IP advisors might be subject to discovery in some jurisdictions, whether the advisor acted inside or outside the jurisdiction and even where such communications by the advisor acting within the jurisdiction were afforded protection from disclosure. The Representative stated that IP rights needed to be enforceable in each jurisdiction where they existed. He further stated that persons should be able to obtain comprehensive and frank advice in confidence from IP advisors on the acquisition and enforcement of IP rights, based on full knowledge of the relevant facts, nationally and transnationally. Therefore, in his opinion, communications to and from such advisors and documents created for the purposes of such advice needed to be confidential to the persons so advised and protected from forcible disclosure to third parties, unless and until the persons so advised voluntarily disclose such communications. Consequently, the Representative urged Member States to support a requirement for confidentiality for such communications and to extend the protection/privilege which applied nationally to IP advice given by qualified or otherwise suitably accredited IP advisors in other countries and regions in order to avoid confidential advice to be disclosed and, thus, the confidentiality in that advice to be lost everywhere. The Representative further explained that the adverse consequences of such loss of the protection included owners of IP rights deciding not to trade in particular nations or not to enforce their rights in such nations, if the consequences of doing so might result in their communications relating to IP advice disclosed and used against them both locally and internationally. In conclusion, the Representative expressed FICPI's strong support for keeping the topic on the agenda of the Committee and suggested the Committee to engage in a further sharing session and to compile a reference document on the topic.

153. The Representative of AIPPI thanked the Secretariat for the work that it had carried out on the important issue being discussed. The Representative referred the attention of the Committee to his statement made at the previous session of the SCP. The Representative highlighted the fact that the issue of confidentiality of communications was relevant not only at the stage of filing the patent application but also after the grant of a patent. The Representative clarified that, for instance, a client might ask foreign patent advisors whether it would be useful or risky to undertake some kind of court proceedings with regard to the counterfeiting of his/her product in a foreign market by the competitor, given the specificity of the legislation in question. In his view, such consultations should remain confidential. Finally, the Representative offered its readiness to take part in the preparation of any document on the issue, with the understanding that different legal traditions in different countries needed to be maintained.

154. The Representative of JPAA stated that it was important to keep the topic of confidentiality of communications between clients and patent advisors on the agenda of the SCP, and that the SCP was the most appropriate forum to discuss the issue. The Representative stated that, in Japan, pursuant to Article 197 of the Code of Civil Procedure, professional representatives, including patent attorneys, were entitled to refuse to testify with regard to matters which they had learned in the course of their professional duties and which should remain confidential. The Representative stated that the right to refuse to testify was important for clients to feel reassured and to disclose their secrets to their professional representatives in order to receive proper advice. The Representative further stated that once information was made publicly available in one country, it was impossible to restore the information as secret in other countries. Recalling a proverb "a small leak would sink a great ship", the Representative stated that any small accident in one country could inevitably spread out across in other countries. Therefore, the Representative was of the view that the confidentiality of communications between clients and their patent advisors should be appropriately kept under an international framework rather than being processed in accordance with each domestic law. The Representative further stated that to discuss the issue, differences between the legal systems in each country and particular elements among each country, such as differences in eligibility requirements for patent advisors and differences between civil law and common law, needed to be considered in a comprehensive way. In conclusion, the Representative stated that a soft law approach was the best way of advancing the discussions on the issue.

#### **AGENDA ITEM 9: TRANSFER OF TECHNOLOGY**

155. The Secretariat presented document SCP/29/6.

156. The Delegation of India commended the work of the Secretariat in preparing document SCP/29/6 regarding information on patent law provisions that contributed to effective transfer of technology, including sufficiency of disclosure. The Delegation noted that Article 7 of the TRIPS Agreement mandated that the protection and enforcement of IP rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. The Delegation stated that technology transfer was one of the objectives of their national IPR policy. It noted that technology transfer was used to get a value for IPR through commercialization and devising suitable contractual licensing guidelines promoting patent pooling and licensing to create IPR-based products and services. The Delegation further informed the Committee that after that initiative, many technologies in India had been transferred from public-funded institutions to private companies. The Delegation stated further that although Article 29 of the TRIPS Agreement established the requirement for sufficiency of disclosure of inventions in patent applications, the appropriate place for discussing that requirement was under the agenda item on quality of patents, including opposition systems. In addition, in relation to the sufficiency of disclosure requirement, the Delegation stated that the applicant had an obligation to comply with the sufficiency of disclosure requirement and that the public should be able to utilize the disclosure for making an improvement to the patented technology. The specification, which would become a public document after the statutory publication, enabled the research community to endeavor to make further development in that area. Further, the Delegation stated that after the introduction of the product patent regime in India in 2005, examination of product patent-related applications, particularly in the field of pharmaceuticals, had become a challenge for the examiners especially with respect to the examination of Markush type claims. In that regard, the Delegation was of the view that most of

the Member States might be also facing similar problems in processing patent applications claimed in the Markush format. Therefore, the Delegation requested the Secretariat to make a survey or a study for ascertaining a common sufficiency requirement for Markush type claims among the Member States.

157. The Delegation of Lithuania, speaking on behalf of the CEBS Group, thanked the Secretariat for the preparation of document SCP/29/6. The Delegation noted that the document compiled information provided in the several previous sessions of the Committee. The Delegation also wished to thank Member States for their valuable contribution while building up that particular document. The Delegation stated that its Group acknowledged the differences in national legal practices on that issue. Therefore, it especially welcomed dissemination of best practises in patent law provisions that contributed to effective transfer of technology and looked forward to having interesting discussions. Further, the Delegation acknowledged work of the Secretariat in that area, including constantly updating the WIPO webpage on technology transfer. The Delegation encouraged WIPO to continue to promote transfer of technology, and expressed its firm belief that legally approved utilisation of technological solutions would be able to boost development. Having said that, the Delegation underlined that IP commercialization and transfer of technology were important issues for the CEBS Members as well. However, they considered that the issue of promotion and education should be in the framework of appropriate fora. In that context, the Delegation noted that the CDIP was specifically designed for promotion of the issues relevant to technology transfer. Therefore, the CEBS Group would support those countries that call for avoiding any duplication of work, bearing in mind coverage of the technology transfer in the CDIP.

158. The Delegation of Austria, speaking on behalf of the European Union and its Member States, thanked the Secretariat for the preparation of the excellent document SCP/29/6. The Delegation stated that the document provided a very good compilation of shared experiences and information exchange between Member States regarding aspects of technology transfer by means of patent law provisions and especially the requirement of the sufficiency of disclosure. The Delegation stated that the country-by-country documentation showed different attempts and initiatives to deal with those topics and how to achieve commercialization once innovation had occurred. Further, the Delegation thanked the Delegations of Canada, Chile, China, Colombia, the Czech Republic, France, Uganda, the United Kingdom and the United States of America for their valuable contributions. The Delegation continued that the sufficiency of disclosure requirement provided a level ground for the public as well as for stakeholders interested in an invention thus promoting the utilization of the invention and, at the same time, distributing the knowledge. The Delegation noted that both aspects contributed to technology transfer. While the Delegation was interested to listen to examples and success stories regarding the impact of patent law provisions to technology transfer, it wished to recall its position not to forget to avoid duplicating the excellent work that had been delivered by WIPO in the framework of the CDIP. The Delegation stated further that there was no doubt that technology transfer was advanced by making appropriate use of the patent system and especially of the knowledge provided by the disclosure of an invention. The Delegation continued that technology transfer was of vital importance for both developed countries and developing countries and a very characteristic feature of the economic world in the twenty-first century. Thus, the Delegation encouraged WIPO to continue to engage in activities to promote such transfer of technology. However, it wished to reiterate that, as far as those activities were mainly or specifically designed for promoting development, they should be discussed within the CDIP.

159. The Delegation of China took note of document SCP/29/6 which provided useful references for all countries. The Delegation stated that efficient and free circulation of technologies had importance and positive impact on technological innovation, development and public interest as a whole. The Delegation noted that some countries had taken measures, such as establishing digital platforms and providing preferential fees, thus effectively promoting



technology transfer and economic development satisfying the public interests. The Delegation further stated that China had taken a number of measures in promoting fair technology transfer, such as establishing operational platforms and establishing open licenses in the draft amendment to its patent law. The Delegation was willing to continue to learn from other countries from their successful experiences on the issue. At the same time, the Delegation expressed its hope that the SCP would pay attention to the difficulties encountered by the developing countries in transfer of technology and seek solutions. The Delegation proposed to the Secretariat to continue to compile and collect laws and regulations of countries in promoting technology transfer, and on that basis, advise countries on the implementation of their laws, and to formulate a study which would be a reference for all countries on the subject of technology transfer.

160. The Delegation of Chile thanked the Secretariat for the preparation of document SCP/29/6, which, *inter alia*, compiled the Committee's discussions on the subject of technology transfer. Particularly, the Delegation valued the fact that the document contained two aspects of the patent system related to transfer of technology: legal provisions under the patent law, such as sufficiency of disclosure, but also practical tools, programs and initiatives, which were based on, or promote the use of, such legal provisions. The Delegation also appreciated that information on activities carried out by INAPI in that area was also included in the document. The Delegation stated further that the National Strategy on Intellectual Property launched by INAPI in 2006, among its objectives, had promotion of transfer of technology. In that regard, INAPI had developed a series of initiatives, including trainings and capacity building on industrial property issues and transfer of technology, such as launching the first pilot program master class on IP in cooperation with WIPO, seminars on international patent strategies and transfer of technology directed at local enterprises, and short capacity building courses on IP for public-funded entities. The Delegation noted the importance of an integral management and a strategy for industrial property in which protection was only first step and the generation of value and the transfer of technology were the final aims. In addition, the Delegation stated that the National Strategy on Intellectual Property had also foreseen norms and rules with regard to the appropriation of results of research undertaken with public funds, taking into account successful experiences of laws of other countries on technology transfer. In conclusion, noting that document SCP/29/6 contained information from various countries on the subject of transfer of technology, the Delegation noted the usefulness of the document for the development of that topic in Chile.

161. The Delegation of Canada, speaking on behalf of Group B, thanked the Secretariat for the preparation of the document on patent law provisions that contribute to effective transfer of technology, including sufficiency of disclosure (SCP/29/6). The Delegation also wished to thank those Member States that had shared their national developments and practices on the issue. The Delegation stated that the document usefully exemplified their position whereby knowledge dissemination and transfer was a fundamental built-in objective of the patent system. The Delegation stated further that WIPO engaged in a variety of activities and initiatives that supported technology transfer, including through patent information services, such as the access to research for development and innovation program, the network of 638 technology and innovation support centers, as well as WIPO GREEN and WIPO Re:Search, which were voluntary multistakeholder platforms that promoted collaboration between technology holders and users. The Delegation noted further that, in addition, the CDIP had been considering technology transfer, including three proposals by Member States and/or conducted by the Secretariat. Referring to document CDIP/21/5, which listed activities and services contributing to the technology transfer carried out by WIPO from 2014 to 2017, the Delegation noted that such activities and initiatives reinforced the patent system's core capacity and objective to promote the transfer of technology. In conclusion, the Delegation expressed its view that

concrete issues and activities related to the role of WIPO and technology transfer should be discussed, without prejudice, in the CDIP, rather than in the SCP. In that regard, the Delegation noted that the CDIP was much more familiar with and suitable for the consideration of concrete projects, and placing such discussions at the CDIP would help avoid any duplication of work.

162. The Delegation of the United States of America extended its appreciation to the Secretariat for preparing document SCP/29/6 as well as to the Member States that had provided information for the preparation of the document. The Delegation stated that it was encouraged by many programs and platforms listed in the document that had been developed in various countries to facilitate the transfer of technology through voluntary licensing of intellectual property rights. However, the Delegation supported the view expressed by the Delegation of Canada, speaking on behalf of Group B, that concrete issues and activities related to the role of WIPO in technology transfer would be better discussed in the CDIP rather than in the SCP.

163. The Delegation of Brazil stated that the topic of transfer of technology opened many opportunities to explore. The Delegation stated that intellectual property rights, in particular the patent system, rested on a compromise, a temporary monopoly on economic exploitation of a product in exchange for the disclosure of its underlying technology to advance knowledge for the benefit of society as a whole. The Delegation referred to Article 1, Section 8, Clause 8 of the United States Constitution, according to which Congress shall have the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”. The Delegation noted that the idea of advancing knowledge and technology had been recognized from the start as a core goal of the intellectual property system. The Delegation continued that the TRIPS Agreement recognized in the Preamble “the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives”. The Delegation stated further that, although many different elements affected knowledge transfer, the patent system played a key role in it. The Delegation continued that that was acknowledged in Article 7 of the TRIPS Agreement which stated that “[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”. The Delegation further quoted Article 66.2 of the TRIPS Agreement which stated “[d]eveloped country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base”. The Delegation also referred to Recommendations 25, 28, 29, 30, and 31 of the WIPO Development Agenda, which highlighted the need to the transfer and dissemination of technology in a manner conducive to social and economic welfare. The Delegation further welcomed document SCP/29/6, which was informative and useful. In the view of the Delegation, Member States could greatly benefit from sharing such provisions, programs and initiatives. The Delegation stated that, thus, the Committee should continue to further explore other patent law provisions that contributed to the effective transfer of technology, including sufficiency of disclosure. Noting the importance of the topic to Brazil, the Delegation expressed its hope that the Committee would conduct more work on the topic. In that sense, it disagreed with other delegations which were of the view that the topic of transfer of technology should be exclusively discussed within the CDIP.

164. The Delegation of Iran (Islamic Republic of) thanked the Secretariat for preparing document SCP/29/6 as well as those Member States that had provided information for the preparation of the document. The Delegation stressed the high importance of the topic for its

country. The Delegation stated that the discussions undertaken at the CDIP with regard to transfer of technology was of a broad nature and did not involve detailed discussions with regard to patent issues. Therefore, in its opinion, there was no duplication of work between the CDIP and the SCP as regards that topic.

165. The Delegation of Canada, speaking in its national capacity, thanked the Secretariat for preparing document SCP/29/6. The Delegation wished to bring to the Committee's attention that a new patent law provision that would contribute to the effective transfer of technology had been tabled to the Parliament of its country. The Delegation stated that the provision would ensure that new owners of standard-essential patents honored licensing commitments made by previous owners, and that the standard setting organizations and those that utilized the standard could rely on those licensing commitments regardless of a change in ownership of the patent. The Delegation noted that the amendment promoted fairness and certainty in the patent system and contributed to transfer of technology by ensuring that businesses that sought to implement standardized technology had the ability to do so.

166. The Delegation of Nepal thanked the Secretariat for preparing document SCP/29/6 which provided useful information as regards the Member States' technology transfer activities. The Delegation noted that the issue of transfer of technology was crucial for developing countries, in particular, the least-developed countries. Referring to Article 66.2 of the TRIPS Agreement, whereby developed countries had an obligation to provide incentives to their enterprises and institutions for the purpose of promoting and encouraging technology transfer to least-developed countries, the Delegation requested the continuation of the discussions of that important topic at the SCP. The Delegation further informed the Committee that, in 2017, its Government had adopted the IP Policy, which made a strong provision as regards the protection of patent rights and transfer of technology. The Delegation stated that specific departments had been created for the management of industrial property and transfer of technology. The Delegation further requested the Secretariat to collaborate with the United Nations Technology Bank for Least Developed Countries established in Turkey and to help those countries in building capacity on technology and other related transfer matters.

167. The Representative of TWN stated that the SCP was the right forum to discuss the challenges posed by patents as regards the transfer of technology. He further stated that, as being a UN specialized agency, WIPO had a mandate to work on that issue irrespective of its forum. Noting that one important way to facilitate transfer of technology in the context of patents was the disclosure requirement, the Representative stated that there was no guideline or format to ensure disclosure in such a way that a person skilled in the art could carry out the patented invention. In that regard, the Representative stated that the Committee should give a mandate to the Secretariat to frame such guidelines. Further, the Representative stated that it was important that the patent offices worked on a technology landscaping based on the patent literatures. Finally, the Representative stated that another important component as regards the transfer of technology was capacity building with regard to the freedom to operate analysis as well as patent opposition systems.

## **AGENDA ITEM 10: FUTURE WORK**

168. After some consultations, the Committee decided on its future work as follows:

- The non-exhaustive list of issues will remain open for further elaboration and discussion at the next session of the SCP.

- Without prejudice to the mandate of the SCP, the Committee agreed that its work for the next session be confined to fact-finding and not lead to harmonization at this stage, and would be carried out as follows:

#### *Exceptions and Limitations to Patent Rights*

- In accordance with the agreement within the Committee at SCP/28, the Secretariat will continue to work on a draft reference document on exceptions and limitations to patent rights in conjunction with patent protection, and will prepare a draft reference document on the exception regarding compulsory licensing for SCP/30. The Secretariat will invite Member States to send any additional inputs for the preparation of the draft reference document on the exception regarding compulsory licensing. The draft reference document on the research exception (document SCP/29/3) will be kept open for future discussion by the Committee. At SCP/30 the Committee will decide on the topic for SCP/31.

#### *Quality of Patents, including Opposition Systems*

- The Secretariat will prepare a further study on inventive step (part 3), giving a particular attention to the topics suggested in paragraph 8 of Annex to document SCP/24/3 (Proposal by the Delegation of Spain).
- The Secretariat will prepare a background document on patents and emerging technologies and submit it to SCP/30.
- With a view to prepare a study based on paragraph 7(b) of document SCP/28/8 on approaches to the quality of the patent grant process, to be submitted to SCP/31, the delegations will continue sharing their practices on this issue, including opposition systems. As a next step, special attention should also be given to the capacity building of patent examiners and offices.

#### *Patents and Health*

- The Committee will carry out a work program contained in the proposal by the Delegations of Argentina, Brazil, Chile and Switzerland (SCP/28/10 REV) regarding a regular update on publicly accessible databases of patent status information concerning medicines and vaccines, which was revised during SCP/29.
- The Secretariat will commence work on a review of existing research on patents and access to medical products and health technologies, as contained in document SCP/28/9, as revised during SCP/29, and will present a final report at SCP/31.
- The Secretariat, as well as invited relevant institutions, will share their experiences on capacity building activities relating to negotiating licensing agreements at SCP/30, giving a particular attention to paragraph 20(a) of Annex to document SCP/24/4 (Proposal by the African Group for a Work Program on Patents and Health).

#### *Confidentiality of Communications between Clients and Their Patent Advisors*

- The Secretariat will continue update the dedicated website "Confidentiality of Communications between Clients and Their Patent Advisors". The Secretariat will invite Member States to send any additional inputs for the preparation of the updated document based on document SCP/29/5.

### *Transfer of Technology*

- The Secretariat will continue to compile information on patent law provisions and practices that contributed to effective transfer of technology, including sufficiency of disclosure, based on the inputs to be received from Member States and discussion within the SCP.

### **AGENDA ITEM 11: SUMMARY BY THE CHAIR**

169. The Chair introduced the Summary by the Chair (document SCP/29/7).

170. The Summary by the Chair was noted by the Committee.

171. The SCP further noted that the official record of the session would be contained in the report of the session. The report would reflect all the interventions made during the meeting, and would be adopted in accordance with the procedure agreed on by the SCP at its fourth session (see document SCP/4/6, paragraph 11), which provided for the members of the SCP to comment on the draft report made available on the SCP Electronic Forum. The Committee would then be invited to adopt the draft report, including the comments received, at its following session.

### **AGENDA ITEM 12: CLOSING OF THE SESSION**

172. The Delegation of Indonesia, speaking on behalf of the Asia and the Pacific Group, thanked the Chair for his leadership in guiding the meeting towards successful conclusion. The Delegation also expressed its appreciation to Vice-Chairs for their contribution, as well as all Member States and regional groups for their constructive spirit throughout the week. The Delegation welcomed the future work and stated that the spirit of progress and constructivism was important for the Committee to do meaningful work under the remit of its mandate. The Delegation stated that its Group looked forward to the draft reference document on compulsory licensing to be submitted to the following session of the SCP. In addition, the Delegation looked forward to the further work on part three of the study on inventive step, patents and emerging technologies, as well as the continuation of sharing of practices and approaches on the quality of patents, including opposition systems with a view to preparing a further study. The Delegation applauded and thanked the Secretariat, the delegates as well as all participants and speakers on the successful half-day conference on publicly accessible databases on patent information status and data, on medicines and vaccines, as well as the sharing of experiences by practitioners on negotiating licensing agreement that had been held during the session. The Delegation further welcomed and looked forward to the implementation of the work program as contained in documents SCP/28/10 and SCP/28/9. The Delegation also welcomed the agreed future work on the confidentiality of communication between clients and their patent advisors as well as on the transfer of technology. The Delegation expressed its appreciation to the conference services and the interpreters for their excellent work that allowed the Committee to have smooth and successful meeting. The Delegation looked forward to another productive session of the SCP. In conclusion, the Delegation reaffirmed the continued commitment of its Group for the work of the Committee.

173. The Delegation of Canada, speaking on behalf of Group B, thanked the Chair for his able and wise guidance and continued commitment through the session of the SCP. The Delegation also thanked the Secretariat for the hard work before and during the session, as well as the interpreters and translators for their professionalism and availability. The Delegation also expressed its appreciation to the presenters and participants in sharing sessions and

conferences. The Delegation also thanked the other regional groups and their respective regional coordinators for the collaboration during the week. The Delegation concluded by stating that Member States could count on the full support and the constructive spirit of the Group B delegations to continue the fruitful discussions that had been taking place in the framework of the Committee.

174. The Delegation of Lithuania, speaking on behalf of the CEBS Group, thanked the Chair for his efforts to move the work of the Committee forwards. The Delegation expressed its appreciation to extremely helpful inputs of the Secretariat, and thanked the Secretariat for their work in preparing the SCP session. The Delegation also thanked interpreters for their tireless work, as well as the WIPO Conference services. Further, the Delegation expressed its satisfaction with substantive discussions carried out during the session on different issues related to functioning of the patent system. The Delegation also thanked all delegations and regional coordinators for the constructive spirit that allowed the Committee to agree on its future work. The CEBS Group looked forward to continuing discussions at the following session of the SCP in a similarly constructive manner. The Delegation wished all capital based delegates to have a safe journey home.

175. The Delegation of China expressed its appreciation to the Chair for its leadership and efforts in guaranteeing the success of the meeting. The Delegation thanked all the coordinators of the regional groups for their flexibility and for the achieved balanced work program which would enable the Committee to obtain the useful information and continue working on various issues. Finally, the Delegation looked forward to having deepened discussions and better results in the future session of the SCP.

176. The Delegation of Austria, speaking on behalf of the EU and its Member States, thanked the Chair for the excellent chairmanship and the way he had guided Member States in the course of the week. The Delegation also thanked the Secretariat for the huge amount of work carried out in preparation of that meeting. Last, but not least, the Delegation thanked the interpreters who enabled the delegations to understand each other. Further, the Delegation stated that the meeting had been characterized by constructive fact-based and interesting work in a cooperative and friendly spirit. The Delegation stated that it had already enjoyed the same spirit during the previous session of the SCP. Noting that lots of valuable information and fruitful discussions had been shared during the week, the Delegation particularly mentioned the sharing session under the agenda item "Quality of patents, including opposition systems" and "Patents and health". Further, the Delegation thanked all delegations which had shared their experiences at the SCP, enabling other delegations to learn about best practices and the different ways of work under different legal systems, which in its view, was a tangible result of the session. The Delegation also noted that the half-day conferences under those agenda items proved to be very interesting. Further, the Delegation noted that the discussion on the issue of confidentiality of communications between clients and their patent advisors had been based on an excellent and comprehensive document prepared by the Secretariat. The Delegation expressed its hope that the continued discussions on that topic would create further awareness about the problem and point a way how to solve it. The Delegation continued that it had discussed with interest the patent-related aspects of technology transfer and the reference paper on the research exception. The Delegation noted that both topics emphasized the importance of the international patent system for economy and society. Finally, the Delegation expressed its satisfaction with regard to agreed future work of the Committee. In conclusion, the Delegation stated that its Group was willing to continue to constructively engage in the work of that important Committee. In addition, the Delegation wished to see even more progress which might be achieved in the good spirit that all delegations had shown during that session of the SCP.

177. The Delegation of El Salvador, speaking on behalf of GRULAC, thanked the Chair for the excellent session and his efforts to achieve a progress. The Delegation stated that it was returning home very satisfied with the results of the session, and looked forward to future sessions in which it would actively participate. The Delegation also thanked the regional groups and their coordinators and all Member States for their flexibility and constructive attitude. The Delegation also thanked the Secretariat for the preparation of the meeting, the conference services of WIPO, as well as the translators and interpreters for their support throughout the session.

178. The Delegation of Morocco, speaking on behalf of the African Group, thanked the Chair for his leadership during the session of the SCP. The Delegation also thanked the Vice-Chairs and the Secretariat, which had made great effort to achieve an agreement during that session. The Delegation wished to reaffirm the importance of the work of the Committee and thanked all those experts who enriched the debate throughout that week, which allowed Member States to acquire greater knowledge on various issues discussed. The Delegation further reaffirmed the commitment of the African Group to making progress within the Committee. In conclusion, the Delegation thanked the regional coordinators, interpreters and translators for their excellent work.

179. The Delegation of Kazakhstan, speaking on behalf of the Caucasian, Central Asian and Eastern European Countries (CACEEC), thanked the Chair of the SCP for his great work in chairing the session, as well as Vice-Chairs, the Secretariat and all participants in the twenty-ninth session of the SCP for the enlightening and fruitful meeting. Noting a considerable progress of the Committee under the topic of exceptions and limitations to the rights, the Delegation stated that two draft reference documents, SCP/28/3 and SCP/29/3, were a positive outcome of the consistent work. The Delegation noted that the two topics considered in those documents were critical for the innovation and development. The Delegation looked forward to the draft reference paper on the topic of compulsory licensing which would be submitted to the following session of the SCP. The Delegation stated further that countries of their region were interested in sharing information on the implementation of compulsory licensing in the Member States and involved barriers. Therefore, the CACEEC Group was in favor of continuing the Committee's work under the topic of exceptions and limitations to the rights. The Delegation expressed its confidence that final versions of the reference documents would be useful for the broader audience. Turning to the topic on quality of patents, including opposition systems, the Delegation stated that it was a key item in the SCP's agenda. Therefore, the Delegation supported further work on that topic and noted its particular interest in sharing Member States' experiences with regard to the evaluation of the inventive step and sufficiency of disclosure for inventions in some fields of technology, including those related to medicines. The Delegation continued that its Group considered that the study on offices' approaches to the assessment of inventive step was well timed. In its view, under that agenda item, the Committee could consider a number of issues relating to the assessment of patentability for both selection inventions and inventions related to polymorphic forms. However, the Delegation noted that the interest of its Group lied in other issues considered by the Committee under that agenda item, including the topic of opposition systems. Accordingly, the Delegation supported further consideration of those subjects in the future sessions of the SCP. The Delegation expressed its belief that the Committee was a good platform to discuss best practices on ensuring patent quality and sharing work products between patent offices. Further, the Delegation extended its thanks to the Secretariat for organizing the highly informative conferences with the involvement of key experts under the agenda item on patents and health. In that regard, the Delegation noted that information concerning the existing databases on inventions related to medicines and on key aspects of licensing in the public health area was of particular relevance for countries in the region. Further, the Delegation noted the importance of discussions on the topic of confidentiality of communications between clients and their patent advisors in view of countries' interest in taking a balanced approach in cross-border cooperation and safeguarding clients'

interests. In the view of the Delegation, further consideration of that agenda item would contribute to better understanding of the challenges faced by patent advisors and their clients in cross-border issues. The Delegation suggested that the Secretariat prepare a questionnaire to uncover those problems. The Delegation stated that sharper focus on the challenges faced by clients and patent advisors would help to bring the Committee closer to the consideration of the proposal of an advisory document on confidentiality of communications. In conclusion, the Delegation thanked all regional coordinators for their constructive and concerted effort, as well as translators, interpreters and administrative staff for their continuous support provided to delegations and wished a safe journey back home to capital-based delegates.

180. The Delegation of the United Kingdom thanked the Chair, the regional coordinators, all the delegations, the Secretariat as well as interpreters for their hard work during that session.

181. The Chair thanked the regional coordinators, all other delegates, the Secretariat and the interpreters for their excellent work towards getting a consensus. The Chair closed the session on December 6, 2018.

*182. The Committee is invited to adopt this draft Report.*

[Annex follows]



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