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Standing Committee on the Law of Patents

Thirtieth Session
Geneva, June 24 to 27, 2019

REPORT

adopted by the Standing Committee

1. The Standing Committee on the Law of Patents (the "Committee" or the "SCP") held its thirtieth session in Geneva from June 24 to 27, 2019.

2. The following Member States of WIPO and/or the Paris Union for the Protection of Industrial Property were represented: Algeria, Angola, Argentina, Australia, Azerbaijan, Bangladesh, Barbados, Belarus, Bolivia (Plurinational State of), Botswana, Brazil, Burkina Faso, Burundi, Cameroon, Canada, Chile, China, Colombia, Costa Rica, Côte d'Ivoire, Croatia, Czech Republic, Denmark, Dominican Republic, Ecuador, Egypt, El Salvador, Estonia, Finland, France, Germany, Ghana, Greece, Guatemala, Holy See, Honduras, Hungary, India, Indonesia, Iran (Islamic Republic of), Ireland, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kuwait, Latvia, Lebanon, Liberia, Libya, Lithuania, Mauritius, Mauritania, Mexico, Monaco, Mongolia, Morocco, Nepal, New Zealand, Nicaragua, Nigeria, Norway, Oman, Pakistan, Panama, Paraguay, Peru, Philippines, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Saudi Arabia, Serbia, Seychelles, Singapore, Slovakia, South Africa, Spain, Sweden, Switzerland, Thailand, Trinidad and Tobago, Tunisia, Turkey, Uganda, Ukraine, United Arab Emirates, United Kingdom, United States of America, Uruguay, Uzbekistan, Viet Nam, Zimbabwe (96).

3. Representatives of the following intergovernmental organizations took part in the meeting in an observer capacity: African Intellectual Property Organization (OAPI), 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) (8).

4. Representatives of the following non-governmental organizations took part in the meeting in an observer capacity: Asian Patent Attorneys Association (APAA), AUTM, Centre for International Intellectual Property Studies (CEIPI), Civil Society Coalition (CSC), CropLife International (CROPLIFE), European Law Students' Association (ELSA International), Fridtjof Nansen Institute (FNI), Institute of Professional Representatives Before the European Patent Office (EPI), Inter-American Association of Industrial Property (ASIPI), International Association for the Protection of Intellectual Property (AIPPI), International Chamber of Commerce (ICC), International Federation of Intellectual Property Attorneys (FICPI), International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Japan Patent Attorneys Association (JPAA), Knowledge Ecology International, Inc. (KEI), Licensing Executives Society (International) (LES), Médecins Sans Frontières (MSF), Medicines Patent Pool Foundation (MPP), The Confederation of European Business (Business Europe), Third World Network Berhad (TWN), 4iP Council EU AISBL (4iP Council) (21).

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/29/8 Prov.2); "Revised Draft Agenda" (SCP/30/1 Prov.2); "Report on the International Patent System: Certain Aspects of National/Regional Patent Laws" (SCP/30/2); "Draft Reference Document on the Exception Regarding Compulsory Licensing" (SCP/30/3); "Further Study on Inventive Step (Part III)" (SCP/30/4); "Addendum: Further Study on Inventive Step (Part III)" (SCP/30/4 Add.); "Background Document on Patents and Emerging Technologies" (SCP/30/5); "WIPO's Experiences on Capacity Building Activities Relating to Negotiating Licensing Agreements" (SCP/30/6); "Confidentiality of Communications Between Clients and their Patent Advisors: Update" (SCP/30/7); "Patent Law Provisions that Contribute to Effective Transfer of Technology, Including Sufficiency of Disclosure" (SCP/30/8); "Revised Proposal of Document SCP/28/7 by the Delegations of France and Spain" (SCP/30/9).

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

AGENDA ITEM 2: ELECTION OF THE CHAIR AND TWO VICE-CHAIRS

10. The SCP unanimously elected, for one year, Ms. Sarah Whitehead (United Kingdom) as chair, and Ms. Grace Issahaque (Ghana) and Mr. Alfred Yip (Singapore) as Vice-Chairs.

AGENDA ITEM 3: ADOPTION OF THE AGENDA

11. The SCP adopted the draft agenda (document SCP/30/1 PROV. 2).

AGENDA ITEM 4: ADOPTION OF THE DRAFT REPORT OF THE TWENTY-NINTH SESSION

12. The Committee adopted the draft report of the twenty-ninth session (document SCP/29/8 PROV. 2), as proposed.

GENERAL STATEMENTS

13. The Delegation of Croatia, speaking on behalf of the Group of Central European and Baltic States (CEBS Group), expressed its appreciation to the Chair for guiding the Committee and looked forward to having a successful session. The Delegation also thanked the Secretariat for the substantial input in the preparation of the thirtieth session of the SCP. The Delegation hoped that successful works of the previous SCP sessions would set the grounds for further harmonization of substantive patent law. The Delegation expressed its appreciation to the Secretariat for the preparation of “Further Study on Inventive Step (Part III)” contained in document SCP/30/4, which would enable further study on the quality of patents as a crucial subject for the success of the patent system. The Delegation also looked forward to discussions on confidentiality of communications between clients and their patent advisors and stressed its support for the soft-law approach. The Delegation further welcomed the sharing session on the quality of the patent grant process within IP offices, including opposition systems, with a special attention given to the capacity building of patent examiners and offices as well as the sharing of experiences by the Secretariat. In that regard, the Delegation welcomed the sharing of experiences by relevant institutions on capacity building activities relating to negotiating licensing agreement. The Delegation noted its positive engagement for the thirtieth session and the importance of keeping the right balance between issues of mutual interest. Finally, the Delegation reiterated its commitment to engage constructively for a productive session.

14. The Delegation of Guatemala, speaking on behalf of the Group of Latin American and Caribbean Countries (GRULAC), expressed its hope to participate in the session in an active and constructive way. The Delegation also thanked the Secretariat for the excellent work in preparing the session and the documents, which would serve as a basis for the discussions. The Delegation noted the importance of the Committee as it tackled questions of substantial impact for the development of countries, particularly on exceptions and limitations to patent rights, patents and health and transfer of technology. The Delegation also noted the importance

of quality of patents as it was essential to protect only new technologies and subsequently allow access to them. The Delegation found great interest in the sharing of information and experiences on the subject under Agenda Item 7. In relation to the exceptions and limitations of rights conferred by patents for research purposes, the Delegation thanked the Secretariat for preparing document SCP/30/3 for its valuable and useful information. The Delegation also thanked the Secretariat for organizing the sharing session on the various capacity building activities on negotiating licensing contracts. In the view of the Delegation, the sharing session was very important and would have a positive and specific impact on the Committee's work. Finally, as regards the transfer of technology, the Delegation reiterated the importance of the flow of information towards developing countries which should be effective to allow access to new technologies. The Delegation thanked the Secretariat for preparing document SCP/30/8 and its correction, and looked forward to discussing the agenda item. In concluding, the Delegation expressed confidence on the success of the Committee under the leadership of the Chair.

15. The Delegation of China expressed its expectation that the SCP would continue to produce progressive results through discussing different subject matters under the leadership of the Chair. The Delegation observed the importance of the patent system in encouraging technological and economic development. The Delegation noted that the Chinese government hoped to increase further research on the patent system and learn from other Member States in building a system that fit the needs of the nation and promoted inventive activities. The Delegation acknowledged the importance of the SCP as a platform for discussions, which played a great role in promoting the development of patent systems. The Delegation expressed appreciation for the efforts made by Member States in contributing to the steady development of the SCP. The Delegation hoped that the patent system would continue to play a role in encouraging innovation and technological development, and the Delegation would continue to constructively participate in discussions and information sharing, especially on the subject of exceptions and limitations to patent rights, patents and health and technology transfer. The Delegation stated that the issues in the agenda played an important role in balancing the interests of patentees and third parties, improving the flexible and effective use of patent system and better realization of social values. Taking into account of the varying degrees of development and needs between different Member States, the Delegation hoped for greater room and flexibility in the discussions. The Delegation expressed its hope that the meeting would be fruitful, and stated its continued intention to facilitate the SCP discussions.

16. The Delegation of Uganda, speaking on behalf of the African Group, thanked the Secretariat for the excellent preparation of the thirtieth session, including the documents that would guide the work of the SCP. The Delegation reaffirmed the importance of the Committee as a multilateral forum for substantive discussions and advancing norm-setting in international patent law and related issues. The Delegation also noted that issues on the agenda should be undertaken without the expectation of any norm setting. In the view of the Delegation, while the role of patents in advancing health and innovation remained under debate, patents in principle promoted innovation by providing incentives to invest in research and development, to enhance socio-economic development. The Delegation stated that a balance between the interests of rights holders and public access to knowledge and innovation must be maintained. The Delegation pointed out the wide range of policy options and flexibilities built into the IP regime for developing countries to pursue national objectives, including exhaustion, criteria for grant of patents, pre-grant and post-grant opposition procedures as well as exceptions and limitations. On patents and health, the Delegation stated its belief that the discussions between the interplay of patents and public health were vital to ensure a coordinated approach. In that regard, the Delegation commended the Secretariat for the preparation on the subject of compulsory license contained in document SCP/30/3, and looked forward to its presentation and discussion. The Delegation further stated that the draft reference document might provide insightful examples of instances where other countries had made full use of the scope of that

exception, and expressed its belief that the document would serve as a useful guide for policymakers to continue improving their patent laws in achieving their objectives. In addition, the Delegation welcomed the convening of an information session in which the Secretariat and invited relevant institutions would share their experiences on capacity building activities relating to negotiating licensing agreements, and looked forward to constructive participation. With regard to the future work on patents and health, the Delegation noted that the proposal contained in document SCP/24/4 would provide an excellent basis for debate on its program. On the issue of quality of patents and opposition systems, the African Group welcomed the information session for sharing experiences on approaches used by Delegations to ensure the quality of patent grant processes within IP offices, including opposition systems with a special focus on capacity building of patent examining offices. As for confidential communication between clients and their patent advisors, the Delegation took the firm view that it was not a substantive law issue, and no norm setting activities should be taken, since the approaches differed across all regions. However, the Delegation restated its openness to discuss further on that issue. In addition, the Delegation highlighted the importance of all relevant WIPO bodies in the implementation of the WIPO Development Agenda Recommendations, recalling the decision of the WIPO General Assembly in 2010, which had requested the relevant WIPO bodies to include in their annual reports to the Assemblies, a description of their contribution to the implementation of the Development Agenda Recommendations. The Delegation requested the Secretariat to include, in the SCP report to the 2019 General Assembly, the SCP's contribution to the implementation of the WIPO Development Agenda Recommendations. Finally, the Delegation reiterated its support in ensuring a successful outcome, and hoped that all WIPO Member States and stakeholders would arrive on mutually accepted outcomes.

17. The Delegation of Tajikistan, speaking on behalf of the Caucasian, Central Asian and Eastern European Countries (CACEEC), expressed its appreciation for the preparation of the documents and work that went into preparing the thirtieth session. The Delegation noted the important efforts made by the Committee that made it possible to organize the thirtieth session, and thanked the Director General and the Secretariat for the fruitful cooperation and constant support. Finally, the Delegation wished for constructive discussions and productive work at the session.

18. The Delegation of Indonesia, speaking on behalf of the Asia and Pacific Group, expressed confidence in the Chair's leadership for the deliberations carried out during the SCP, which it believed would lead to successful outcomes. The Delegation also expressed appreciation for the hard work put in by the Secretariat in preparing the session. At the outset, the Delegation stressed that patent laws were territorial, and noted the importance of maintaining flexibility in domestic patent laws for policy makers to craft, amend, or delay domestic implementation of certain patent law provisions in accordance with national development priorities and social and economic realities. The Delegation further stated that the flexibility allowed governments the necessary policy space to foster innovation. In its opinion, the work of the Committee was important in maintaining the balance between the rights of patent owners and the larger public interest, particularly in the area of public health, technology transfer, and patent-related flexibilities. The Delegation reiterated that it would constructively participate in contributing towards a productive discussion on that issue. On the issue of quality of patents including opposition systems, the Delegation noted their eagerness in taking part in the sharing session, and to learn approaches used by other Member States in ensuring the quality of the patent grant process within IP offices, including the capacity building of patent officers and examiners within the opposition system. The Delegation also expressed hope that the sharing session would provide better understanding in improving and further enhancing the efficiency of the current patent system in a manner sensitive to the diverse needs of the Member States. The Delegation further thanked the Secretariat for the "Further Study on Inventive Step (Part III)" as reflected in document SCP/30/4, which assessed inventive step in the chemical sector, and looked forward to the presentation of the study. In addition, the Delegation supported

discussions on the opposition system, and requested that the Committee give equal consideration to both opposition systems and quality of patents. In the view of the Delegation, there should be a work program on opposition systems that could assume the form of a questionnaire, exploring the different kinds of opposition mechanisms available, procedures, approaches and constraints in their use, and how the system could be strengthened. In addition, the Delegation noted that the Committee should arrive at a common understanding about the quality of patents: whether it meant efficiency in completing patent applications, or the quality of patents granted to ensure patent offices did not grant patents of questionable validity. The Delegation looked forward to the discussion on exceptions and limitations of patent rights and further guidance on new topics, and thanked the Secretariat for the draft reference document on compulsory licenses as reflected in document SCP/30/3. The Delegation also looked forward to discussions on document SCP/30/7, confidentiality of communication within clients and their patent advisors, as well as discussion on document SCP/30/8, patent law provisions that contributed to effective transfer of technology including sufficiency of disclosure. With regards to the topic of patents and health, the Delegation looked forward to the sharing of experiences on capacity building activities relating to negotiating licensing agreements, including discussion on document SCP/30/6 on WIPO's experiences, and discussions on regular updates on publicly accessible databases of patent status information. The Delegation hoped that the sharing session would provide a better understanding on the connection between patent systems and medicines, and looked forward to the presentation and discussion of the proposal by the Delegations of France and Spain on artificial intelligence and patents. Finally, the Delegation noted that members of the Asia and Pacific Group would intervene in their national capacity on specific agenda items.

19. The Delegation of Canada, speaking on behalf of Group B, thanked the Patent Law Division, the Conference Section and the Secretariat for the preparation of the thirtieth session of the SCP. The Delegation welcomed the work conducted at the twenty-ninth session of the SCP on the basis of a balanced work program. The Delegation noted that the SCP was the only multilateral forum of its kind, and should foster and hold technical discussions on substantive patent law issues in line with the mandate of the SCP. The Delegation further thanked the Member States that had provided the Secretariat with updated information for the SCP Electronic Forum, further assisting it in serving as a unique and useful reference tool. The Delegation noted that the quality of patents continued to be a priority. Having appreciated the sharing session and the half-day conference that was held during the twenty-ninth session, it looked forward to the sharing session on approaches to the quality of the patent grant process within the IP offices, including opposition systems. The Delegation also looked forward to the subsequent study to be undertaken by the Secretariat on the quality of the patent grant process, which was agreed to be delivered at the subsequent session. For discussions on inventive step, the Delegation fully supported the discussions. In addition, the Delegation thanked the Secretariat for the preparation of the comprehensive "Further Study on Inventive Step (Part III)", as discussed at the twenty-ninth session and distributed as document SCP/30/4, which focused on the assessment of inventive step in the chemical sector. The Delegation further thanked the Member States and the regional patent offices that had submitted information to the Secretariat in preparation of the agenda item. On the topic of patents and emerging technologies, distributed as document SCP/30/5, which focused on artificial intelligence and patentability, the Delegation thanked the Secretariat for the document and welcomed further discussion on the topic of artificial intelligence based on the document and the revised proposal by the Delegations of France and Spain in document SCP/30/9. Furthermore, the Delegation noted its great interest on the topic of confidentiality of communications between clients and their patent advisors, and expressed its belief that a non-binding soft-law convergence of approaches would contribute to a more predictable and higher quality patent framework. Finally, the Delegation stated its intent to engage in constructive discussions and work on other issues, such as exceptions and limitations to patent rights and patents and health and technology transfer, provided that those discussions would be balanced and take into account the interests of all

stakeholders. The Delegation noted that the discussions within the SCP should not duplicate efforts underway elsewhere at WIPO or in other international organizations. With respect to the contribution of the SCP to the implementation of the Development Agenda Recommendations, the Delegation stated that the established and agreed practice for the consideration of such issued should be followed.

20. The Delegation of Romania, speaking on behalf of the EU and its Member States, thanked the Secretariat for its work in preparing the thirtieth session of the SCP. The Delegation noted the importance of the previous work of the Committee in discussing and advancing important topics and deciding on the future work of the Committee. The Delegation noted its commitment to constructively engage in the discussions based upon the agreed work program. Further, the Delegation expressed support for the agenda and the mandate of the SCP, which it believed implied discussing the non-exhaustive list of issues on a fact-finding basis. It noted that while it appeared challenging to achieve further patent harmonization in the SCP, the Delegation emphasized that harmonization of substantive patent law should be seen as the mid and long term aim of the Committee, and that the present fact-finding work and discussions were highly relevant for future work. The Delegation noted the importance of advancing work on the quality of patents, and thanked the Secretariat for preparing a "Further Study on Inventive Step (Part III)" contained in document SCP/30/4, and the Member States' contribution to the document. The Delegation noted that continuation of the sharing sessions on quality of patents would be of great benefit for the Secretariat's forthcoming study on approaches to the quality of the patent grant process, which was agreed to be delivered at the subsequent session, and encouraged Member States from across all regional groups to participate. The Delegation looked forward to discussing the newly revised proposal presented by the Delegations of Spain and France contained in document SCP/30/9 as well as the background document SCP/30/5 on emerging technologies, and discussions on the topic of client-patent attorney privilege in document SCP/30/7. In addition, the Delegation also looked forward to interesting and fruitful discussions on publicly accessible databases on patent status information concerning medicines and vaccines, as well as the sharing of experiences by the Secretariat and relevant institutions on capacity building activities relating to the negotiation of licensing agreements in the field of patents and health. In that regard, the Delegation stressed that any further work in that area should reflect a balanced approach and take into account the various relevant factors. In the view of the Delegation, such work should not go beyond the mandate of the SCP and WIPO, and discussions about other factors that might have an impact on access to medicines should be left for more appropriate fora. In conclusion, the Delegation noted its commitment to the work of the Committee and looked forward to a constructive session.

21. The Delegation of Colombia thanked the Secretariat for the constant work, documents and continuous support. The Delegation extended support to the statement made by the Delegation of Guatemala on behalf of GRULAC. The Delegation stated that it attached great importance to the SCP and its contribution to achieving the Sustainable Development Goals. On the issues of exceptions and limitations to patent rights and patents and health, the Delegation stated that the Committee had started the relevant negotiations and exchange of experiences which would help contribute to achieving the objectives of the SCP. With regard to technology transfer, the Delegation stated that discussions should continue within the SCP as innovation constituted a key pillar of policies in Colombia, and that it was important to strike the right balance within the patent system. The Delegation further reiterated its interest in the discussions with regards to quality of patents. Finally, the Delegation stated that it was fully committed to the discussions at the SCP and hoped for valuable results.

22. The Delegation of Iran (Islamic Republic of) assured its full cooperation during the Committee's deliberations. The Delegation aligned itself with the statements of the Asia and Pacific Group as delivered by the Delegation of Indonesia. The Delegation stated that the

Committee as a multilateral forum, provided a platform for discussing patent-related issues, should set a balanced work program, which would provide the opportunity for a fruitful exchange of views on a wide range of topics related to patents. The Delegation expressed its belief that discussions on the topic of exceptions and limitations to patent rights, patents and health and technology transfer were significant to balance the interests of patent holders with the public interest of making effective use of flexibility in the patent system and to better realize the social value of the patent system. The Delegation stated that the deliberations would help the Committee to better understand challenges encountered by developing countries and least developed countries (LDCs) in their economic and social development, and explore ways to better adopt the patent system to meet national needs and priorities. The Delegation stated that it continued to believe that international harmonization would not benefit the Member States, given the variations in levels of social, economic, and technological development along with the different approaches and policy interests of the Member States. In addition, it stressed that exceptions and limitations to patent law was important in enabling the proper functioning of the patent system. The Delegation expressed its appreciation to the Secretariat for preparing the draft reference document on compulsory licensing contained in document SCP/30/3 and looked forward to discussions on that topic. On the quality of patents and the opposition system, the Delegation looked forward to the sharing session on approaches used by the Delegations to ensure the quality of patents grant process within intellectual property offices. The Delegation also emphasized the importance of the sharing session concerning the capacity building of patent examiners and offices, which would lead to the further improvement of the efficiency of the current patent system in a manner sensitive to the different needs of the Member States. Concerning the issue of patents and health, the Delegation looked forward to the sharing of experiences and capacity building activities relating to negotiation of licensing agreements including document SCP/30/6 on WIPO's experiences. The Delegation expressed its hope that the Committee's deliberations would provide better understanding on patent-related barriers to access medicine. As for the issue of confidentiality of communications between clients and their patent advisors, the Delegation opined that the topic was not a substantive patent law issue, and should not require any norm-setting action from the Committee. Finally, the Delegation expressed its hope that the Committee would succeed in advancing discussions on issues of particular relevance to all common interests.

23. The Delegation of Belarus thanked the Secretariat for preparing the work of the thirtieth session, particularly on exceptions and limitations to patent rights. The Delegation noted that it gave considerable importance to the work of the SCP, as it helped to exchange information of great practical importance, and was pleased to see that the relevant documents on technology transfer and the quality of patents had been prepared. It pointed out that the multilateral exchange of information was very useful for all Member States, and stated its willingness to contribute to all of the discussions, particularly on the exceptions and limitations and transfer of technology. The Delegation expressed its appreciation for the various activities organized within the Committee in order to facilitate exchange of information on those important topics, and wished the Committee success.

24. The Delegation of Uganda, in its national capacity, expressed confidence in the leadership of the Chair and committed to engage constructively in discussions through the different agenda items. The Delegation also thanked the Secretariat for the excellent preparations of the thirtieth session, including logistics and the meticulously prepared documents that would guide the proceedings of the agenda. The Delegation fully aligned itself with the opening statement made by the African Group, and expressed keen interest in the agenda items on patents and health and transfer of technology, which were directly related to Uganda's National Intellectual Property Policy recently passed by the Cabinet on May 27, 2019. On patents and health, the Delegation noted that its National Intellectual Property Policy vision of stimulating development hinged greatly on the health of its people, and the need to create a favorable environment to enable the production and dissemination of all medicines. The Delegation emphasized the role

of the Committee in making essential medicines available to all while balancing the interests of the patent holder. It expressed its hope to benefit more from the session of sharing experiences by the Secretariat and invited relevant institutions on capacity building activities relating to licensing agreements as indicated on the agenda. On the topic of technology transfer, the Delegation thanked the Secretariat for the preparation of document SCP/30/8 and previous documents such as document SCP/29/6. The Delegation stated that it appreciated the fact that the document not only presents legal provisions under the law but also the practical tools, programs and initiatives, which were used to promote such legal provisions in different member countries. The Delegation further noted that while it had updated its patent regime to include provisions such as sufficiency of disclosure, clear contents of a patent application, publication of a patent application, the Delegation was open to learn from the approaches of other Member States. Finally, the Delegation reaffirmed its support in ensuring a successful outcome of the thirtieth session of the SCP.

25. The Delegation of Bolivia supported the statement made by the Delegation of Guatemala on behalf of GRULAC. The Delegation thanked the Secretariat for preparing the thirtieth session and for the documents, and reiterated its willingness to discuss in a constructive manner. The Delegation also considered the flexibilities a vital component to consolidate national policy that enabled the availability of goods and services. The Delegation considered it important to address Agenda Item 8 on Patents and Health. The Delegation also found the prepared documents extremely useful, and hoped that the exchange of experiences would enhance mutual understanding of the relationship between patents and medicines. The Delegation reiterated the importance of dealing with that issue with a view to achieving a balanced patent system to enable real access to medicines, particularly in achieving the Sustainable Development Goals (SDG Agenda 2030), specifically Goal 38 for universal health coverage. The Delegation hoped that the work of the Committee would be useful in facilitating participatory and productive debate.

26. The Delegation of India expressed expectation for a positive and vibrant discussion in the thirtieth session of the SCP. The Delegation reiterated its statement made in earlier SCP sessions that the role of WIPO as the international body in the field of intellectual property warranted it to actively pursue a fine balance in the intellectual property rights and socio-economic concern of the world population. The Delegation commended the efforts of the Secretariat for initiating such discussions and for the meticulous preparation of the documents continuously and in a timely manner. The Delegation affirmed that similar to previous sessions, it would actively participate in all discussions, but reiterated its continued stance that such discussions should be limited to fact-finding and should not be aimed at any harmonization attempt, and stated its strong opposition to any such efforts. The Delegation thanked the Secretariat for preparing the draft reference document SCP/30/3 on exceptions and limitations, particularly focusing on the use of compulsory license and hoped for a lively discussion among all the Member States. It underlined that compulsory licensing was one of the most important exceptions with respect to access and affordability of medicines, especially for the developing countries and LDCs and thereby beneficial to the public at large. The Delegation also recalled its earlier statements and emphasized that to that end, there were also some other exceptions such as government use and the Bolar provision. The Delegation further thanked the Secretariat for the meticulous preparation of the document SCP/30/4 on “Further Study on Inventive Step (Part III)”, which mainly focused on assessing inventive step in the chemical sector, including Markush claims. The Delegation stated that the quality of patent was the most essential element in patenting process, and the relationship between quality of patents and opposition systems should be studied objectively. In that regard, the Delegation was of the view that a well-defined opposition system added value to the process of the patent examinations and thereby helped to ensure quality in patent claims. The Delegation thanked the Secretariat for the preparation of the background document SCP/30/5 on patents and emerging technologies and artificial intelligence, which would ensure that IP policy makers would not lag

behind such developments. The Delegation thanked the Secretariat for preparation of document SCP/30/8, stating that there should be a balance of rights and obligations, and the protection of rights should be based on the technological content disclosed in patent applications. The Delegation stated that the applicant had an obligation to comply with the requirement of sufficiency of disclosure to enable use by the public once the protection had lapsed. The Delegation highlighted that the agenda item on sufficiency of disclosure might be discussed under the agenda item on quality of patents. Finally, the Delegation affirmed its active participation in the deliberation of the Committee and commitment to constructive and participative discussion on various issues.

27. The Delegation of Botswana aligned itself with the statement made by the Delegation Uganda on behalf of the African Group. The Delegation stated that it looked forward to fruitful discussions in all the topics included in the agenda, and affirmed full support for the leadership of the Chair. The Delegation also expressed appreciation for the hard work of the Secretariat in preparing for the meeting. On the topic of quality of patents including opposition systems, the Delegation noted its appreciation for the sharing session due to its importance, and believed that the experience learned from the session would encourage and motivate Member States in ensuring the granting of quality patents and enhance capacity building for IP offices to develop an efficient patent system. In concluding, the Delegation stated that it looked forward to the fruitful discussions during the session.

28. The Delegation of the Republic of Korea expressed appreciation for the leadership of the Chair and the Secretariat's preparation of the SCP. The Delegation recognized that the SCP had been a forum for the Member States to engage in substantive fruitful discussions on technical issues pertaining to patent law and international cooperation. In addition, it also noted that the SCP provided Member States with opportunities for sharing beneficial experiences and insights pertaining to important issues such as exceptions and limitations to patent rights, overall patent quality and work sharing and technology transfers and innovations in the field of health and medicines. The Delegation affirmed that the SCP had allowed Member States to take advantage of the current patent system to the greatest extent possible, and expressed its commitment to the balanced development and usage of patent system to effectively recognize the IP rights of inventors. The Delegation expressed its hope to further global interest through social innovation by enhancing the lives of people, and stated its commitment to ensure discussions carried out would be carefully regarded in light of the greater good.

29. The Delegation of Canada, in its national capacity, expressed its appreciation for the guidance of the Chair. The Delegation stated that it would constructively participate and contribute towards work undertaken by the Committee. The Delegation also thanked the Secretariat for the preparation of the thirtieth session, including the documents prepared under the topics of exceptions and limitations to patent rights, quality of patents, including opposition systems, patents and health, confidentiality of communications between clients and their patent advisors, and transfer of technology. The Delegation looked forward to constructive discussions on those topics based on a balanced work program, and to the various sharing sessions scheduled throughout the week. The Delegation also expressed its intent to share the experiences of the Canadian Intellectual Property Office (CIPO) on approaches used to ensure the quality of patent grant processes, as part of the thirtieth session's sharing session on that topic. Finally, the Delegation acknowledged the positive and constructive engagement between the Member States in recent sessions of the SCP, including the cross-regional collaboration that had been vital in advancing the work of the Committee. The Delegation looked forward to engaging further with the Member States in a collegial atmosphere and to a productive session.

30. The Delegation of the United Kingdom aligned itself with the statements made by Group B as delivered by the Delegation of Canada, and by the Delegation of Romania on behalf of the European Union and its Member States. The Delegation looked forward to working with other

delegates during the thirtieth session and the subsequent sessions of the Committee. The Delegation was also grateful for the hard work of the Chair and Vice-Chairs in leading the balanced work plan of the Committee. The Delegation expressed its hope that the good work would be continued by the newly elected, and affirmed its constructive engagement under their stewardship. The Delegation also thanked other delegations across the regional groups for supporting the election of the United Kingdom's candidate, Ms. Sarah Whitehead, to the position of Chair. The Delegation expressed confidence that her previous experience in the Delegation of the United Kingdom to the Committee would be a source of special insight to help guide positive discussions and foster valuable exchange of information. The Delegation also expressed gratitude to the Secretariat for the hard work in organizing the thirtieth session and producing the various documents. The Delegation took a particular interest in the "Quality of Patents" agenda item, including the final installment of the sharing sessions with a special emphasis on capacity building of patent examiners and offices. The Delegation stated that the invaluable exchange of information on that topic would be of great benefit for the Secretariat's forthcoming study on approaches to the quality of the patent grant process, which was agreed to be delivered at the subsequent session. The Delegation thanked colleagues that had already contributed to the discussion, and encouraged Member States from across all regional groups to participate in sharing experiences to ensure that the future study would be as comprehensive as possible. Furthermore, the Delegation hoped that the sharing process and its outputs would allow delegations and offices to learn and compare how the quality of patents were assessed and improved in different jurisdictions. In its view, it allowed individual delegations to use the information in a manner appropriate in their individual circumstances.

31. The Delegation of Argentina, affirmed its commitment to participate in the SCP constructively and actively. The Delegation also thanked the Secretariat for the excellent work in preparing the thirtieth session and preparing the documents. The Delegation was pleased by the substantive nature of the documents prepared by the Secretariat, especially the document on inventive step. Finally, the Delegation looked forward to a productive SCP session.

32. The Delegation of Ecuador thanked the Secretariat for the preparation of the documents, and expressed its support to the statement made by the Delegation of Guatemala, speaking on behalf of GRULAC. The Delegation further thanked the Secretariat for preparing document SCP/30/3, exceptions and limitations to patent rights which contains information on legislation in various countries. The Delegation expressed its belief that the document would help other offices to correctly apply exceptions and limitations to patent rights, and thus covered aspects such as protection of public interest, anticompetitive practices, national emergencies, etc., all of which were covered by its national legislation. In relation to its national law, the Delegation then stated that compulsory licenses were codified under Title III, Chapter 2, Section 1 of the Organic Code on the Social Economy of Knowledge, Creativity and Innovation, which had been in force since December 9, 2016.

33. The Representative of TWN raised three points. First, the Representative raised concerns on the transparency of pharmaceutical products on Pat-INFORMED. The Representative noted that the database did not provide complete information on whether applications had been rejected or withdrawn, or when oppositions had been filed. In that regard, the Representative noted that there were no mechanisms to verify the information uploaded by originator companies in the database, and delay caused in access to generic medicines would undermine public health. The Representative also raised concerns about WIPO's relationship with Pat-INFORMED, and urged Member States to review Pat-INFORMED and verify the information. Second, the Representative noted that the use of TRIPS flexibilities was impeded by the proliferation of North/South agreements. In the view of the Representative, the TRIPS plus standards had significantly increased the cost of medicines and erected barriers to timely generic competition. The Representative encouraged Member States to resist such pressure. Third, the Representative urged Member States to be wary of entering into a

Memorandum of Understanding (MoU) for the training of patent examiners. The Representative noted that such technical training provided by developed countries would increase reliance on the standards established by the Member States. In its opinion Member States should define and apply patentability standards according to public interest considerations.

34. The Representative of KEI welcomed the Secretariat's publication of the draft reference document SCP/30/3 on compulsory licensing. The Representative noted that the Secretariat's document endeavored to provide an overview of compulsory licensing within the context of the international legal architecture whilst taking into account state practices on compulsory licensing. The Representative stated that there was one shortcoming in WIPO's draft reference document on compulsory licensing, which was the absence of analysis of situations where non-voluntary use was permitted as a limitation on remedies. In the view of the Representative, WIPO's study should be revised to examine 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. The Representative also requested the Committee, at the subsequent session, to convene an expert workshop to address the experience of states in permitting the non-voluntary use of patents on medical inventions as a limitation on the remedies available in Part III of the TRIPS Agreement, including cases of running royalties for infringement of medical devices and diagnostic tests, and the export of those products outside the framework of Article 31*bis* under the TRIPS Agreement. Furthermore, the Representative proposed that the SCP investigate the extent to which the exclusion from patentability regarding the treatment of humans applied to new cell and gene therapies, such as CAR T treatments for cancer. The Representative recommended that the Committee convene an expert workshop on the patenting of cell and gene therapies. In addition, the Representative cited the resolution by the World Health Assembly in March 2019 to "continue supporting existing efforts to determine the patent status of health products and promote publicly available user-friendly patent status information databases for public health actors." The Representative then requested the SCP to discuss the implementation of WHO's transparency resolution, which included addressing the transparency for patent landscapes relating to biologic drugs and new cell and gene therapies, enabling better information sharing over litigation on patent validity and scope. Finally, the Representative raised the question of whether a UN agency should rely upon the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) to manage its project, in view of the potential conflict of interest.

AGENDA ITEM 5: REPORT ON THE INTERNATIONAL PATENT SYSTEM: CERTAIN ASPECTS OF NATIONAL/REGIONAL PATENT LAWS

35. Discussions were based on document SCP/30/2.

36. The Delegation of Belarus thanked the Secretariat for updating the Electronic Forum. The Delegation found the format of submitting information in that manner was useful as the Committee might be updated with the latest developments without studying all the relevant legislation. The Delegation also noted the need to bring the legislation in line with the PLT which it had joined in 2006. On the subject of patentable invention, the Delegation noted several exclusions to patentability, such as methods for medical treatment. The Delegation informed that the health administration of Belarus had made such exclusions from patentability to disallow monopolies in that area, and pointed out that therapeutic treatment by doctors should not be prevented by patents. The Delegation noted that the legislation also included priority issues on provisional application. The Delegation further referred to changes in relation to designs and utility models.

37. The Delegation of France thanked the Secretariat for organizing the preparatory work of the thirtieth session and on the quality of documents. The Delegation noted four changes to the intellectual property legislation in France, and that the plan of action for the growth of enterprises had been promulgated on May 23, 2019. First, the plan strengthened the utility certificate system which would enter into force by the Summer 2019, prolonging the time period from six to ten years. The Delegation further noted the possibility of converting the application of a utility certificate to a patent. Second, the law provided for the setting up of the introduction of a provisional patent application that would last for 12 months, making it possible to facilitate access to industrial property, startups and SMEs and to obtain a priority date with a minimum amount of formalities. Third, the Delegation noted that an opposition procedure would be set up and enter into force on January 1, 2020, where any third party would thus have the possibility of opposing a granted patent within 12 months from the grant of that patent. Fourth, the law would allow the office to examine the inventive step during the patent examination process as from May 22, 2021, which would make it possible to increase the quality of patents granted by the French Patent Office.

38. The Delegation of Romania, speaking on behalf of the European Union and its Member States, thanked the Secretariat for preparing document SCP/30/2. The Delegation also thanked the Delegations of Algeria, Australia, Belarus, Bosnia and Herzegovina, the Czech Republic, Ecuador, Georgia, Guatemala, Kazakhstan, Panama and Portugal for their inputs on the SCP Electronic Forum. The Delegation noted the importance of keeping the SCP website up to date, to maintain a useful reference for the discussions and better understanding of various aspects of regional patent legislation and national patent systems. In addition, the Delegation noted that any information on recent developments and changes in national IP laws were always highly relevant to all stakeholders. In that context, the Delegation raised the example of the European Union's recent adoption of a regulation that allowed, under certain conditions, the manufacturing of generic medicines in respect of medicines protected by a supplementary protection certificate after the expiry of the patent. The Delegation noted that the exception provided for in the EU Regulation 933 of 2019 would be subject to strict conditions and only be available for two purposes, export outside the European Union to countries where no intellectual property protection existed, or stockpiling in the European Union up to six 6 months prior to the expiration of the supplementary protection certificate.

39. The Delegation of Norway thanked the Secretariat for the preparation of the thirtieth session. The Delegation informed of amendments which would be made to the Norwegian patent legislation on July 1, 2019, to be more aligned with the international framework. The Delegation specified two points with regards to the amendment. First, for the re-establishment of rights after failure to meet a deadline, the "due care" requirement would be replaced by the "unintentional" criteria. Second, the restoration of right of priority had been introduced, thereby withdrawing its reservation expressed during the PCT Working Group session in June 2019.

40. The Delegation of Croatia, speaking on behalf of the CEBS Group, thanked the Secretariat for preparing document SCP/30/2. The Delegation also thanked the Member States for their input on the SCP Electronic Forum and the Secretariat for keeping the website up to date. The Delegation further affirmed the importance of such discussions in facilitating better understanding of regional and national patent systems and serve as a reference and good basis for future discussions.

41. The Delegation of Portugal stated that it answered Circular C. 8828, and requested that the updated information be reflected on the website. The changes to the Industrial Property Code of the Portuguese Legislation (Industrial Property Code) would take effect on July 1, 2019.

42. The Delegation of the Dominican Republic expressed gratitude to the Secretariat for organizing the thirtieth session. The Delegation informed that it had, through a resolution, modified the time period during which applicants could amend their application after the substantive examination had begun. The Delegation noted that applicants that had filed a patent application involving an invention that did not meet the inventive step requirement might, upon suggestion of the examiner and after the examination had begun, amend the patent application, provided that the claims were not expanded.

43. The Delegation of Canada, in its national capacity, stated that as per its statement made during the earlier session of the SCP, several amendments had been made to the Patent Act as part of Canada's national IP Strategy. The Delegation stated that those legislative amendments had since received Royal Assent, as of December 13, 2018, under Bill C-86 (A second Act to implement certain provisions of the budget tabled in Parliament on February 27, 2018, and other measures). The Delegation expressed its belief that the amendments would help strengthen Canada's IP system by clarifying acceptable business activities and preventing abuse of the patent system; clarifying existing exceptions to patent rights, ensure that the threat of litigation did not stifle new innovation; and reducing abuse of the patent system by those who threaten or pursue litigation in bad-faith. The Delegation noted that the targeted amendments to discourage certain behaviors that hinder innovation and enhance clarity in the IP regime would help ensure a more level playing field for all market participants. The Delegation noted that the amendments to Canada's Patent Act addressed the issue of "patent trolling" by establishing minimum requirements in demand letters received. In addition, the Delegation further noted that the amendment sought to address bad faith allegations of patent infringement that did not provide sufficient information to determine the merits of the allegation, thereby placing recipients in a better position to decide how to respond. The Delegation stated that targeted requirements were to be set out in the regulations to ensure a balance between discouraging bad behavior and maintaining demand letters as a low-cost method to assert a patent right. To improve clarity of the patent system, the Delegation also pointed out that Canada had amended the Patent Act to allow prior statements made to the Canadian Intellectual Property Office (CIPO) about a patent to be admissible as evidence in court during patent litigation. The Delegation also referred to the statements made in the previous SCP sessions on the reform, which had included codified research exemption in Canada's Patent Act, strengthened prior user right, as well as provisions to ensure that subsequent owners of standard essential patents honor licensing agreements made by previous owners. The Delegation further noted the enactment of the College of Patent Agents and Trademark Agents Act, which established an independent, self-governing college to regulate Canadian patent agents and trademark agents. The Delegation noted its intent to update on those amendments in greater detail during relevant agenda items, discuss with any interested members, and provide the relevant information to the SCP Secretariat to update the SCP Electronic Forum.

44. The Delegation of India thanked the Secretariat for preparing document SCP/30/3, which contained various information on national regional patent laws, prior art, novelty and inventive step, disclosure, exclusions and exceptions and limitations to the rights. The Delegation also supported the compilation, provided such compilation did not lead to any item of harmonization and was limited to discussion.

AGENDA ITEM 6: EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

45. Discussions were based on documents SCP/14/7, SCP/19/6 and SCP/30/3.

46. The Delegation of Croatia, speaking on behalf of the CEBS Group, thanked the Secretariat for the preparation of the draft reference document on the exceptions regarding compulsory licensing in document SCP/30/3. The Delegation acknowledged the great amount

of work dedicated to it and stated that the document constituted a valuable set of information and source of reference for further discussion on exceptions and limitations to patent rights. The Delegation noted that exceptions and limitations to patent rights might be relevant and justified in certain situations, *inter alia*, to safeguard the interests of the general public, especially in handling public health problems. In the view of the Delegation, a proper balance between the interests of patentees and of the general public must be achieved. In addition, the Delegation noted the importance of establishing and maintaining publicly accessible databases on patent information, including patent legal status, on medicines. It supported finding satisfactory and balanced solutions to challenges and inequalities in the field of public health, within the scope of the mandate of the Committee. The Delegation looked forward to hearing from other Member States on that issue.

47. The Delegation of Canada, speaking on behalf of Group B, thanked the Secretariat for the preparation of document SCP/30/3. The Delegation expressed its belief that innovation in all technological fields was fostered by an effective patent system, and the delicate balance between the interests of the right holders and that of the general public should be maintained. The Delegation pointed out that while exceptions and limitations were at times appropriate in specific circumstances, the use of exceptions and limitations in a way that undermined the incentive inherent to the patent system might be detrimental to innovation and ultimately to society. The Delegation noted that WIPO and the SCP had already undertaken substantive work in the area of exceptions and limitations, including expert studies, questionnaires, seminars, and Member States' contributions on practical experiences and case studies as shown on the extensive documentation on the WIPO website. The Delegation further stated that the many valuable references were available to any country who sought to consider its domestic legislative arrangements and adjusted them according to its special needs and priorities while ensuring compliance with international norms.

48. The Delegation of Romania, speaking on behalf of the European Union and its Member States, thanked the Secretariat for the preparation of the draft reference document on exceptions regarding compulsory licensing contained in document SCP/30/3, which provided a useful compilation of different experiences and information, and a good overview of the international legal framework. The Delegation noted the challenges and constraints which might be faced by certain countries in handling public health problems, and that access to safe, effective, quality and affordable essential medicines and vaccines for all was a major challenge and a key Sustainable Development Goal which must be supported by all. In that regard, the Delegation stated its commitment in increasing access to affordable medicines and to finding solutions to the world's pressing public health challenges and inequities. The Delegation however, emphasized that the SCP could not go beyond its mandate, and encouraged delegations to continue to adopt a balanced approach, taking into account all the various factors of relevance to patents and health. The Delegation pointed out that there were many aspects of the health system that played an important role in ensuring accessibility and affordability of medicines, such as incentives to research and innovation, availability of qualified health workers, the provision of affordable medicines, as well as the adequate financing of the sector and others. Finally, the Delegation expressed its continued engagement in the discussions on that topic.

49. The Delegation of Brazil thanked the Secretariat for preparing document SCP/30/3, which in its view provided a balance between the rights of patentees and the protection of societal values. The Delegation noted its engagement in those discussions which started with document SCP/14/7 that it had presented, and stressed that exceptions and limitations were an integral and necessary part of a strong and effective patent system. Additionally, the Delegation stated that the basic tenet of the patent system was that legislation should provide incentives that lead 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 emphasized that it was under such framework that exceptions and limitations should be addressed. Taking into account that all Member States had the obligation to pursue a balance between the interests of the intellectual property right holders and those of society as a whole, the Delegation stressed that preserving the balance was important to safeguard the legitimate interests of all stakeholders of the patent system. The Delegation highlighted the regulatory review exception, also known as the Bolar exception, which played an important role in providing the realization of that balance, especially by ensuring that the market power granted by a patent did not create anti-competitive externalities beyond the term of protection of 20 years. The Delegation further noted the importance of compulsory licensing as an exception to restore the balance in the special cases when its use was required, such as, but not limited to, emergency health situations or the anti-competitive use of patents. It also stated that the exception should be used within the rules provided in the TRIPS Agreement and the Doha Declaration on Public Health. In the view of the Delegation, finding a balance between incentives to innovate and enhance access to technologies embodied in the patent is crucial. The Delegation then proposed a subsequent theme for Member States to explore, which would be on the preparation of individually prescribed medicines. The Delegation then expressed its belief that Member States would profit from the compilation of the exceptions and limitations provisions by the Secretariat in a single document, a simple material that would provide a valuable reference to different legislations on the subject. Finally, the Delegation hoped for a fruitful discussion, and expressed its readiness to engage with other Member States in developing the subsequent subject matter in the Committee.

50. The Delegation of Iran (Islamic Republic of) stated that exceptions and limitations to patent rights played an important role in supporting the appropriate functioning of the patent system. The Delegation viewed that patent rights could not be absolute, and should be subject to exceptions to benefit the public. In that regard, the Delegation noted the importance of a flexible policy space to allow Member States to develop and adopt a set of exceptions and limitations to suit their own needs, regardless of the development level. The Delegation stated its openness to discuss with other Member States on that issue.

51. The Delegation of Uganda, speaking on behalf the African Group, commended the efforts of the Secretariat for the preparation of the document on compulsory licensing. The Delegation noted that the document contained information on complex subjects, legal provisions, and experiences of Member States, which would constitute a useful guide for Member States, examiners, patent attorneys, and researchers. In addition to that document and other preceding documents, the Delegation expected further reference documents to be presented on other topics, as agreed by the Committee. The Delegation noted the importance of compulsory licensing as an important policy tool for government authorities to address the failure of markets to promote universal access to medicines and health technologies. In its view, for the patent system to be effective, access to fruits of innovation including health technologies required recognition and respect of the exclusive rights granted to innovators alongside the limitations and exceptions to those rights. The Delegation noted that while compulsory licensing was provided under national laws, the practical effectiveness of compulsory licensing was not known clearly. However, the Delegation expressed its belief that its relevance was not diminished, and countries should retain the flexibility to grant such licenses. To conclude, the Delegation requested the Secretariat to disseminate the reference document and the two earlier draft documents to the wider public, including educational and research institutions, national IP offices, and other interested stakeholders.

52. The Delegation of Pakistan noted the practical importance of exceptions and limitations in balancing public welfare and personal interest. The Delegation supported a balanced approach of patent grant and government use of the compulsory license by taking into account of the public interest. The Delegation expressed appreciation for the draft reference document on compulsory license that had been reflected in document SCP/30/3. The Delegation viewed the

compulsory license provision as an important tool in promoting competition and increase affordability of drugs, while ensuring that patent owners obtain compensation for the use of their invention. In addition, the Delegation noted that a comprehensive review of exception and limitation in line with the TRIPS Agreement allowed Member States to adopt measures to promote public interest for their socio-economic and technological development, enabled generic manufacturers to expedite market approval, thus facilitating access to affordable medicines. The Delegation encouraged WIPO to build upon the existing work and enhance its technical and legal assistance, especially to developing countries, to raise awareness about the approaches to exceptions and limitations.

53. The Representative of TWN noted non-voluntary licenses as a crucial flexibility to increase access to medicines and reduce cost of medicines. The Representative stressed that the procedure for compulsory licensing should not be cumbersome and injunctions should not be issued on compulsory licensing orders during the review process. The Representative then made several observations on the document. First, the Representative stated that paragraph 191 of document SCP/30/3 would benefit from more detail on tactics used by certain governments and industries to undermine the use of compulsory license. The Representative stated that such extrinsic influence was illegal, as it amounted to interference in the internal affairs of sovereign State. The Representative also called upon court cases that authorized compulsory licenses in the context of Article 44.2 of the TRIPS Agreement where permanent injunction was refused and payment of royalties issued to be reflected in document SCP/30/3. Second, the Representative pointed out that paragraph 222 that stated that compulsory licensing would have a chilling effect on R&D should be clarified, and the Delegation called upon WIPO to seek evidence and transparency in providing R&D costs undertaken by the pharmaceutical companies. The Delegation stated that studies showed that R&D costs by pharmaceutical companies were highly inflated than the amount actually spent on R&D, especially in the case of blockbuster drugs the R&D costs were recovered by the sales and profit of the first year. Third, the Delegation provided further insight on paragraphs 218, 219 and 229, which stated that price negotiations might lead to better price outcomes than compulsory licenses, by citing an MSF Study on lessons of Brazil and Thailand in 2007, which found that price negotiation did not help in reducing cost as much a compulsory license would. Fourth, with regard to paragraph 228, the Delegation stressed that voluntary licenses granted by patent holders did not necessarily lead to technology transfer. She raised the example of India, at which a quick analysis of the patent working statement filed by the pharmaceutical patent holders revealed that voluntary licenses granted to generic companies only for marketing the patented product, without technology transfer and majority of the patented drugs were being imported into the country. The Representative noted that document SCP/30/3 might benefit from feedback from observers as well as Member States, and called upon countries to take urgent steps to address the challenge of access to affordable medicines, in particular multi drug resistant tuberculosis drugs, delamanid and bedaquiline, which were widely patented in most high tuberculosis burdened countries. The Representative highlighted that an estimated 558,000 people developed drug-resistant tuberculosis (DR-TB) in 2017, but only 25 per cent of those estimated cases were treated. In that regard, the Representative cited a study which stated that “[t]he estimated price of longer individualized treatment regimens could now reach more than US$2,000 for people who need at least 18 months of bedaquiline, which would represent a 50 per cent price increase over previous standard treatment. For people who might need both bedaquiline and delamanid for as long as 20 months, the price increase could reach 500 per cent, with a treatment regimen priced at around $9,000.” In concluding, the Representative called upon Member States to make use of compulsory license or government use to ensure access at affordable prices, rather than relying on unsustainable donation programs, and that countries where TB medicines were not patented were called upon to explore opportunities for generic production to supply those with high TB burden.

54. The Secretariat made a presentation on document SCP/30/3. The presentation is available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_a.pdf.

55. The Delegation of China thanked the Secretariat for detailed analysis of the topic of compulsory licenses provided in document SCP/30/3 and its appendix, which provided the compilation of provisions in various countries. The Delegation considered that it was a good reference for learning about those provisions. The Delegation recommended the Committee to pay attention to problems faced by countries and other stakeholders in implementing that exception at the national and regional levels. The Delegation further supported the continued discussions on the topic in the SCP to better understand the different views and provide countries with relevant references.

56. The Delegation of the United States of America, noting that document SCP/30/3 highlighted various applications of the exception regarding the compulsory licenses, thanked Member States that had provided information for preparation of the document. The Delegation aligned itself with the statement made by the Delegation of Canada on behalf of Group B as regards the document. Further, the Delegation noted that implementation of that exception, like any other exception, should strike a delicate balance, as an unrestrained application of that exception had potential to undermine patentee's rights, reduce incentives to invest in research and development for new inventions, unfairly shift the burden for funding such research and development to foreign markets and discourage the introduction of new important inventions. The Delegation stated that, to maintain integrity and predictability of patent systems, it was critical that governments ensured transparency and due process related to that exception. The Delegation encouraged Member States to use that exception in limited circumstances and after making every effort to obtain authorization from the patent owner, on reasonable commercial terms and conditions. The Delegation expressed appreciation to the Secretariat for preparation of reference documents SCP/29/3 and SCP/28/3 and stated that it was looking forward to compilation of similar documents with respect to other exceptions and limitations presented in document SCP/16/3. Noting that on the topic of exceptions and limitations to the rights, the SCP had already carried out a very large amount of work, the Delegation stated that work on producing reference document on other exceptions and limitations should be completed before any expansion of that agreed approach. The Delegation was also of the view that no additional work in the SCP was warranted at that point on the compulsory license exception in view of the work already carried out and the documents that resulted from it, including document SCP/30/3.

57. The Delegation of the Russian Federation stated that document SCP/30/3 had been prepared by the Secretariat as a result of a decision which had been taken at the previous session of the Committee. The Delegation noted that the right to grant compulsory licenses to prevent the abuses which might result from the exercise of exclusive rights was first provided in the Paris Convention for the Protection of Industrial Property. The Delegation further noted that the policy objectives of that exception was to ensure public interest in the access to the invention. In addition, the Delegation stated that the relevant provisions in the TRIPS Agreement were Article 31 and 31*bis*. Turning to the legislation of the Russian Federation, the Delegation informed the Committee that, in its country, grounds for the issuance of such license were protection of national security and defense as well as an epidemic outbreak of a particularly threatening disease, which were considered extreme circumstances. The Delegation stated that the detailed procedures on the issuance of compulsory licenses were being developed in its country. In addition, to implement Article 31*bis* of the TRIPS Agreement, corresponding amendments to the Civil Code of the Russian Federation were being prepared. Further, the Delegation stated that another ground for the grant of a compulsory license in its country was a case of dependent patents. The Delegation stated that all those grounds were aimed at creating a balance of interest between the right holder and society, making patented inventions, including patented medicines, more accessible to the population. Noting that, in the national legislation, a compulsory license could be granted if the second patent represented an

"important technical achievement/progress" and had "significant economic advantages" over the first patent, the Delegation stated that while those wordings reflected Article 31(l) of the TRIPS Agreement, no interpretation of those terms were provided in the Agreement. According to the view of the Delegation, in interpreting those terms, no reference should be made to the patentability of the inventions under discussion, such as inventive step. The Delegation continued that, what needed to be looked at in defining those terms, as far as medical products were concerned, were, for example, whether such products provided a better therapeutic effect or they had a less toxic effect than the original medicine, etc. As regards the cases of issuance of compulsory licenses in the Russian Federation, the Delegation stated that all of the cases heard had been settled between parties in an amicable agreement. In conclusion, the Delegation supported further discussions on the issue of the exceptions and limitations to the rights, including on the compulsory license, to be continued within the Committee.

58. The Delegation of Ghana thanked the Secretariat for the comprehensive document on the topic of compulsory licensing. The Delegation informed the SCP that the Ghana Patent Act had undergone review and the amendment bill was being considered by the parliament. The Delegation stated that the amendment bill had reformed the provisions on exceptions and limitations by reflecting Ghana's policy priorities and conforming to its international obligations. The modified provisions sought to facilitate the usage of technological knowledge for national development, and provided opportunities for domestic industries to consider the use of TRIPS flexibilities, such as compulsory licensing and parallel imports facilitating access to affordable medicines. Further, taking note of document SCP/30/3, the Delegation stated that it recognized that exceptions and limitations to the rights played a critical role in the patent system by providing a balance of interest between the interests of the patentee and the general public. The Delegation further stated that the compilation of national and regional provisions on exceptions and limitations to the rights provided a useful resource for Member States to appreciate the different legal systems adopted by the Member States that served their national needs. The Delegation further welcomed the sharing sessions on the topic. Finally, the Delegation expressed its hope that the Committee would make significant progress in advancing discussions on issues of common interest to all Member States.

59. The Delegation of Iran (Islamic Republic of) expressed its appreciation to the Secretariat for preparing the Draft Reference Document on Compulsory Licensing, contained in document SCP/30/3, as well as Member States which had provided their inputs for the preparation of the document. The Delegation noted that the document was very well-structured and that, in general, the provision of that document was the right step in fulfilling WIPO's and SCP's mandate to assist Member States to benefit from the patent system. In particular, the Delegation noted that by shedding further lights to compulsory licensing exceptions, the reference document provided insightful examples of instances where countries had made use of those exceptions. The Delegation further stated that the document contained a good description of the exception, its policy objective, the scope of the exception as well as challenges faced in the implementation of the exception and its results. Noting that its national law also provided that exception, the Delegation stated that it looked forward to a reference document on another topic to be developed by the Secretariat.

60. The Delegation of Croatia, speaking on behalf of the CEBS Group, thanked the Secretariat for providing the draft reference document on the exception regarding compulsory licensing. Acknowledging the amount of work dedicated to that issue, the Delegation considered it as a valuable set of information and a valuable source of reference for further discussion on the topic of exceptions and limitations to patent rights. Further, the Delegation stated that exceptions and limitations to patent rights might be relevant and justified in certain situations, *inter alia*, to safeguard the interest of the general public, especially in handling public health problems. At the same time, the Delegation noted that the proper balance between the interests of patentee, on the one hand, and of general public on the other hand, must be

achieved. The Delegation stated that the CEBS Group was aware of the importance of establishing and maintaining publicly accessible databases with patent information status on medicines, and supported finding satisfactory and balanced solutions to challenges and inequalities in the field of public health, within the scope of the mandate of the Committee.

61. The Delegation of Brazil thanked the Secretariat for the well-balanced document on compulsory licensing, contained in document SCP/30/3. The Delegation stated that the document provided a useful and comprehensive review of the work undertaken by the SCP on the topic. Referring to Section II of the document, the Delegation stated that the general rationale observed was that countries felt that the compulsory license mechanism was a tool for achieving the economic and social interests of societies. The Delegation further noted that technical capacity was one of the barriers to the use of compulsory license and that industrial capacity in the relevant technical field was a key. In that regard, the Delegation recalled the discussions in the WTO resulting in the amendment of the TRIPS Agreement. The Delegation noted that the document provided some information about that special compulsory licensing system. The Delegation further stated that the complex interaction of patents with the legal and economic systems was also part of the reference document, such as the interaction with the provisions of data protection. The Delegation stated that the appendix to the document provided national and regional provisions on that subject which could be used by the Secretariat in the legislative assistance activities. Further, the Delegation stated that more economic studies could be done to clarify aspects of the use of compulsory licenses. The Delegation stated that, for instance, one study findings described in paragraph 225 of the document that "there were circumstances in which welfare effects increased globally when compulsory licensing was used, even in light of its effect on innovation" could be further analyzed, with the involvement of the WIPO Chief Economist.

62. The Delegation of Spain thanked the Secretariat for the preparation of document SCP/30/3, containing an exhaustive study on one of the exceptions to patent rights, which was well-known, most controversial, and least used. The Delegation stated that, in Spain, very few requests for the grant of compulsory licenses had been made (six in the period from 1986 to 2010), and no compulsory license had ever been granted. The Delegation noted, however, that examples in the study showed that contrary to popular belief, compulsory licenses had been granted in those countries considered to be most developed. Further, the Delegation wished to refer to some of the most important paragraphs in the reference document. In particular, the Delegation stated that paragraph 219 showed that a threat of the possible granting of a compulsory license was used as a tool to reduce the price of a pharmaceutical. Further, referring to paragraph 220 of the document, the Delegation noted the estimated savings achieved in some countries like Brazil, Ecuador, Thailand, and Malaysia. Finally, the Delegation noted that paragraph 222 showed that the habitual use of the compulsory licenses would affect incentives for innovation and that such licenses should only be used in exceptional circumstances. The Delegation further stated that, generally speaking, it was a very interesting document, which put that exception in its place, as something truly exceptional which should only be used when there were extraordinary circumstances which justified its use. Further, the Delegation informed the Committee as regards the legislative changes taking place in the EU with the support of the Spanish Government. In particular, the Delegation stated that new regulation on the supplementary protection certificate would enter into force on July 1, 2019 and would apply to certificates filed as from July 1, 2022. The Delegation stated that the principal characteristics of the legislative amendment would permit the manufacture of the active ingredients and the medicinal products under the SPC protection to stock those products up to six months prior to expiration of the related SPC and to export the relevant product to third countries. The Delegation expected that that legislative amendment would facilitate access to generic and biosimilar medications once the certificates expired.

63. The Delegation of Japan expressed its appreciation to the Secretariat for its great efforts in preparing the draft reference document on the exception regarding compulsory licensing (document SCP/30/3). The Delegation wished to reiterate that the discussions under that agenda item 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.

64. The Delegation of India thanked the Secretariat for the preparation of the draft reference document on the exception regarding compulsory licensing as prevalent in different countries. The Delegation stated that the relevant statutes of the Indian Patents Act provided for a robust, effective and balanced compulsory licensing system which was in compliance with the TRIPS Agreement. The Delegation informed the Committee that, in India, a first compulsory license had been granted by the patent office on March 9, 2012, to an Indian pharmaceutical company for the generic production of Bayer Corporation's Nexavar, a lifesaving medicine used for treating liver and kidney cancer. The Delegation stated that Bayer sold that drug at exorbitant price (one month dosage costing around 2.8 Lakh INR). The Delegation stated that the Indian pharmaceutical company seeking the compulsory license had offered to sell it around for 9000 INR, making it affordable for people. The Delegation further stated that two applications for compulsory license was refused in India: first, in the matter of cancer drug Dasatinib, the applicant had not made any credible attempt to procure a voluntary license and therefore could not be said to have satisfied the statutory requirement that the applicant must have negotiated in good faith with the patentee. The Delegation stated that since the applicant did not make out a *prima facie* case for the grant of a compulsory license, the application had been dismissed. Second, in the matter of diabetic drug Saxagliptin, the application had been submitted on the grounds that the reasonable requirements of the public with respect to the patented invention had not been satisfied, that the patented invention had not been available to the public at a reasonably affordable price and that the patented invention had not worked in the territory of India. The Delegation stated that that case had been refused by the Controller on the following grounds – (i) the applicant had failed to establish that the reasonable requirement of the public was not being met, since there were other DPP-IV inhibitors also available in the market besides Saxagliptin; (ii) the applicant had failed to establish that the patented invention had not been made available to the public at a reasonable affordable price, since compared to other available brands, Saxagliptin had been competitively priced. Additionally, applicant's drug was cheaper by only Rs.9/tablet; (iii) there was no merit in the contention that the invention was not being worked in India as the drug was being imported into India. Further, the Delegation wished to take that opportunity to assure the Member States that India would actively participate in the discussions on the topic of the compulsory licensing and would be also ready to share the benefits of the strong robust compulsory license system as prevalent in India. The Delegation noted that the Indian statute also reaffirmed India's strong commitment for protecting the public health and access to medicine related issues.

65. The Delegation of the Republic of Belarus thanked the Secretariat for the preparation of document SCP/30/3, which was very useful. The Delegation stated that the possibility of issuing a compulsory license was enshrined in the patent law of its country as from 1993, when the first law of the Republic of Belarus "On Patents for Inventions" had been adopted. The Delegation continued that, in particular, the law stated that the Council of Ministers of the Republic of Belarus had the right to allow the use of the invention without the consent of the patentee against payment of the monetary compensation comparable to the market price of the license in the interests of defense of the Republic of Belarus and public order, as well as in case of natural disasters, catastrophes, epidemics and other emergency circumstances. The Delegation stated further that the need to develop a normative framework for the issuance of such licenses as well as practice of using such licenses in relation to technologies of priority importance for the development of health care, energy saving and other socially significant

areas of activity, had been declared in the strategy in the field of intellectual property for 2012-2020 of the Republic of Belarus, approved by the Government. The Delegation continued that, according to the current legislation, there were three conditions necessary for the issuance of compulsory licenses: (i) non-use or insufficient use of the invention by the patentee within three years from the date of publication of the patent information; (ii) when such non-use or underuse led to insufficient supply of the relevant goods, works or services in the market; (iii) refusal of the patentee to enter into a license agreement on the conditions corresponding to the established practice. The Delegation stated further that if those conditions were met, any person willing and ready to use the invention might apply to the court with a request to grant a non-exclusive compulsory license. The court would grant such a license defining the scope of use, size, timing and procedure of payments, unless the patentee would prove that the failure to use or insufficiently use the patented invention, utility model or industrial design was due to valid reasons. The Delegation stated that the right to use an invention obtained under such a license might not be transferred to other persons, and that the patentee might demand in court the termination of the compulsory license in case of termination of the circumstances which served as the basis for granting such a license. In addition, the Delegation stated that the legislation also provided for the possibility of granting a compulsory license for dependent patents. The Delegation noted that, however, according to the practice of Belarusian courts, there were no cases of a compulsory license request. Therefore, its country did not have experience in issuing such licenses. The Delegation further stated that, in relation to the procedure of issuance of such license, one issue had not been fully resolved. In particular, the Delegation explained that according to the Belarusian legislation, any license, including a compulsory license, should be registered with the patent office upon payment of a fee, as prescribed under the law. In this connection, it was unclear whether the Court's decision would be sufficient for registration of a compulsory license or whether the Court would have to oblige the parties concerned to request such registration and, in this case, who would pay the related fees. The Delegation recalled, in this regard, there was a case when the court of one country had obliged the patentee to register such an agreement with the patent office. In conclusion, the Delegation stated that they would like to hear the experiences of other countries on that issue.

66. The Delegation of the Dominican Republic noted the importance of maintaining compulsory licensing exception in the law. The Delegation stated that the existence of such a provision in the law was a very useful negotiation tool, even though such license might not be granted in the end. Noting that a compulsory license should be granted in exceptional circumstances only, the Delegation stated that, in its country, that tool had been used in the area of AIDS treatment resulting in the grant of a voluntary license with better price of the concerned medication. The Delegation also stated that the budgetary constraints of its government, high prices of patented biotechnological pharmaceuticals and absence of biosimilars permitted the government to finance only a limited number of patients. Furthermore, the Delegation requested the WTO, WHO and WIPO to undertake a study on the real cost of medicine development for the purpose of setting the right royalty rate in case of compulsory license grants.

67. The Delegation of Canada, speaking on behalf of Group B, as regards the possible future work, noted that a one-size-fits-all approach would not be acceptable to Group B. The Delegation stated that, nevertheless, they would be able to consider work by the Secretariat on the next reference document on the topic prior use exception or use of articles on foreign vessels, aircrafts and vehicles. Further, the Delegation stated that, as adequate time for discussion had been provided in relation to the reference documents on research exception and regulatory review exception, they wished to conclude future discussions in relation to those reference documents.

68. The Representative of KEI requested the Secretariat to revise the draft reference document on compulsory licensing to include a section on cases where non-voluntary use had been employed as a limitation on remedies. The Representative provided some background on such use of non-voluntary licenses. In particular, the Representative stated that, in 2006, the Supreme Court of the United States of America, in a decision involving eBay, the online auction service, had held that injunctions on patents could only be issued if other remedies for infringement were rejected, including granting compulsory licenses on infringed patents. The Representative continued that, since 2006, the courts in the United States of America had issued a number of compulsory licenses on patents, including compulsory licenses that had benefited Microsoft, Toyota, DirectTV, Johnson and Johnson, Abbott Laboratories and other leading technology and manufacturing firms. The Representative stated further that, in the field of medical technologies, courts in the United States of America had rejected injunctions and ordered running royalties in several cases, among others, in cases on oral contraceptives, transcatheter heart valves, contact lenses, and hepatitis C diagnostic tests. Further, as regards to eBay cases involving non-medical technologies, the Representative stated that, in 2009, in *Paice v. Toyota*, United States District Court Judge David Folsom had issued an ongoing royalty rate in light of patent infringement by three of Toyota's vehicles. Paice had filed a lawsuit in 2004 alleging that Toyota's Prius, Highlander SUV, and Lexus RX400h SUV vehicles had infringed on patents held by Paice relating to the drive train for hybrid electric vehicles. The Representative stated further that Toyota had been found to be infringing on one patent and a jury awarded Paice 4,269,950 US dollars in damages. The Representative stated that the court had set an ongoing royalty rate as a percentage of wholesale vehicle price per model in question. The rates decided were 0.48 percent on each Toyota Prius, 0.32 percent on each Toyota Highlander, and 0.26 percent on each Lexus RX400h sold for the remaining life of the patent. Further, the Representative cited Judge Randall Rader who had stated that "District courts have considerable discretion in crafting equitable remedies, and in a limited number of cases, as here, imposition of an ongoing royalty may be appropriate. Nonetheless, calling a compulsory license an "ongoing royalty" does not make it any less a compulsory license." Further, in relation to a case *Apple Inc v. Motorola* (2012), the Representative stated that judge had cited the eBay decision noting that neither party had been entitled to injunctive relief as neither party demonstrated that "damages would not be an adequate remedy". The Representative stated that, in fact, the judge had specifically noted that a "compulsory license with ongoing royalty is likely to be a superior remedy in a case like this because of the frequent disproportion between harm to the patentee from infringement and harm to the infringer and to the public from an injunction.".

69. The Representative of TWN, supporting the statement made by the Representative of KEI, stated that the absence of information on judicial non-voluntary licenses, whereby the court allowed the use of patented injunction subject to payment of royalties, to be a major gap of the draft reference document. Further, the Representative found that there was limited information on the use of non-voluntary licenses by competition authorities. Noting that the use of non-voluntary licenses in the competitive cases was recognized in Article 31 of the TRIPS Agreement, the Representative pointed out that, in 2007, for example, the Italian Competition Authority had required to grant royalty free licenses to allow manufacture and sale of active ingredient and drugs used for prostate problems as well as male pattern hair loss in Italy. Further, the Representative disagreed with the statement made in paragraph 217 of the draft reference document that, as reported by the Member States, compulsory licensing mechanism had been rarely used. In relation to paragraph 191, the Representative reiterated that a major factor affecting the use of non-voluntary licenses was extrinsic influences which, in the view of the Representative, were not sufficiently addressed in the document. In this regard, the Representative stressed that the use of unilateral trade sanctions was a violation of WTO rules and that that issue had not been reflected in the reference document. Further, in relation to paragraph 222, the Representative pointed out that apart from the assertion of the pharmaceutical industry, there was no real verifiable evidence of the true cost of R&D. In

addition, the Representative added that many developed countries, such as, Canada, the United States of America, Italy and Germany, had been issuing non-voluntary licenses without any evidence of declining in innovation. With regard to paragraphs 224 to 229, the Representative stated that those paragraph reflected selective literature and not key findings concerning the use of compulsory licenses. Furthermore with respect to statements made by some delegations that the compulsory license should be used in an exceptional circumstances, the Representative pointed out that there was no such condition in the TRIPS Agreement. In this regard, the Representative referred to Article 7 and 8 in the TRIPS Agreement concerning the objectives of the Agreement and the Doha Declaration on the TRIPS Agreement and Public Health which allowed WTO Members to take measures to protect public health.

70. The Representative of JIPA, on behalf of JIPA and JPMA, wished to reiterate that they were of the view that providing excellent medicines to many patients all over the world was a mission of governments and companies in both, developed countries and developing countries. The Representative stated further that JIPA/JPMA believed that R&D of new drugs was essential in improving global access to medicines in developing countries. The Representative continued that, however, the discovery of revolutionary drug was an extremely difficult endeavor with extraordinarily low rate of success. Therefore, the Representative stressed that there was a need to carefully administer the current patent system so that it would provide incentive for innovation. The Representative continued that, although limitation of patent rights, including the compulsory licenses had been discussed in the previous sessions of the SCP, JIPA/JPMA believed that other factors, such as regulatory shortcomings, supply chain problems, lack of healthcare system financing were restricting global access to medicines and not IP rights. Therefore, JIPA/JPMA recognized that multilayered challenges needed to be tackled in order to address the issue of global access to medicines. The Representative stated that, along with those thoughts, Japanese companies actively engaged in those approaches. Further, the Representative introduced examples of Japanese pharmaceutical companies' engagements in order to improve access to medicines. In that respect, the Representative stated that Takeda and the National Institute of Allergy and Infectious Diseases (NIAID) had entered into a joint venture to examine the feasibility of using Takeda's microneedle patch technology to administer a protein antigen-based, transmission-blocking malaria vaccine developed by NIAID's Laboratory of Malaria Immunology and Vaccinology (LMIV) through WIPO Re:Search. Further, the Representative stated that Astellas had launched the Astellas Global Health Foundation (AGHF), a new international philanthropic organization dedicated to improving access to health in underserved global communities. Key areas of focus for the AGHF initially would be neglected tropical and communicable diseases, children's health and mental health in low-income communities and low-and middle-income countries where Astellas did not have a commercial presence. Further, the Representative informed the Committee that Mitsubishi Tanabe Pharma had been advancing joint research with Medicines for Malaria Venture (MMV), a research institution focused on the treatment of malaria, and that GHIT Fund would provide a grant for the joint research. The Representative stated further that Chugai had been working on a project for developing a new medicine for dengue fever in collaboration with Singapore Immunology Network. The GHIT Fund had recognized that the project might contribute to "fight against neglected tropical diseases in developing countries", and had decided on the grant of approximately 4.4 million US dollars. Further, the Representative stated that, Japanese pharmaceutical companies were actively involved in enhancing easy accessibility of information about the patent status of a specific medicine. Specifically, the Representative stated that Takeda, Astellas, Daiichi Sankyo, Eisai and Shionogi participated in WIPO hosted Pat-INFORMED, and the patent information related to 30 products had been already published through that database. The Representative expressed his belief that initiatives such as Pat-INFORMED provided easily accessible and understandable information about the patent

status of a specific medicine in a particular country. The Representative concluded by stating that their activities were contributing to not only improving global access to medicines but also enhancing accessibility of information about the patent status of a specific medicine in a particular country through Pat-INFORMED.

AGENDA ITEM 7: QUALITY OF PATENTS, INCLUDING OPPOSITION SYSTEMS

71. Discussions were based on documents SCP/17/7, 8 and 10, SCP/18/9, SCP/19/4, SCP/20/11 Rev., SCP/23/4, SCP/24/3, SCP/28/7 and 8 and SCP/30/4, 5 and 9.

72. The Delegation of Canada, speaking on behalf of Group B, stated that its Group was proud to see the SCP holding the sharing session on approaches to ensure the quality of the patent granting process within IP offices, including opposition systems. The Delegation stated that mechanisms ensuring the quality of the examination processes within the patent offices helped to support the grant of quality patents and, thus, supported the patent system in the achievement of its broad objectives. Noting that there was a variety of national and regional practices in that area, the Representative stated that they looked forward to hearing about those practices. The Delegation expressed its hope that the valuable exchanges at that and other sessions of the SCP would enable the Secretariat to produce an insightful study on the broad spectrum of approaches being employed by the offices to ensure the quality of the patent granting process.

73. The Delegation of Croatia, speaking on behalf of the CEBS Group, reiterated the interest and support of its Group to advancing the work on quality of patents in the Committee, which was at the core of the patent system. The Delegation further thanked the Secretariat for preparing the comprehensive document SCP/30/4. The Delegation stated that the assessment of the inventive step was crucial to the quality of patents, as its accurate evaluation ensured that exclusive rights were granted to inventions which contributed to the state of the art, and on the other hand fulfilled the patent system's objectives. The Delegation continued that the comprehensive study on practice around the world for assessing the inventive step in the field of chemistry as well as further exchanges of practices and information among experts on the issue of quality of patents were of great importance to be discussed in the SCP. The Delegation stated that good understanding of practices of various patent offices related to the inventive step was the basis upon which international work sharing and cooperation should be built. The Delegation continued that the widespread use of work sharing among offices of various sizes and of different levels of development was the step forward in future development of the patent system and, therefore its Group strongly supported such direction. Further, the Delegation stated that, as it had become evident during previous sessions of the Committee, third party observations, opposition proceedings or other administrative post-grant invalidation systems could affect the granting of high-quality patents. The Delegation stated that measurements of quality of the examination procedures were of great importance for achieving high quality of patents. The Delegation was therefore pleased to continue with the sharing session on approaches used by delegations to ensure the quality of the patent grant process within IP offices, including opposition systems, and it looked forward to the agreed study to be prepared by the Secretariat for the forthcoming SCP meeting. Noting that technological advances directly affected patent issues, the Delegation stated that artificial intelligence (AI) solutions might sooner or later be reflected in patent law. Therefore, the CEBS Group acknowledged the new revised proposal presented by the Delegations of Spain and France (document SCP 30/9) and it welcomed the new activities included in the proposal, such as information-sharing sessions on the use of AI for the examination of patent applications and

patentability of AI-related inventions. The Delegation was of the view that such activities would benefit all by improving their understanding of the real impacts of new technologies on the patent system. In conclusion, the Delegation thanked the Secretariat for the preparation of document SCP/30/5 and looked forward to its presentation.

74. The Delegation of Romania, speaking on behalf of the EU and its Member States, thanked the Secretariat for preparing the comprehensive study on the practices around the world for assessment of inventive step in the chemical sector, contained in document SCP/30/4. The Delegation also thanked those Members States which had provided inputs for the preparation of the document. The Delegation stated that the inventive step requirement was a core part of the substantive patentability requirements and its correct evaluation ensured that the exclusive rights were awarded only to inventions whose contributions to the state of the art deserved it. The Delegation stated further that the guidance provided by the study might be considered particularly useful, because the art of chemistry might be characterized by its experimental nature. The Delegation explained that, in comparison to electronic or mechanical field, research outcomes in the chemistry sector were less predictable. The Delegation stated that, for example, it was not always easy to predict technical effects of a chemical compound only from its structure, and thus the technical effects needed to be verified and confirmed by experimental data. The Delegation stated further that the EU and its Member States expected that the studies on inventive step would help the Committee to gain a better understanding of that requirement. The Delegation continued that, although there were various approaches on the factors that defined the “concept” quality of patents, and its meaning might be different for different stakeholders in different contexts, it sensed a converging understanding of the main issues. Therefore, the Delegation was confident that the findings of the questionnaire on the term “quality of patents”, and the various sharing sessions on that topic, including the one to be held during that session, would prove useful in carrying out our work in the area of quality of patents. Further, the Delegation stated that exchanges of practices and information among experts on the issue of quality of patents were one of the most important things to be addressed in the SCP. In addition, the Delegation stated that further deepening of the understanding of the offices’ practices related to the inventive step was the basis upon which international work sharing and collaboration could be built. The Delegation noted that the EU and its Member States had consistently supported a more widespread use of work sharing among patent offices of different sizes and on different levels of development. Further, the Delegation stated that they also supported the continuation of sharing sessions on the quality of the patent grant process. In that regard, the Delegation looked forward to learning more from other delegations, in particular regarding the capacity building of patent examiners and offices, and expressed its hope that those valuable contributions would result in an insightful study on approaches to the quality of the patent grant process by the Secretariat, which had been agreed to be delivered at the following session. To achieve that, the Delegation encouraged Member States to participate in the sharing session, so that the future study could be as comprehensive as possible. The Delegation stated further that, in recent years, there had been rapid developments in the field of AI that may sooner or later be reflected in patent law. Therefore, the Delegation appreciated the new revised proposal presented by the Delegations of Spain and France (document SCP 30/9) and expressed its view that the new activities included in it, such as information-sharing sessions on the use of AI for the examination of patent applications and patentability of AI related inventions, would benefit all Member States in gaining a better understanding of the real impacts of new technologies on the patent system. Further, the Delegation thanked the Secretariat for preparing document SCP/30/5 on emerging technologies. The Delegation stated that the EU and its Member States recognized that the patent system should contribute to the promotion of technological innovation as well as to the transfer and dissemination of technology, for the benefits of the society at large, through

balanced rights and obligations of technology producers and users of technological knowledge. As the Delegation acknowledged that digital technologies, including AI technology, were common challenges to all countries, it believed that the discussion on that topic could provide countries with solutions and possible ways of addressing those challenges.

75. The Delegation of Uganda, speaking on behalf of the African Group, commended the Secretariat for preparing the sharing session on approaches used by delegations to ensure the quality of the patent grant process within IP offices, including opposition systems, with special attention given to the capacity building of patent examiners and offices. The Delegation stated that quality of a patent was understood to refer to the quality of a patent itself and also to the quality of patent granting process within an IP office. The Delegation continued that, it was also understood that the quality of a patent had a close link to a substantive patentability criteria applied in an examination process in respective country. The Delegation further stated that its Group shared the concerns of other Member States about increasing decline of quality of patents across all regions, which were attributed to a number of factors, including technical capacity in IP offices of developing and least developed countries, declining standards of patentability across all regions, and increase in the volumes of patent applications, including on new technologies. With respect to the opposition systems, the Delegation stated that the African Group firmly believed that an efficient opposition system improved the quality of patents, and that such a system should be a safeguard to the quality of a patent. The Delegation further stated that an opposition system should be accessible and not be bogged down by costs and human capacity issues involved in different layers of the process. Turing again to the sharing session on approaches used by delegations to ensure the quality of the patent grant process within IP offices, the Delegation stated that it would be a valuable exercise for Member States to learn about such approaches used by other offices. However, the Delegation stressed that whereas sharing of experiences were important, they were only one of the several complementary ways to address the declining quality of patents. The Delegation continued that, for many IP offices of its region, the best way to address the challenges regarding patents and opposition systems was to improve the capacity of patent examiners through training in different technological fields. Therefore, the Delegation requested the Secretariat to increase its assistance and capacity building activities for patent examiners and offices in developing countries and LDCs.

76. The Delegation of the Republic of Korea considered that the quality of patents was a major factor in effectively creating innovative technologies, protecting the inventors and improving efficiency of patent administration of governments. The Delegation further stated that in the Industrial Revolution Era, or new Emerging Technologies Era, characterized by the transition of technology, the quality of patents should be the most important aspect to consider. The Delegation noted that it was closely related, not only to quality of granted patents, but also to administrative power of the governments to improve quality of patents, to reduction of duplicative work and to economic efficiency, as a result. The Delegation considered that the cooperation for better examination − work sharing between offices − were the most important tools to promote and guarantee the quality of patents. Noting further that while the question as to whether to grant a patent or not belonged to each IP office, the Delegation stated that work sharing was indifferent from the independent power of patent offices in granting patents. Rather, the Delegation noted, it could be helpful in granting the high-quality patents. The Delegation concluded by stating that, from that point of view, it was very meaningful to discuss the further study on inventive step (document SCP/30/4), and that it supported the revised proposal of document SCP/28/7 by the Delegations of France and Spain (document SCP/30/9).

77. The Delegation of Brazil thanked the Secretariat for the compilation of documents SCP/30/4, 5 and 9 and expressed its appreciation to the work undertaken towards illustrating the situation in different Member States and offices on those important themes. The Delegation also appreciated the efforts of all Member States and offices for providing

information and explanation regarding their relevant approaches, which was helpful to better understand the decisions taken and solutions found nationally, thus contributing to a more streamlined patent granting process. The Delegation stated that it had submitted information to the Secretariat on the directives used by Brazil regarding the analysis of inventive steps of patents in the chemical sector, which had profited from public consultations and had been published in December 2017 in order to give more transparency on the utilized methods and standards. Specifically, the Delegation stated that it had included information on inventive steps on the following areas: the Markush formula, salts, n-oxides, esters and ethers, pro-drugs, intermediate compounds, stereoisomers, polymorphs, solvates, clathrates, co-crystals, combination of compounds, and new medical use. The Delegation continued that multilateral and regional initiatives, such as WIPO CASE, acted as a facilitator of collaboration and cooperation among IP offices. Regarding the proposal by the Delegations of France and Spain, the Delegation stated that it understood that Member States could benefit from the exchange of experiences on AI, including how AI would affect the IP field in its various aspects. Noting that there had been dizzying developments in the field of AI, the Delegation stated that according to the WIPO Technology Trends 2019 report, AI-patenting started to take off only five years ago, with 40 percent increase in AI-patent applications during the period under study. The Delegation stated that according to its view, the very early state of discussions and the constant developments on that topic advised that discussions in the SCP should not yet advance to norm-setting activities. The Delegation stated that governments and patent offices were still undertaking studies and analyses in order to reflect on how they should adapt their processes and procedures to address the issue. In that regard, the Delegation supported the exchange of information among Member States and encouraged the Secretariat to work on the matter.

78. The Delegation of Iran (Islamic Republic of) thanked the Secretariat for preparing documents SCP/30/4 and 5. Referring to the history of the Committee discussions on that agenda item and divergent responses to the questionnaire on the term “quality of patents”, the Delegation noted that there was no common understanding on the term “quality of patents” among Member States. According to the view of the Delegation, that was a strong indication that quality of patents could not be enhanced by simply adopting the practice of other patent offices or by collaborating with other offices through work-sharing activities. In its view, work sharing was a matter of precision and should be left to bilateral or regional level. The Delegation stated that if any Member State was interested to share some or part of its work with other Member States, there was a room for them under the current legal framework. In light of that, the Delegation continued to believe that maintenance of that topic under that agenda item should not be construed as a tool for harmonization of patent law or norm-setting at that stage. The Delegation stated that that understanding was in accordance with Article 27.1 of the TRIPS Agreement which did not define the patentability requirement, giving the governments enough room to define and apply criteria according to their needs and priorities. The Delegation maintained the position that quality of examination needed to be improved substantively to conform with national policy objectives of each country so that high social cost of granting patents on insignificant improvement would be avoided. To that end, the Delegation stated, experience sharing could advance quality of patents and improve the technical expertise of patent offices through bilateral and regional cooperation between patent offices. The Delegation reiterated that, in its opinion, any initiative undermining the principle of the patent law and patentability criteria would jeopardize the system as a whole, and that the Member States needed a political space for establishing a mechanism that would take into account their own priorities, objectives and concerns. To conclude, the Delegation encouraged the Committee to focus on capacity building activities to developing countries and LDCs, such as development of databases, search tools and similar instruments.

79. The Delegation of Morocco thanked the Secretariat for the quality of the documents prepared for that session of the SCP, and welcomed the sharing session on approaches used by delegations to ensure the quality of the patent grant process within IP offices, including opposition systems. The Delegation stated that, in Morocco, in order to guarantee the quality of patents, various steps had been undertaken. In particular, the Delegation stated that as regards the patent granting process, considerable improvements had been made through the amendments to the Law No. 17-97 on the Protection of Industrial Property, followed by the development of various tools and indicators to improve the quality of patents. The Delegation further stated that three aspects were important in that regard: legal, technical and managerial. As regards to the legal aspect, the Delegation stated that the entry into force on December 2014 of Law No. 17-97, had made it possible to evaluate the system for registering patents in Morocco towards an examination system permitting the Office to establish search report and patentability opinions to guarantee the applicants a proper level of patentability examination, as well as to adopt a system of validation recognizing the examination made by the EPO to ensure patent protection for foreign applicants who had designated Morocco, without necessarily having cumbersome examination procedure. On the technical aspect, the Delegation stated that, in order to accompany the legal aspect and to make sure that issued patents were in line with international standards, the Office adopted high-performance search tools which made it possible for the examiner to carry out a thorough examination. Specifically, the Delegation stated that, since 2009, the examiners had being trained on the use of various databases and tools, such as EPOQUE Net, ORBIT, WPI and IEEE. The Delegation continued that, in addition, the Office focused on interconnected digital infrastructure, which made it easier to manage patent applications, such as IPAS, WIPO Scan, EDMS, WIPO Publish, DAS, and ePCT. Turning to the managerial aspect, the Delegation stated that, in order to ensure that procedures and the rules were harmonized with the law, the Office had proceeded to formalizing the working methods and elaborating documents related to the quality of patents, notably, the directives, the procedures and briefing notes. Further, the Delegation stated that, in addition, in order to increase performance, improve productivity, avoid issuing low-quality patents, optimize the costs, speed up the processing of applications as well as avoid waste of resources and to increase the clients satisfaction, the Office had adopted “Lean Six Sigma”. The Delegation continued that, in order to do that, the Office needed to use specific tools, including Qlickview, which was an intelligent business platform and data visualization for the analysis of patent applications. The Delegation stated that such a tool was dynamic dashboards for the administration management, analysis and follow-up the patent applications, permitting, principally, the control and monitoring of process performance measurement indicators, such as First Office Action, publication period, issuance period and productivity of the examiners. The Delegation continued that, equally, to ensure good quality of issued patents and to align with international standards of patent examination, the Office had provided training and skill acquisition courses to patent examiners in two ways: first, a basic training, which provided newly recruited examiners with all the knowledge and skills they needed to carry out an examination. The Delegation stated that for each new recruit, a four month mentoring and training period was provided, which enabled them to learn on the job and start to draw up their first search reports with support from their mentor. The Delegation continued that the second way of training was a continuing training which was destined for all examiners enabling them to improve their skills and knowledge. The Delegation stated that such a training was provided by partner agencies, such as EPO and WIPO in the form of training in the office or seminars through the WIPO Academy as well as distance learning.

80. The Delegation of Portugal thanked the Secretariat for the elaboration of document SCP/30/4, entitled “Further Study on Inventive Step (Part III)”. The Delegation considered the study to be very important for all Member States. The Delegation stated that the study allowed sharing information among Member States, providing a stronger knowledge and understanding of assessment of inventive step in the chemical field, which in its opinion was a complex field. Further, the Delegation observed that, though its Office had submitted the

information on assessment of inventive step in the chemical sector by its Office, their response had not been included in document SCP/30/4. Further, the Delegation thanked the Secretariat for the elaboration of document SCP/30/5 on emerging technologies, because it could provide solutions to address the challenges arising from those technologies. The Delegation reiterated its support and commitment to the discussions on the topic "quality of patents". Therefore, the Delegation had supported various proposals that could improve the quality of patents, including the revised proposal by the Delegations of France and Spain contained in document SCP/30/9. The Delegation noted that those new technologies, such as AI, would have an impact on the search for the state of the art but also on the patent law. Therefore, the Delegation considered that those activities and studies were very important, because they would help the Member States to understand the real impact of AI on the patent system.

81. The Delegation of Ghana associated itself with the statement made by the Delegation of Uganda, on behalf of the African Group. The Delegation stated that the quality of granted patents by the national offices was pivotal to the patent system. The Delegation expressed its appreciation to the Secretariat for the preparation of the detailed study on that important topic. The Delegation looked forward to the sharing session on approaches used by delegations to ensure the quality of the patent grant process within IP offices, including opposition systems. Noting that the quality of patents depended to a large extent on the capacity and skills of patent examiners and transparent procedures for the grant, the Delegation stated that IP offices in developing countries and LDCs should be assisted in enhancement of the capacity of their patent examiners in the different technological fields to enable them to issue high quality patents and efficient use of shared reports from other offices.

82. The Delegation of Ecuador stated that patent quality was a vital element in order to ensure the patent system served its purpose of incentivizing innovation and facilitating the transfer of knowledge. In its view, the quality of patents should be interpreted as the protection granted to those inventions which meet the patentability requirements. The Delegation expressed its wish to ensure the proper functioning of the patent system, including the elimination of those elements which did not serve the purpose. The Delegation emphasized that the maintaining of high quality patentability standards were the stimulus for innovation. In that line, the Delegation thanked the Secretariat for preparation of document SCP/30/4, and the related presentation, which was very important for patent examiners. The Delegation also expressed its appreciation to the Delegations of France and Spain for their revised proposal contained in document SCP/30/9, which it supported. Further, the Delegation stated that, considering that the examination techniques linked to AI had not been massively shared, they needed more information for the possible protection of those inventions.

83. The Delegation of India commended the Secretariat for the efforts taken to prepare a further study on inventive step (Part III) (document SCP/30/4), which mainly focused on the assessment of inventive step in chemical field, including Markush claims. The Delegation reiterated the statement made at the twenty-second session of the SCP with respect to the study on inventive step that any deliberation and discussions in that regard should not be construed as a tool for harmonization of inventive step requirement. The Delegation stated further that inventive step was one of the main patentability requirements to ensure that a patented invention involved a technical advancement over prior art or having economic significance or both and that the invention was not obvious to a person skilled in the art. The Delegation noted that the TRIPS Agreement did not provide any specific definition of the patentability requirements, leaving the matter to Members to define them in accordance with their national laws. Further, the Delegation stated that opposition systems also played a vital role in granting quality patents. The Delegation continued that, after introduction of the pre-grant opposition in the Indian patent system, many patents had been refused. The Delegation stated that an effective opposition system acted as a filter during the patent prosecution and ensured not only quality of the patent, but also minimized the cost involved by

minimizing the chances of future litigation process. The Delegation informed the Committee that in India, any general public may file a pre-grant opposition (after a patent application was published and before the grant of a patent) before the Controller, whereas only an interested person was allowed to file a post-grant opposition within one year from the date of grant of a patent. The Delegation noted that such a system ensured transparency in patent system and improved the quality of patents. The Delegation stated further that the Indian Patent Office, as an International Searching Authority (ISA) and an International Preliminary Examining Authority (IPEA), was also a part of the PCT/MIA quality subgroup. The Delegation stated the importance of a Quality Management System (QMS) to ensure the quality of the International Search Reports (ISRs) and the International Preliminary Examination Reports (IPERs) prepared by the Indian ISA/IPEA. Further, turning to the issue of Markush claims, the Delegation stated that, such claims allowed a large number of compounds being claimed in a single claim. The Delegation explained that in case of determining inventive step for an invention expressed in Markush claims, the examiners faced a lot of hurdles, as the said structures related to millions of possible compounds. The Delegation continued that, effective search strategy and comprehensive search was vital to check the novelty and asses the inventive step of the Markush claims. The Delegation stated further that, in accordance with Section 2(1)(a) of the Indian Patents Act, an invention would have inventive step if the invention was (a) technically advanced as compared to existing knowledge or (b) having economic significance or (c) both and that made the invention non-obvious to a person skilled in the art. The Delegation stated that, in case of Markush claims, it was to be checked whether the compound had been disclosed specifically in the prior art document or not. The Delegation further cited the provision of the Patents Act which stated “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant, is not patentable. For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure for, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”. The Delegation further stated that the Hon’ble Supreme Court of India in a landmark judgement had clarified that efficacy in that regard referred to a “therapeutic efficacy”. In conclusion, the Delegation proposed that a further study on Markush claims be conducted at the SCP in greater detail to strengthen the tools of examination of such claims. The Delegation also proposed to conduct a study on opposition systems to help improving the quality of patents.

Sharing session on approaches used by delegations to ensure the quality of the patent grant process within IP offices, including opposition systems (special attention is given to the capacity building of patent examiners and offices).

84. The Delegation of Japan made a presentation on the initiatives of the Japan Patent Office (JPO) on enhancing the quality of patent examination for the emerging technologies. The presentation is available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_k_sharing_session_on_quality_japan.pdf.

85. The Delegation of Spain made a presentation on the quality management at the Spanish Patent and Trademark Office (OEPM). The presentation is available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_l_sharing_session_on_quality_spain.pdf.

86. The Delegation of Mexico made a presentation on the topic of patents quality at the Mexican Institute of Industrial Property (IMPI). The presentation is available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_m_sharing_session_on_quality_mexico.pdf.

87. The Delegation of the Republic of Korea made a presentation on capacity building of patent examiners at the Korean Intellectual Property Office (KIPO). The presentation is available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_n_sharing_session_of_quality_republic_of_korea.pdf.

88. The Delegation of Canada made a presentation on the topic of patent quality at the Canadian Intellectual Property Office. The presentation is available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_p_sharing_session_on_quality_canada.pdf.

89. The Delegation of the United Kingdom made a presentation entitled “Patent Examiner Exchange: United Kingdom – China”. The presentation is available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_o_sharing_session_on_quality_united_kingdom.pdf.

90. The Delegation of Germany thanked the Secretariat for the preparation of that session of the SCP and the provision of the meeting documents, which were of the highest quality. Further, the Delegation thanked the Delegations of Japan, Spain, Mexico, the Republic of Korea, Canada and the United Kingdom for excellent and informative presentations delivered at the sharing session on approaches used by delegations to ensure the quality of the patent grant process within IP offices, including opposition systems. The Delegation stated that the highest quality of patents was one of the most important objectives of the German Patent and Trademark Office (DPMA). Therefore, the DPMA payed particular attention to high level of quality during the patent granting process. The Delegation continued that, ensuring that high level of quality began already with the recruitment of patent examiners. The Delegation informed the Committee that previous year, 177 new posts for patent examiners had been approved by German *Bundestag*, and further 73 recruitment possibilities provided for 2018 and 2019 budgets of DPMA. The Delegation stated that 113 new examiners had been recruited since autumn 2018 and that the DPMA would continue recruitment in 2019. The Delegation further stated that the German Patents Act specified for the recruitment of patent examiners that, as a rule, only those who held a University degree in engineering or science and had at least five years of work experience in one of those fields should be recruited. The Delegation stated that such a requirement ensured that the examiners could contribute to the examination work with their specific expertise from the very beginning of their careers. The Delegation further stated that, in addition, the newly recruited examiners received trainings when they started their work at the DPMA. The Delegation continued that, over a period of three years in total, the participants would be required to obtain essential and profound legal knowledge and learn how to use the IT systems of the DPMA. In addition, the DPMA trained newly recruited staff in other intellectual property areas, such as trademark or design law, to convey the comprehensive understanding of intellectual property. The Delegation stated that such trainings were conducted by judges of the Federal Patent Court and experienced staff of the DPMA. The Delegation continued that, at the same time, the daily work of the newly hired examiners was individually supervised by experienced mentors over a period of 18 months. The mentors were available to answer any type of questions examiners could have. The Delegation further stated that, the DPMA also offered optional qualification opportunities for examiners in their further careers. In particular, the Delegation stated that, for several years, the DPMA had been inviting external lecturers from industry and universities to a “Day of Technology”. In May 2019, for example, the DPMA examiners had been able to obtain information on networking technologies.

At that event, experts from Toyota, Technical University of Berlin and Friedrich-Alexander-University Erlangen-Nuremberg had given lectures on AI and smart homes and autonomous driving. Further, the Delegation stated that examiners could also attend numerous language courses in Japanese and Chinese. The exchange of examiners with other patent offices allowed the examiners to gain further qualifications, which were useful in patent granting process, in particular, in conducting searches. The Delegation stated that the search and examination performed by the DPMA examiners ensured high level of quality. Although the examiners worked independently, each decision was submitted to a second experienced senior examiner. The Delegation stated that that was part of the quality management system, which had been adopted over the years to fit the specific needs of the DPMA and was constantly being further developed. The Delegation stated that that ensured that the decisions of the examiners were consistent with the legal requirements of German patent law. The Delegation continued that, during patent examination the examiners of the DPMA worked exclusively with an electronic file. Implementation of electronic workflow which controlled the process flow enabled a uniform and orderly procedure. The Delegation stated that the electronic file also accelerated the examination procedure and contributed to a high level of quality. Further, the Delegation stated that, in addition to those measures to ensure maximum of search and examination quality, the German Patent Act provided for possibilities of intervention by third parties. In particular, the Delegation stated that, according to Section 44(2), first sentence, of the German Patent Act, the request for examination might be filed not only by the applicant but also by any third party within seven years from filing the application. The Delegation noted that the provision gave third parties the opportunity to initiate the examination of the application and to speed up the procedure. The Delegation also stated that a third party might at any time during the examination procedure file a relevant prior art known to him concerning the subject matter of the application, and thus influence the examination procedure as laid out in section 43(3), second sentence, of the German Patent Act. The Delegation continued that, neither through the filing of a request for examination nor through submissions of the prior art did the third party became a part of the proceedings. Further, the Delegation stated that it was also possible to file a post-grant opposition at the DMPA. In particular, the Delegation stated that up to nine months after the publication of a grant of the patent, any third party might submit a written opposition to the grant of a patent stating the reasons (Section 59 of the German Patent Act). A division of the DPMA was responsible for handling opposition proceedings. The panel consisted of three persons: a chairman of the Division, a rapporteur and an assessor. The Delegation noted that, even in the case of several oppositions against the same patent, only one procedure with the participation of all parties took place. The Delegation stated further that the high quality of patent examination and the associated high degree of legal certainty of the patents granted by the DPMA were reflected in statistics of opposition proceedings. As regards the statistics, the Delegation stated that, during the period from 2013 to 2017, about 75,000 new patents had been granted by the DPMA. Of those, nearly 1,800 patents had been challenged in opposition proceedings between 2014 and 2018, of which about half had been maintained as granted or in limited form. The Delegation noted that, thus, even after review in opposition proceedings, more than 98 percent of the patents granted by the DPMA remained valid.

91. The Delegation of Sweden thanked all the other Delegations that had contributed to the sharing session. The Delegation stated that the Swedish Patent and Registration Office (PRV) followed those discussions with great interest. In particular, the Delegation stated that, since the year 2007, the PRV had an ISO 9001 certification on quality management. The Delegation stated that their work on quality included steps such as peer controls of first written opinions and annual quality checks. The Delegation further stated that they also had a number of patent experts that followed the new case law from both the Swedish Patent and Market Courts and EPO in their respective technical and legal fields. The Delegation continued that those patent experts, among other things, checked all potential rejections of applications as well as all intensions to grant. Further, the Delegation stated that a new role had been created at the PRV

called “search expert”. Those experts evaluated new databases and examined new search tools to establish a best practice. The Delegation stated that, since those practices could be different depending on the technical field, there were two search experts at each of six technical units. The Delegation noted that the system had been well received by examiners and had increased their interest in trying new search strategies and that it had also highlighted the importance of the search in the aim to ensure a good quality of patents.

92. The Delegation of Australia thanked the Secretariat for their preparations for the session as well as Member States for providing information on their approaches to ensure the quality of their patent grant processes. The Delegation stated that, like many offices, they sought to continuously improve the quality of their examination work. In that regard, the IP Australia was taking a number of initiatives. Specifically, the Delegation stated that IP Australia had commenced review of its quality review system. The review would look at the various parts of the quality review system to ensure that it provided quality outcomes that were linked to organizational strategic goals. The Delegation continued that the review would specifically cover the method and the focused on quality sampling as well as attributes of its quality standards. IP Australia was also working on an overall framework of complimentary initiatives to improve the quality of its work and the management and incentivization of its staff. The Delegation stated that IP Australia was working on enhancing its examination under the examination excellence program. The Delegation further stated that several initiatives for that project were already underway, including improvements to the examination manuals, investigating potential uses of automation and Artificial Intelligence and enhancements of search. The Delegation stated that they were seeking to reinvest the efficiency gains from those initiatives into improvement in quality. Further, the Delegation stated that IP Australia recognized the need for culture of trust and collaboration, which enabled excellence in all aspects of their work. The Delegation continued that their current performing incentivization arrangements were at odds with the contemporary approach. It would develop a performance setting framework which would consist of six main components: production, quality, timeliness, corporate contribution, learning and development and behaviors. The Delegation stated that managers were encouraged to manage the output of their teams in a more holistic way with regard to those six performance components under a partnership model that focused on peoples’ strengths to get the best outcome for customers, while, at the same time, acknowledging the corporate contribution that people made to their team and the wider strategic outcomes of IP Australia.

93. The Delegation of the Czech Republic shared the information on the capacity building of their patent examiners, in addition to the presentation on quality management system applied by the Czech IP Office, which it had delivered at the previous session of the SCP. The Delegation stated that, in 1963, the Czech IP Office had established its own IP related educational institution called the “Industrial Property Training Institute”. The institute provided a two-year distance learning program which was designed for professionals in the field of industrial property assistants, patent attorneys, commercial lawyers active in the IP domain, entrepreneurs, research and development experts, students, and the wider public. The Delegation continued that each new employee of the Czech IP Office, including patent examiners, completed that program. Tutors were mainly employees of the Office or IP experts from other governmental bodies or private sector. Participants were trained not only about the international, regional and national protection procedures and enforcement of IP rights, but also about the usage of the IP databases, in particular, on how to search different IP databases, how to create the search inquiry in the most efficient way, how to classify inventions, or how to create the IP strategies including the IP evaluation or licensing. The Delegation continued that, more concretely in the field of patent law, participants had learned about the requirements of the patent application, search and examination, specifics of patent procedure in terms of particular subject matter of different technical fields, such as chemical, electric, pharmaceutical as well as computer-implemented inventions. The Delegation stated that the special attention was drawn

to formulation of claims in the above-mentioned technical fields. In addition, the Delegation stated that they were also informed in details about the topographies of semi-conductor products and supplementary protection certificates for medicinal and plant protection products. The Delegation stated further that, the participants also became familiar with the post-grant procedures, such as a revocation or a declaratory judgment. This study was concluded by the defense of a final IP specialized thesis and by passing the final oral examination on the main subjects, namely rights to designations, patent information and searches as well as protection of technical solutions and designs. The Delegation informed the Committee that 30 to 45 participants applied for that distance learning program every year. The Delegation stated that, in addition, the Czech IP Office published IP-related publications such as international treaties dedicated to the field of patent law, the European Patent Convention, the legal protection of inventions and utility models or the patent information and search databases. The Delegation further stated that the Czech IP Office also issued a professional journal called “Industrial Property” which contained IP-related articles, information on the European legislation, information on the latest case law, and short actual IP related information. Further, the Delegation stated that patent examiners regularly took part in trainings on the patent grant process with a special focus on search and examination organized by the European Patent Academy for the offices of the EPC Contracting States, and that they also participated in training workshops or conferences organized by the EPO, WIPO, or other IP offices, dedicated to the various patent search and examination elements. In addition, the Office also run a specialized English language course focused on the IP terminology. In conclusion, the Delegation welcomed the continuation of the sharing session focused on the quality of patent grant process. In its view, the contributions made during such sessions had contributed to and enriched the overall pool of information available to the Secretariat for the preparation of the agreed study.

94. The Delegation of China thanked the Delegations which had made presentations during the sharing session on approaches used by delegations to ensure the quality of the patent grant process within IP offices, including opposition systems. The Delegation specifically thanked the Delegation of the United Kingdom which made a presentation on the patent examiner exchange program between the Offices of the United Kingdom and China. The Delegation stated that such exchange focused on two technical areas. The examiners would commonly select cases for review through the exchange of cases. The Delegation stated that the participants have deep exchanges as regards differences and commonalities between the two offices. The Delegation noted that such exchanges had played a facilitating role in improving understanding of each other’s approaches to examination. The Delegation also stated that, in practice, they had boosted mutual confidence and trust. The Delegation expressed its hope that, in the future, they would have similar exchanges with different IP offices. Taking the opportunity, the Delegation shared with the SCP what they had been doing in boosting the granting of high quality patents. They were of the view that patent offices played an important role in improving the quality of patents. The Delegation stated that, on the one hand, the capacity building was important in improving the quality of patents. The Delegation continued that, on the other hand, they were trying to improve the quality control by establishing a comprehensive quality check system and using multiple measures. The Delegation stated that they also had the evaluation of the quality of examiner’s work, and that they had a system to obtain feedback from the applicant and the public. The Delegation also stated that the Office had developed various manuals on quality. At the same time, they tried to improve management of the agencies in the relevant profession. In conclusion, the Delegation expressed its hope to hear more about relevant practices from other IP offices.

95. The Delegation of the United States of America thanked the Delegations for their very informative presentations made during the sharing sessions. The Delegation gave an update to the information it provided at the previous sessions of the SCP on the ongoing quality initiatives undertaken in the USPTO, i.e., the national Collaborative Search pilot with the Japan Patent

Office (JPO) and the Korean Intellectual Property Office (KIPO), PCT Collaborative Search and Examination pilot with the IP5 Offices and Prior Art Initiative. The Delegation explained how the Collaborative Search Pilot functioned. Further, the Delegation noted that, as stated by the Delegation of the United Kingdom with regard to their exchange programs, the collaborative search pilot allowed the examiners in each office to benefit from the possible different search databases available the other office and the different language expertise of the examiner in the partner office. The Delegation stated that initial results from the first phase of their program had been promising. In particular, the Delegation stated that they had observed an increase in the allowance rate and a lower appeal rate, compared with the applications going through the normal prosecution process. The Delegation further stated that, in the second phase of that pilot, which would last from November 1, 2017 until October 31, 2020, some changes were made to further streamline the examiner and applicant processes. The Delegation also stated that they were also evaluating ways to expand the pilot, including working with other IP offices. Turning to the PCT Collaborative Search and Examination pilot, the Delegation stated that, under the pilot, examiners from the IP5 Offices in their capacity as International Authorities under the PCT with different working languages were collaborating on the search and examination of a single international application. The Delegation stated that under that pilot the selected searching authority would perform a search and prepare a provisional international search report and written opinion. The provisional report and written opinion as well as a record of the search were shared with the other offices. The peer offices performed additional search as they deem necessary and provided comments back to the main searching authority. The main authority then prepared a final international search report and a written opinion, taking into account the observations of the peer contributions. The Delegation informed the Committee that the second year of the operational phase of the current pilot, would start on July 1, 2019. The Delegation stated that, for the first half of the operational phase of the current pilot the majority of applications had been limited to the English language. However, during the second half of the project phase, applications in French, German, Chinese, Japanese and Korean languages would also be accepted by the IP5 Offices that operate in those languages. As regards to its internal Prior Art Initiative, the Delegation stated that that initiative was aimed at leveraging electronic resources to collect information such as prior art search reports and other information from relevant sources, including related U.S. applications, counterpart foreign and PCT applications, and to automatically import that information into the file wrapper of a U.S. patent application at the earliest point in time. The Delegation stated that during the previous session in December 2018, it had informed the Committee that, at that point, the initial rollout of the first phase of the initiative had just begun: it had been deployed to examiners in a single art unit and had been limited to importing references into the file under examination from the immediate U.S. parent applications. The Delegation stated that, since its presentation in December, the initial phase had been expanded to eight additional art units which included at least one art unit from each of their technology centers. The Delegation stated that, as their resources permitted, they expected to move on to subsequent phases of the initiative, including expanding the rollout to all examiners and importing from additional sources, such as counterpart foreign applications and PCT applications.

96. The Delegation of Singapore thanked Member States for their active contribution and sharing of information on the subject under discussion. This Delegation believed that work on quality of patents was of high importance. The Delegation stressed that high patent quality was essential to ensure the fine balance between incentivizing and rewarding innovation and public access to meaningful disclosure of new technologies. The Delegation further stated that, as custodians of patent grants, it was crucial for IP offices to be equipped with requisite knowledge to ensure high patent quality. The Delegation further stated that the Intellectual Property Office of Singapore (IPOS) had in place a robust system to train its examiners and that they were given instructions and mentorship to develop capabilities. The Delegation stated that that was supplemented with frequent exchanges and sharing with industrial experts. The Delegation further stated that IP Academy of IPOS covered various topics beyond patent examination, such

as IP enforcement, valuation and commercialization. The Delegation further informed the Committee that, in addition, to improve patent quality through patent proceedings, third party observations and post-grant re-examination would be formalized and introduced as part of Singapore reforms to IP dispute resolutions system. The Delegation stated that those proceedings were aimed at providing cost effective options for third parties to challenge patents and applications in an effort to ensure that only patentable inventions enjoyed patent protection. The Delegation stated that such legislative amendments for third party observations and post-grant re-examinations were planned for the second half of 2019. The Delegation looked forward to a positive progress in the area of improving patent quality, including on the proposals to strengthen activities for capacity building.

97. The Delegation of the Russian Federation thanked the Member States for their presentations delivered during the sharing session under that agenda item. The Delegation stated that Rospatent also gave a great importance to quality of patents. The Delegation stated that, as far as patents were concerned, 500 examiners conducted search and examination in various fields of technology. As International Searching and International Preliminary Examining Authorities under the PCT, in 2018, the Rospatent had received around 4,000 applications. The Delegation stated that, in addition, in the framework of various PPH programs, the Rospatent had received around 1,500 requests to conduct examination. The Delegation stated that quality of patents related to the ability of the patent to withstand to infringement claims as well as quality of patent granting processes, such as quality of search and examination as well as timeframe to process patent applications. The Delegation stated that they had principally adopted a new approach in handling patent matters. Specifically, the Delegation noted the development of digital technologies and stressed the improvements in the deployment of electronic services by the Rospatent. In particular, the Delegation mentioned the use of Artificial Intelligence in order to carry out the patent examination, as well as automatic translation of applications. The Delegation stated that Rospatent was aiming to significantly decrease the timeframe of its operations and increase the quality of its services. Further, the Delegation requested the SCP to conduct a study on optimal timeframes for examination of patent applications. The Delegation expressed its interest in hearing from other Member States on that issue.

98. The Delegation of France shared some elements as regards the strengthening capacity of its examiners. Specifically, the Delegation provided the following information: each patent examiner had to undergo eight weeks diploma study at the Center for International Intellectual Property Studies (CEIPI) of the University of Strasbourg. In addition, examiners could take EPO courses in various formats, including in e-learning format. In addition, the language courses were organized for those examiners who wished to improve their language skills. The Delegation further stated that the number of patent examiners had increased over the previous years, having reached 113, and that they planned to recruit 15 more examiners following to the legislative changes that the Delegation had mentioned at the previous day of the SCP session, specifically relating to the opposition system and examination of inventive step criterion. The Delegation also stated that the Office was planning to organize trainings as regards the opposition system with the assistance of the EPO and other institutions. Finally, internal directives would be reviewed and e-learning modules would be created internally to help capacity building of examiners.

99. The Delegation of the Republic of Belarus was pleased to note the progress that the Committee had made on the topic of quality of patents, including opposition systems. While noting that the Belarusian legislation did not contain a definition of the quality of patents, the Delegation stated that, in order to ensure the quality of patents, it was necessary that patents be granted only on inventions that fully meet all the conditions of patentability. Noting that the quality of patents could be affected by various factors, the Delegation mentioned some of those factors, i.e., the availability of qualified specialists, the availability of appropriate technical

capabilities, the interaction between experts and applicants, and the existence of opposition systems. The Delegation informed the Committee that the Belarusian legislation did not contain a provision on the possibility of filing an opposition at the pre-grant stage. Nevertheless, a patent could be declared as invalid or partially invalid on various grounds, including in case the protected invention did not meet the conditions of patentability as prescribed in the law. The Delegation was of the view that a small number of revocation cases or the complete absence of such cases was one of the indicators of the quality of the granted patents. In that regard, the Delegation stated that, since 2008, no single national patent had been revoked. In conclusion, the Delegation supported the suggestion made by the Delegation of the Russian Federation to look into the issue of timelines of office procedures.

100. The Delegation of Cameroon stated that due to the reforms which had been taking place at OAPI since two years, the Office of Cameroon had been reaching out various offices as regards the training of their examiners, such as the EPO and JPO. The Delegation observed two types of inventors: (i) universities, research centers and qualified inventors; and (ii) private persons. The Delegation stated that as regards the applications filed by type (i) of inventors, they provided three stages of examination: first, an examination by the qualified experts at the universities; second, examination conducted at the Patent Office of Cameroon; and third, examination conducted at OAPI. Turning to type (ii) of independent inventors who were generally not trained in patent matters and had difficulties in drafting claims, the Office was in the stage of putting in place a system of support. In that regard, the Delegation wondered whether other offices also provided specific support to those kind of inventors. In conclusion, the Delegation supported the proposal by the Delegation of the Russian Federation to look into the issue of timelines of office procedures.

101. The Representative of OAPI stated that the issue of quality of patents was of great interest to OAPI. Further, the Representative stated that its main legislation was amended in 2014. The main changes were related to the introduction of the substantive examination, introduction of publication of patent applications and the possibility of recourse during the process. The Representative continued that, in December 2018, the Administrative Council of OAPI had taken a resolution which provided for the three year implementation strategy of the substantive examination. The Representative stated that during those three years, OAPI would be working on three directions: legal (ensuring that all the procedures in terms of search and examination were established), material (establishing the needed databases and access to them) and capacity building. As regards the capacity building, the Representative stated that generally the examiners would be trained at OAPI as well as with the involvement of other partner institutions. The examiners would also be trained at CEIPI in Strasbourg. Further, the Representative stated that in order to increase the quality of patents, OAPI had been working on raising awareness on patent matters and building capacity of employees of research centers located in Member States by establishing various guidelines and directives.

102. The Representative of TWN stated that administrative post-grant opposition systems were crucial in improving the quality of patents. The Representative stated that those systems offered third parties an opportunity to oppose the grant of patent before and/or after its grant. The Representative continued that, participation of third parties who were well informed in the technology provided an additional layer of scrutiny supporting the patent offices to arrive at an objective and rational decision on grant or non-grant of patents. Further, she stated that, such systems also offered an early opportunity for competitors to check the patentability of inventions, reduced the uncertainties with regard to the boundaries of an invention, brought more transparency in the grant process and promoted a strong patent system where only real inventions were rewarded by patents. The Representative stated that, in short, such systems supplemented the resources available to the patent office, ensuring quality of granted patents. Further, the Representative stated that, from a public policy perspective, as well as a development perspective, a robust administrative opposition ensured that patents were not

granted on undeserved inventions. The Representative stated that, as such, patents would in any way block competition and prejudice consumers. She continued that, in the health sector, administrative oppositions were actively used by generic manufacturers as well as civil societies, including patient groups to oppose pharmaceutical patent applications which did not meet the national patentability criteria. In that regard, she listed some successful opposition cases in India and Argentina relating to pharmaceutical products. Noting further that opposition systems were a common feature in many national and regional laws, the Representative stated that, despite the benefits of the system, a number of laws did not incorporate such a system. The Representative strongly urged Member States as well as regional IP offices to institute both administrative pre- and post-grant opposition systems. Finally, as regards work-sharing initiatives mentioned by some delegations, the Representative expressed concerns about such initiatives in improving quality of patents.

Inventive Step

103. The Secretariat introduced document SCP/30/4, entitled “Further Study on Inventive Step” (Part III).

104. The Delegation of the Dominican Republic pointed out the difficulties associated with the examination of molecules that had a similar structure but were not completely identical. It noted that while those molecules could overcome the requirement of novelty, with regard to inventive step, the following two scenarios might arise: first, if both molecular structures were similar but not identical and their technical effect were different, there would be no problem in evaluating the case as there would be a new effect; a second scenario would arise when the molecules were similar but not identical and the technical effect was the same. The Delegation noted that that second case posed difficulties to the examiner, because the change in the molecular structure might be just a small improvement that does not add a new technical effect to the molecule. The Delegation continued that problems could also arise in the case of Markush claims in relation to the variability of the invention that might be produced by adding, for instance, nitrogen, and the subsequent filing of a patent application for the selection of compounds. The Delegation expressed its view that authorities should consider those issues and how to deal with them in the coming future.

105. The Delegation of the United States of America thanked the Secretariat for the preparation of document SCP/30/4 as well as Member States that provided information for the preparation of the document. The Delegation expressed its support to previous statements made by Group B. Specifically, the Delegation noted that inventive step and its assessment were crucial to the quality of patents and to the achievement of the patent system’s objectives. The Delegation stated that document SCP/30/4 highlighted various approaches to inventive step in the chemical field, for instance, the document provided insight to Markush claims, which was a common claim drafting format in that field of technology. The Delegation stated that, as the study noted, those claims set forth a list of alternatives from which a selection was made. The Delegation continued that, in the United States of America, that type of claim drafting dated back to 1924 and derived its name from a case presented before the U.S. Patent Office known as “*Ex-parte* Markush”. The Delegation appreciated the study explanations, the different approaches to inventive step, notably those of Brazil, Costa Rica, Ecuador and EPO. Noting that similar approaches to inventive step were followed in many countries, the Delegation wished to underline that point of similarity among countries. The Delegation stated that the requirements of inventive step/non-obviousness was a complex topic and one whose understanding contributed to increased patent quality. In conclusion, the Delegation thanked the Delegation of Spain for submitting the underlying proposal for that study.

106. The Delegation of Canada, speaking on behalf of Group B, thanked the Secretariat for the preparation of the further study on inventive step which focused on the assessment of inventive step in the chemical sector, as well as those Member States that had provided input for the preparation of the document. The Delegation reiterated the view of Group B that the assessments of the inventive step was crucial to the quality of patents and to the achievement of the patent system's objectives. The Delegation stated that the further study contributed to enhancing their understanding of the concepts discussed as well as the corresponding practices of Member States.

107. The Delegation of Japan stated that, to achieve the objectives of the patent system, which were to encourage the creation of inventions and promote innovations, it was important to properly examine inventions to verify that they met patentability requirements, especially that of inventive step. In that regard, the Delegation wished to express its appreciation to the Secretariat for its great efforts in preparing the following working documents on inventive step: SCP/28/4, SCP/29/4 and SCP/30/4. The Delegation noted that those documents were very informative and useful in terms of appreciating the value of inventions and properly evaluating the inventive step. The Delegation stated further that JPO's Examination Guidelines and Handbooks became well-established, based on the experiences through the years. Yet, the Delegation noted, JPO was continuously working to further improve them. The Delegation continued that, in the process of considering the best possible examination practices, the JPO had discussed examination practices with both domestic and foreign users, and took their views into account. Noting that it was very informative and useful to share each Member State's view and expertise on the quality of patents at the SCP, the Delegation stated that it would be pleased to contribute to further discussions in that regard based on their experiences.

108. The Delegation of Spain thanked the Secretariat for carrying out the study on inventive step as well as those delegations that had contributed to the study by giving their inputs. The Delegation further noted that the study was of excellent quality. Noting that the abundant examples provided in the document, the Delegation stated that those examples enabled them to see the slight differences in evaluation of inventive step between countries and regions, particularly with regard to polymorphs. The Delegation believed those differences were not that relevant. The Delegation further stated that the study under discussion was the last in a series of studies elaborated by the Secretariat based on its proposal in documents SCP/24/3 and SCP/19/5. Noting the rich content of the document which was available to all interested in the subject, the Delegation underlined the value of the Committee, i.e., enabling sharing among delegations coming from all corners of the globe, all levels of development in conditions of equality. The Delegation further noted the inclusion of the issue of Markush claims in the study, as a number of Member States had requested. The Delegation continued that inventive step was the patentability requirement that was most difficult to evaluate and that, therefore, a correct understanding of it was key for the correct functioning of the patent system. Therefore, the Delegation wished that the topic be revisited in subsequent sessions of the SCP, for instance in relation to the proposal co-sponsored by the Delegations of France and Spain in document SCP/30/9 and the questions presented by the Delegation of Japan as regards inventive step and AI, if the other Member States of the SCP supported such discussion.

109. The Delegation of Brazil thanked the Secretariat for preparing document SCP/30/4 and delegations for providing information on respective legislation on the subject. The Delegation stated that the document was very useful and informative in providing an overview on the issue of inventive steps in the chemical sector. The Delegation encouraged the Secretariat and other delegations to continue exchanging information on the topic.

110. The Delegation of the Russian Federation thanked the Secretariat for the excellent quality of document SCP/30/4 and the related presentation. As regards the practice of its country on the subject matter, the Delegation stated that due to the amendments introduced to the

examination guidelines of Rospatnet in December 2018, it was no longer possible to obtain protection for features of chemical compounds that did not relate to the content of the composition, such as, for example, features relating to size of pills or physical characteristics of the gel, its viscosity or fluidity. The Delegation explained that such features would not be taken into account in determining novelty and inventive step, because they were considered to be inherent part of the composition. The Delegation further stated that Rospatent continued to work on improving approaches to patenting of dependent substances, taking also into account experiences of foreign countries. The Delegation was of the view that it was necessary to introduce more stringent requirements as regards the assessment of inventive step of such secondary inventions. The Delegation stated that, according to the amendments planned, new forms of well-known chemical compounds, salts or derivatives thereof that would not show new unknown properties in qualitative or quantitate manner would not be considered to be complying with inventive step requirement. In conclusion, the Delegation supported further work on the assessment of inventive step in the chemical sector to be continued within the SCP, including the discussions on the selection inventions and Markush claims.

111. The Representative of the South Centre stated that robust patent examination practices were critical for ensuring that patents were rewarded for genuine inventions rather than mere discoveries. In this regard, the South Centre welcomed a study presented in document SCP/30/4. The Representative noted that the study was particularly important from a public health perspective with regard to the examination of pharmaceutical patents. The Representative continued that, as the European Commission's Pharmaceutical Sector Report of 2009 had noted, strategic or artful patents over already protected inventions had the capacity to extend the breadth and duration of patent protection and delay or block market entry of generic medicines. The Representative stated that the South Centre supported developing countries to establish patent policies, laws, regulations and practices that supported production and procurement of affordable and quality medicines to increase their in-country availability in the public and private sector. Further, the Representative stated that the South Centre provided technical assistance to make public health policies and the IPR regimes mutually supportive. He further stated that, a number of South Centre publications were available on how countries could strengthen pharmaceutical patent examination. The Representative stated that, for example, a recent South Centre policy brief described how the inventive step requirement for pharmaceutical follow-on inventions could be strengthened by applying the "obvious to try" with a reasonable expectation of success test with examples of how that test had been applied to pharmaceutical follow-on inventions by courts in the United Kingdom and the United States of America. The Representative was of the view that a rigorous application of that test provided a useful mechanism to redress strategic patenting.

112. The Representative of MSF thanked the Secretariat for the preparation of a very useful and interesting document. Further, as regards to the Markush claim the Representative stated that from their experiences, such claims could raise a huge amount of uncertainty and face issues with regard to patentability. The Representative suggested that the Secretariat looked further to the examination of different types of Markush claims and how they would potentially create conflict with other patentability criteria, such as sufficiency of disclosure requirement, as well as implications of such claims on the timely entry of generic medicines.
Further, the Representative stated that the United States of America had been struggling to conduct examination of such claims starting from 1920s until recent years, as the expansive use of such claims had caused uncertainties and examination backlogs.

113. The Representative of TWN stated that Article 27 of the TRIPS Agreement read in conjunction with Articles 7 and 8 of the Agreement allowed Members a full freedom in defining the inventive step criterion to ensure only genuine inventions were granted patent protection for 20 years. The Representative continued that, in the pharmaceutical field, there was a serious concern regarding the quality of pharmaceutical patents that were being granted by the patent

offices. The Representative stated that, a 2005 study by the Center for Drug Evaluation and Research had revealed that a number of new chemical entities had fallen in the last 15 years and yet the number of patents that had been granted for changes in chemistry and formulations had been consistently increasing. The Representative continued that, other studies had revealed that patents on alternative molecular forms, formulations, compositions were of lower quality as compared to the primary patent, and that they did not offer any genuine therapeutic innovation, but only presented therapeutic effects similar to those drugs that had already been marketed. The Representative stated that, in Chile, the analysis of primary and secondary patents had found that about 22 percent had been primary patents and 78 percent of the granted patents had been on marginal improvements of existing drugs. In addition, the Representative cited the European Commission's Pharmaceutical Sector Report, which had found that the patent holding companies used numerous strategies including creating the patent thickets around a successful drug to extend its monopoly. In particular, the Representative stated that the Report had found that nearly 40,000 patents had been granted, of which about 87 percent had been on secondary patents, and that the estimated loss had been 3 billion Euros. Turning to document SCP/30/4, the Representative stated that the document did not address the issue of how inventive step could be used as a tool to ensure quality of patents. The Representative further recommended the following approaches with regard to assessment of inventive step. Specifically, the Representative stated that pharmaceutical formulation and composition covering crystalline forms were inherent property of the solid state and that they were not man-made inventions, and therefore would not meet inventive step criterion. The Representative continued that, a combination of known and existing drugs dosage regimes offered no technical advance, and that achieving that was a usual ability of a person knowledgeable in the formulation of pharmaceutical products, hence it was obvious. Further, the Representative stated that tablet capsules, which were different ways of administering the drug to the patient, was very often known to a person skilled in the pharmaceutical field. The Representative continued that, hydrates were well-known in the art to be used for increasing solubility and bioavailability, therefore, they should be considered to be obvious answer, offering no therapeutic effects or technical advance compared to the existing prior art. The Representative also stated that, similarly, new use of existing drug did not involve inventive step as the drug had already been in the public domain. As regards the Markush claims, the Representative stated that they should be disclosed in a way to comply with the requirements of sufficiency of disclosure and to comply with the requirements of inventive step. The Representative concluded by underlining the importance of undertaking a rigorous assessment of inventive step.

Patents and Emerging Technologies

114. The Secretariat introduced document SCP/30/5, entitled "Background Document on Patents and Emerging Technologies".

115. The Delegation of Spain thanked the Secretariat for document SCP/30/5. The Delegation noted that the document provided a valuable introduction to AI and the challenges and issues related to it and patent law. In its view, the document showed that AI technology had already existed for some time but it had become even more important because of the enormous availability of data and the greater computing power which existed nowadays. The Delegation stated that the Spanish Patent and Trademark Office was, like most patent offices, aware of the need to start studying the implications of the more widespread use of AI technology from the point of view of how it functioned and of patent law related issues. It explained that the Spanish Patent and Trademark Office had set up a multidisciplinary group made up of members from both technology and legal fields, which focused, among other topics, on the use of AI in patent searches since there were many companies that were using patent search services based on AI algorithms which helped them to obtain a list of important or relevant documents listed in the order of importance, just by copying and pasting the text of the description and/or the claims in

a box provided for that purpose. The Delegation noted that, although in its experience the results achieved in trials for using AI technology in patent search had not been convincing, it believed that AI would be part of the future patent searching. The Delegation further noted that the multidisciplinary working group set by the Spanish Patent and Trademark Office also focused on the challenges of AI from the point of view of patentability, many of which had been referred to in document SCP/30/5, such as: (i) the patentability of AI algorithms as computer programs, which are protectable in a large number of countries, particularly in Europe based on the "technical solution to the technical problem" formula; (ii) the patentability of inventions generated autonomously by AI that might arise in the near future; (iii) the ownership of such AI generated inventions, the need for the inventor to be a human and the concept of electronic personality and the rights and obligations attached to it; (iv) the prior art connected with AI algorithms and the distinction between the prior art generated by AI and algorithms that generate prior art; (v) the identity of the person skilled in the art who would be considered for determining the patentability of AI related inventions; and (vi) the determination of liability in the event of infringement caused by AI. The Delegation stressed the importance of studying all those issues in depth and continue discussing those topics in detail in subsequent SCP sessions.

116. The Delegation of Canada expressed its view that document SCP/30/5 together with the proposals set forth in document SCP/30/9 should be the foundation of a robust work program on AI and other emerging technologies as they related to patent law. In the Delegation´s opinion, document SCP/30/5 should be regarded as an excellent reference point for several information exchange sessions on the use of AI based tools for patent examination and substance, the assessment of the inventive step and sufficiency of disclosure of inventions using AI or the determination of prior art generated by AI.

117. The Delegation of France expressed its view that it was vital that the patent community looked more carefully at the best way of dealing with the arrival of emerging technologies using AI. The Delegation emphasized that, as it had already been pointed out by the Delegation of Japan, some patent offices had already started to look at how to deal with those new technologies, in particular with issues connected with AI. In the Delegation´s view, it was vital for the Committee to start to look at those issues in order to promote better understanding of AI related issues and patents. The Delegation proposed that such process could be carried out in two steps. First, it noted that AI technology raised essential questions connected to patentability, but it also provided a promising tool for IP offices that might have a positive impact on the internal work of offices, especially in smaller offices with fewer human resources, for instance, by facilitating prior art searches and refining patent classification tools as well as by increasing the quality of the services provided by offices by using chat bots. The Delegation stated that it would be interesting for the subsequent session of the SCP to have a sharing session to hear about different initiatives that had been implemented by different offices in that area and to gain from those experiences of implementing tools that were using AI to facilitate the processing of patent applications. Second, the Delegation proposed that the Secretariat also organize, during the subsequent session of the SCP, a one day information sharing session on issues that were becoming more and more important for both small and large patent offices, such as the patentability of inventions like AI based software, the use of AI to help to create inventions and inventions generated autonomously by AI.

118. The Delegation of Argentina thanked the Secretariat for document SCP/30/5 and expressed its believe that recent technological developments generated great challenges for IP protection systems, and therefore it was important to better understand how those new technologies worked in a broad sense and how to best deal with challenging issues in national patent offices. In the Delegation´s view, the Committee was a suitable forum to discuss patents and new technologies and deal with related issues.

119. The Delegation of Brazil noted that the use of AI for patent examinations had begun to be introduced in various patent offices, including the Brazilian Patent Office, which had begun to insert AI tools and blockchain technologies within its processes in order to improve the automatic search of patent applications. The Delegation stated that the Brazilian Patent Office had also put in place a partnership for the creation of a search tool based on the use of key words and classification of documents with the aim to assist patent examiners and expedite the examination of patent applications. Furthermore, the Brazilian Patent Office had also been developing a neural network-based in-house program to be introduced in the processing of its management system for the pre-classification of patent applications and subsequent distribution of them to the technical divisions.

120. The Delegation of China stated that document SCP/30/5 had provided a good basis for delegations to further their understanding about emerging technologies and patents with the growth of AI and other emerging technologies which bring along challenges and opportunities to the patent system. The Delegation noted that it was necessary to consider the relationship between emerging technologies and patents in two parts: first, by considering how to use those new technologies to improve the work of patent offices in examining patent applications and thus the efficiency and capacity of patent authorities; and second, by considering how the patent system could protect those technologies. The Delegation noted that some countries had already conducted research and accumulated experience in that area and that they supported that subsequent sessions of the SCP include an exchange of information on that subject matter to further understand the different practices in different countries.

121. The Delegation of the Russian Federation thanked the Secretariat for preparing and presenting document SCP/30/5. The Delegation stated that the document raised very important issues about the role of the patent system and how it would operate in relation to emerging technologies. The Delegation considered that it was necessary to look at questions regarding AI technologies such as the determination of the subject of patent protection as well as the issue of patent ownership in the case of inventions created by using AI in order to grant equal protection to inventors by taking into account the technical features and the technical achievements of the invention. Further, the Delegation noted that AI advances had led to an increase in the number of patent applications, blockchain technology had been used in various areas. The Delegation was of the view that in order to have a balanced patent system, it was necessary to look at the issues relating to substantive patent law such as patentability of AI related inventions. It expressed its belief that the work of the Committee could help Member States to gain a better understanding of how the patent system is going to have to develop, as AI and emerging technology develop alongside it. As regards the use of AI to expedite the work of patent offices, the Delegation explained that the Rospatent had been paying particular attention to the inclusion of emerging technologies in its work, for example, by using AI when checking applications for patent protection as well as Patsearch, an algorithm based patent search system. The Delegation noted that the use of AI technology could reduce the difficulties faced by patent office and help to speed up the way in which offices process patent applications. Over the last two years, using an automated search through Russian language documents had allowed the Rospatent to identify approximately 60 percent of documents that could be the basis for the refusal to the grant of patent protection within the first 20 results listed. The Delegation therefore thanked the Delegations of France and Spain for their proposal and proposed that the Committee continue discussions on those issues at subsequent sessions.

122. The Delegation of Singapore thanked the Secretariat for preparing background document SCP/30/5. The Delegation expressed its support to the revised proposal by the Delegations of France and Spain in document SCP/30/9 to exchange information concerning the use of AI as well as the patentability of AI. The Delegation highlighted the importance that AI had been gaining and the increasing demand for AI technologies, as enterprises explored

new ways to deploy AI solutions to transform business and gain a competitive edge. It noted that AI solutions were being commonly applied in a wide range of sectors including manufacturing, logistics and health care. The Delegation was of the opinion that patent offices and policymakers should ensure that patent regimes were ready to meet the ever-changing needs of innovative businesses and individuals. The Delegation then stated that IP Office of Singapore had launched an accelerator initiative called "AI Squared" in April 2019, which accelerated the prosecution of qualifying patent applications from application to grant to as much as six months. Further, with the launch of AI Squared, the IP Office also revised and updated patent information guidelines to provide for clarity on patent eligibility of AI inventions. The Delegation noted that the AI Squared initiative complimented Singapore´s shift towards a digital economy and supported innovative enterprises that were looking to bring AI products faster to the market. The initiative also underscored Singapore's commitment to emerge and protect high value innovations in AI technologies. The Delegation also noted that the IP office had also embarked on initiatives to develop AI driven solutions for patent search and examination. The Delegation expressed it support to the proposal for the Secretariat to organize sharing sessions on the use of AI in patent application examination and issues related to patentability of AI inventions at subsequent SCP sessions.

123. The Delegation of the United Kingdom thanked the Secretariat for providing the background document on emerging technologies. The Delegation expressed its belief that the document provided an excellent overview to assist all delegations in understanding the technological nature of some of those emerging technologies and an essential step before the IP implications could be considered by the Committee. It noted that the document also highlighted a number of challenges and opportunities posed by those technologies in relation to patent law and practice and IP procedures, which would serve as a strong foundation for valuable discussions in the Committee in the future. The Delegation stated that, in general, the UK's IP framework was technology neutral and required relatively few amendments to keep pace with new technologies and that such approach was expected to remain the same, while ensuring that the legislative and policy framework continued to produce a balanced IP system. The Delegation noted that the UKIPO was working on gaining a clear understanding of challenges and to explore the top IP questions around AI such as ownership, incentives, competition, liability, data access and ethics and that the outcome of such work would be used for defining policies dealing with those technologies. It pointed out that, as a major part of those efforts, the UKIPO in partnership with WIPO hosted an international conference entitled "AI Decoding IP" and expressed its gratitude for the active participation, with over 200 stakeholders from the global IP community, and positive feedback. It explained that the conference had explored the commercial, legal, economic and ethical implications of AI as it related to IP setting the stage for an international debate. The Delegation also referred to the UK IPO´s report "Artificial Intelligence - a worldwide overview of AI patents" on the current trends in AI patenting activity worldwide with particular focus on inventions from the UK. It revealed the rapid growth of AI patent applications, and the propensity for UK applicants to seek protection abroad, which reflected the global nature of the sector. Finally, the Delegation expressed its interest in future conversations with WIPO on IP and AI and recognized the importance of the role of patents in incentivizing the growth of AI technologies and of continuing discussions on the topic within the SCP.

124. The Delegation of Japan thanked the Secretariat for its great efforts in preparing document SCP/30/5. It noted that the JPO was continuously working on further improving its Examination Guidelines and Handbooks in the field of emerging technologies. For example, it explained that to help applicants acquire patents in the field of emerging technologies, the JPO had published Internet of Things (IoT) related example cases in 2016, and additional example cases in the field of IoT, AI and 3D printing in 2017. Further, it noted that in 2018 the JPO had revised the section for software-related invention in its Examination Guidelines and Handbooks and more recently, in January 2019, it had added and published 10 examples in Japanese and

English on how JPO's examiners determined the patentability of AI-related inventions. The Delegation also highlighted its contribution during the sharing session of the present Committee by sharing information on case examples of AI-related inventions regarding the examination of the description and inventive step requirements as well as the eligibility for patentability, which could serve as a guide for users to follow when acquiring patent rights. The Delegation was of the view that all those efforts would contribute to appropriately evaluating and protecting inventions related to AI.

125. The Delegation of the United States of America thanked the Secretariat for preparing document SCP/30/5. The Delegation expressed its view that the technologies emerging from AI in the future would have a significant impact on many aspects of the prosecution of patents in IP offices. In its opinion, it seemed clear that IP offices would have to resolve questions such as those relating to the patentability of software-implemented inventions, which would likely be one of the basis for AI development. Further, the Delegation noted that questions were also likely to arise in the meaning of human made inventions and on how to disclose inventions such as those that included deep learning and neural networks, which carried out processes that sometimes were unknown to the human user. The Delegation expressed its interest in that the SCP continue addressing many of the patent related questions brought about by those new technologies and its support to the proposal by the Delegations of France and Spain to hold a sharing session during the subsequent SCP session focusing on tools for enhancing the work of patent examiners in patent offices, followed by another sharing session focusing on patentability and other related questions.

126. The Representative of APAA congratulated the Chair and Vice Chairs on their election and thanked the Secretariat for the preparation of document SCP/30/5. The Representative expressed her support to the revised proposal of document SCP/28/7 by the Delegations of France and Spain in document SCP/30/9. She noted that AI technology was rapidly growing and it had already been utilized in many fields that had an impact on human lives. She referred to the growth of patent data related to AI which had been reported by WIPO, which also had shown that the average annual growth rate for patents in AI was higher than the rate across all areas of technology. The Representative expressed her view that AI related technology would have a significant impact on human lives as well as in the IP area in the near future and noted that the Emerging IP Rights Committee, a Standing Committee within the APAA, had conducted a study on the impact of AI on the creation and ownership of IP. She stated that many members had answered to the questionnaire that ownership should go to the users, AI developers or public domain but not to AI itself. Further, she stated that all responses had noted that there was no easy answer in that emerging area in order to remove uncertainties and that further investigation and discussion on the possible necessity of amendment of the current IP laws were required. She proposed that in subsequent sessions, the SCP hold a sharing session on the situation and experience in handling AI related IP issues including ownership of IP created by AI, patentability as well as utilization of AI for the patent examination in member countries and also discuss the possibility of providing guidance on dealing with the issue.

127. The Delegation of Spain thanked the Delegation of France for the support and collaboration in preparing the proposal in document SCP/30/9. It then highlighted the two main points of the proposal to continue discussions on AI within the SCP. First, the document had proposed that a sharing session take place at the thirty-first session of the Committee for the exchange of information on the use of AI in patent examination, for example in the automatic classification of patent documents, the use of chat bots to assist applicants and patent examiners in their work, by using automatic translation, in searching patent documents by using AI based algorithms, etc. Second, the document had proposed that another sharing session focusing on the patentability of inventions related to AI or involving AI take place a year later at

the thirty-second session of the Committee, which could include the issue of the patentability and ownership of inventions autonomously created by AI. The Delegation stated that given the very specialized nature of those matters, it was of the view that it would be appropriate to have experts who could provide useful information for both small and larger patent offices.

128. The Delegation of the United Kingdom thanked the Delegations of Spain and France for their proposal in document SCP/30/9. It noted that although the proposal was limited to patent issues, WIPO should continue to pursue a joint approach across the different IP Committees on that topic. Regarding the contents of the proposal, the Delegation stated that the proposed sharing session on the use of AI for the search and examination of patent applications was of particular interest to the United Kingdom as it might highlight ways in which AI could be used to increase office efficiency and the quality of the patent grant process. The Delegation expressed its interest in sharing its experience in using AI assisted search in the subsequent session of the Committee and keep contributing meaningfully to future discussions on that topic.

129. The Representative of TWN recognized the role that AI could play in reducing the burden of workload in the patent offices. She expressed her view that developing countries which were poor and did not have the technologies to examine their patent applications should be cautious with AI based technologies and the harmonization of patent laws that may undermine TRIPS flexibilities and result in proliferation of patent monopolies that prevent generic competition.

AGENDA ITEM 7: PATENTS AND HEALTH

130. Discussions were based on documents SCP/16/7 and 7 Corr., SCP/17/11, SCP/24/4, SCP/28/9 Rev. and 10 Rev., and SCP/30/6.

131. The Delegation of Croatia, 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 technologies would not be possible without respecting intellectual property rights where patent protection played a very important role. The Delegation then expressed its belief that patents, as an incentive for research and development, were part of the solution to the problem of availability of future medical products. The Delegation referred to document SCP/30/6 and thanked WIPO for implementing fruitful capacity building and training initiatives, including through the successful technology licensing program and through courses provided jointly by WIPO and Member States. In conclusion, the Delegation looked forward to sharing of experiences by the Secretariat and relevant institutions on capacity building activities relating to negotiating a licensing agreement.

132. The Delegation of Canada, 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. Group B also looked forward to the session for the sharing of experiences by the Secretariat and relevant institutions on capacity building activities related to the negotiating of a licensing agreement. Group B referred to document SCP/30/6 and congratulated WIPO and Member States for the fruitful capacity building and training initiatives, including the successful technology licensing program, and through courses provided jointly by WIPO and Member States. The Delegation took note with interest of the proposal put forward by the Delegations of Argentina, Brazil, Chile and Switzerland, contained in document SCP/28/9 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.

133. The Delegation of Romania, speaking on behalf of the European Union and its Member States, requested the Chair’s permission to pass the floor to the Representative of the European Commission.

134. The Representative of the European Commission thanked the Secretariat for preparing document SCP/30/6, illustrating the experiences of the International Bureau of WIPO on its capacity building activities in the area of negotiations of licensing agreements. The Representative considered training dedicated to licensing of IP to be important for both licensors and licensees. In her view, that could foster the uptake of protected innovations, to the benefit of all. Therefore, the EU encouraged WIPO to continue offering training on licensing negotiations to potential licensors and licensees. The Representative noted that access to safe, effective, qualitative and affordable medicines and vaccines for all remained a major challenge and a key Sustainable Development Goal that should be supported. She further noted that accessibility and affordability of medicines could and should be fostered in many ways, for example through incentives to research and innovation, such as intellectual property rights, which incentivized innovation leading to new and improved treatments, as well as other factors such as the availability of qualified health workers or the adequate financing of the sector. The EU was of the view that a careful balance between incentives to innovation and access to medicines needed to be maintained, including in the discussions within the SCP. With respect to patent rights, the Representative pointed out that a number of exceptions and limitations already eased access to patented inventions in the EU, for example the Bolar exemption and the “Regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems”. The EU and its Member States thanked the Secretariat for organizing a sharing of experiences by the Secretariat and invited relevant institutions on capacity building activities relating to negotiating licensing agreements. For the EU and its Member States, capacity building, increasing transparency and awareness raising were considered to be promising initiatives to the benefit of all, as they could contribute to reduce cost and friction.

135. The Delegation of China thanked all the experts from different institutions who made presentations during the sharing session of experiences on capacity building activities relating to negotiating licensing agreements. The Delegation stressed the importance of protecting innovation on the one hand, and on the other hand, underlined the need for full consideration of public health. Therefore, the Delegation stated that further research 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.

136. The Delegation of Uganda, speaking on behalf of the African Group, stated that the patent system played an important role in promoting creativity and innovation, in particular in the health sector. However, the Delegation noted that despite the development of groundbreaking inventions of new medicines and medical technologies, the world continued to be severely challenged by gaps and the failure of markets to effectively address health care burdens and emerging diseases. The Delegation pointed out that a balanced use of the patent system was essential 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, by which extending exclusive rights over patents would not create an absolute barrier to access to medicines and medical technologies. The Delegation recalled the proposal in document SCP/24/4 and welcomed the progress that had been made in implementing some of the elements in that proposal, including some of the topics that had been used as a basis for sharing experiences on capacity building relating to negotiating licensing agreement, among other things. The Delegation also welcomed the work of the Secretariat in relation to publicly accessible databases on patent information status and data, on medicines and vaccines. Regarding future work, the African Group particularly expressed its interest in that the Secretariat continue examining the challenges faced by Developing Countries and LDCs in incentivizing innovation and health care technologies, where patents had proved to be an insufficient motivator and invited Member States and stakeholders to engage constructively on the proposal for a mutually acceptable and beneficial outcome.

137. The Delegation of Iran (Islamic Republic of) recalled SDG Goal 3 aimed at ensuring the right to access to health as a fundamental and basic human right. The Delegation noted that the SCP was the only international forum where countries could share experiences on the use of health related patent flexibilities, and thus its work in that direction was crucial to promote the very dedicated balance required for the patent system. The Delegation expressed its belief that discussion on patents and health and the future work program on the issue should assist countries to adapt their patent law and make full use of patent flexibilities in accordance with public health needs in compliance with international obligations. The Delegation expressed its support for the SCP to adopt an ambitious work plan in line with the proposal of the African Group in document SCP/24/4.

138. The Delegation of the Dominican Republic acknowledged the importance of the IP system for innovation, but noted that the issue of price rises in certain patented medicines which, in her view, should not be ignored. The Delegation stressed the importance of discussions oriented towards the real cost of innovation, a matter that was actually at the mandate of WIPO but also within the scope of action of other agencies, especially the WHO and the WTO. In her view, the economic arguments towards the need for more funding from governments and the real cost of innovation and benefits obtained by pharmaceutical innovation needed to have a more solid base focused on the study of real facts.

139. The Delegation of Japan shared its view that access to medicines was an important issue. It noted that the issue of access to medicines involved various factors, including other factors than the patent system, such as each country's health-care system, the quality and quantity of medical human resources, local production capacity, access to medical facilities, and distribution channels. The Delegation believed that financial incentives for developing new drugs encouraged more R&D activities and benefited people around the world. Therefore, appropriately protecting IP rights was critical in providing inventors' incentives to develop innovative medicines and devices, which would save millions of lives in the world. Thus, the Delegation was convinced that that issue could be dealt with more effectively by taking a more comprehensive approach towards responding to the various factors, while giving due consideration to the positive effects of the patent system.

Sharing of Experiences on Capacity Building Activities Relating to Negotiating Licensing Agreements

140. Mr. Marc Sedam, Chair-Elect of AUTM made a presentation on AUTM's capacity building activities relating to negotiating licensing agreements. The presentation is available at: https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=440271.

141. Mr. Stefan Kohler, Partner, the Licensing Executives Society International (LESI), made a presentation on its experiences in capacity building activities relating to negotiating licensing agreements. The presentation is available at: https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=440252.

142. Ms. Elizabeth Riter, Director, Brazilian Forum of Innovation and Technology Transfer Managers (FORTECH), Porto Alegre, made a presentation on its experiences in capacity building activities relating to negotiating licensing agreements. The presentation is available at: https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=440253.

143. Mr. Antoine Dintrich, Director General, the European Institute for Enterprise and Intellectual Property (IEEPI), made a presentation on its experiences in capacity building activities relating to negotiating licensing agreements. The presentation is available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_g_sharing_session_on_patents_and_health_ieepi.pdf.

144. The Secretariat made presentations on WIPO Academy's and the Department for Transition and Developed Countries' capacity building activities relating to negotiating licensing agreements. The presentation on WIPO Academy's activities is available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_h_sharing_session_on_patents_and_health_wipo_academy.pdf.

145. The Representative of the WHO made a presentation on WHO's current work to achieve universal health coverage, with particular focus on IP licensing and access to medicines and health technologies. The presentation is available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_i_sharing_session_on_patents_and_health_who.pdf.

146. The Representative of the WTO made a presentation on WTO's capacity building activities relating to the TRIPS Agreements and public health.

147. The Representative of UNCTAD made a presentation on its capacity building activities for technology transfer and R&D collaboration. The presentation is available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_j_sharing_session_on_patents_and_health_unctad.pdf.

148. The Representative of TWN commented on the presentation made by Mr. Sedam and stated that she did not agree with the statement made by him that the compulsory licensing mechanism was not used in the United States of America. The Representative noted that that country was one of the frequent users of compulsory license and that the mechanism was, in particular, used to curb anticompetitive practices by businesses, especially where it involved injunction proceedings. The Representative stated that it would be pleased to share with the Committee those numerous cases involving medical technologies as well as non-medical technologies. The Representative further noted that the compulsory licensing was a very important public policy tool widely used in developing countries as well as in developed countries, and that the use of it was not only limited to the pharmaceutical area.

149. In response to a comment made by the Representative of TWN, Mr. Sedam stated that in his presentation he referred to the use of March-in rights provision provided in Section 203 of 35 U.S.C.

150. The Representative of MSF asked Mr. Sedam whether he could provide more information as regards the experiences of using sample clauses provided in the AUTM's website. Further noting that the classification of countries, i.e., developing country, least-developed country, economically disadvantaged countries etc., did not necessarily represent the disease burden and the health needs of those countries, she asked whether such a classification was, in his view, still valid. Further, she asked Mr. Sedam whether he could share his experiences of how the non-suit clauses found in sample agreements had been used in certain countries to help generating the dissemination of the medical product. She also asked how to make sure that the clauses in the technology transfer agreement generate and support the downstream access, especially affordability and accessibility.

151. In response to the questions posed by the Representative of MSF, Mr. Sedam referred to the AUTM's website which listed nine points to consider in licensing the university technology. As regards to question on classification of countries, Mr. Sedam stated that they were practitioners, and not necessarily the policymakers. Further, Mr. Sedam stated that AUTM's manuals and licensing agreements were merely samples, which were the basis for further negotiation and that AUTM did not take the point that the specific clause in the sample agreement in its entirety must be inserted in every healthcare license by its members. As regards to the last question, Mr. Sedam stated that the technology transfer model in his country worked effectively because the commercialization rates had increased dramatically. He also noted that the revenue from licensing was not a right metric for technology transfer success and that the discussions in that regard had been migrating to utility and actual use of the particular technology versus royalty income.

152. The Representative of KEI stated that a product called enzalutamide (Xtandi), a drug used to treat a prostate cancer, had been developed with grants from the National Institutes of Health and the Department of Defense of the United States of America. The Representative reported that the drug was licensed by UCLA to Astellas and that in the United States of America it cost 130,000 US dollars a year for a cancer patient, and 447 million US dollars to Medicare in 2014.

153. The Representative of TWN requested panelist if they could share details of the licensing agreements terms. Reporting the case of climate friendly technologies, where the licenses contained restrictive clauses, she wished to know to what extent licensing terms actually improved public interests and promoted access to the technology. She also noted that the term "technology transfer" should be understood in a broader sense than the term "technology licensing".

154. Mr. Kohler responded to the Representative of TWN that the scope of licensing contracts was different from one case to another. In general, licensing agreements contained various restrictions, such as territorial restrictions and exclusivities. He further noted that as intellectual property was a property, it was normal that its owner had the right to decide to keep it or to license it to third parties. He stated that in the absence of such right, the technology owner would not disclose technology and, in the end, no technology transfer would have taken place. He further agreed with the Representative of TWN that the licensing the technology was not necessarily meant technology transfer.

155. Ms. Riter agreed with Mr. Kohler's explanation, and added in relation to the notion of the concept of "technology transfer" that, in general, that concept was used in a broad sense. She explained that, for instance, in a case where the university transferred technology through services of collaboration or analysis or when a very specialized equipment was being

transferred to provide specific services for a company, it was not a technology licensing agreement but an agreement of services. Furthermore, Ms. Riter noted that some universities no longer use the term “technology transfer” but the expression “exchange of knowledge” because the relationship between companies and universities was not just an act of transferring, but an act of exchanging the knowledge. She further noted the evolution of different forms of transferring the knowledge generated by the academic institutions to the market.

156. The Delegation of the Dominican Republic asked Mr. Kohler whether he would agree that a licensing contract should not contain restrictive clauses that would go beyond the period of patent protection. She further underlined the importance of the requirement of sufficiency of disclosure for dissemination of invention. Particularly, she stated whether there were any contradiction between that requirement and the fact that a licensing agreement should contain sufficient information to perform the patented technology by the manufacturer.

157. Mr. Kohler responded that while, usually, the term of a patent licensing agreement went together with the term of the patent, in situations where know-how and patents were being licensed it was possible that the term of the license agreement went beyond the term of the patent. However, Mr. Kohler noted that such clauses were not frequently found in pharmaceutical or healthcare licenses. As regards to the second question, Mr. Kohler stated that the basic trade-off for granting the patents was that the invention had to be disclosed in a way that the average expert could reproduce it. Therefore, the granting of the patent implied the technology transfer between the patent owner and the society.

158. Ms. Riter wished to add in relation to the questions posed by the Delegation of the Dominican Republic that, in some developing countries, for example, in Brazil, a lengthy patent granting process was a challenge for concluding the licensing agreements. The solution proposed was to have two sets of conditions in an agreement: first, conditions relating to a situation if a patent was finally delivered and, second, conditions relating to a situation if a patent application was refused. As regards to the second question posed by the Delegation of the Dominican Republic, she stated that in their experience, they try to ensure that the licensing agreement contain clauses which would guarantee the transfer of related know-how through technology assistance from them, the patentee, to the industry licensee in order to guarantee that the content of the patent was applied by the licenses correctly, and that the industry could actually follow the process covered by the patent.

159. The Representative of MSF suggested that the Committee should also discuss the practical examples of how licensing terms had been determined and implications certain terms and clauses. In addition, she suggested that further discussion would be to focus on what kind of government regulation on the licensing practice would be helpful for monitoring how the patent rights had been exercised and to what extent the society had benefited from the licensee agreement, not only in terms of economic growth but, for instance, in health sectors, in number of patients benefiting from those licenses, and affordability of medicines.

Regular Update on Publicly Accessible Databases on Patent Information Status and Data on Medicines and Vaccines

160. The Delegation of India reaffirmed the statement made in the previous session of the SCP session that databases on patent information status and data on medicines, such as MedsPal and Pat-INFORMED were very helpful. The Delegation stated that the patent system should maintain a balance between public health and accessibility of medicines to the public at affordable prices. Further, in its view, Member States also had a responsibility to take necessary efforts so that medicines could be available to public at large. Thus, the Delegation invited Member States to come forward to work towards the access to medicines in developing

countries and LDCs, while continuing their duty to grant patents according to the relevant legal provisions. The Delegation further reiterated its stand on the inclusion of INN in the patent specification, which would facilitate the substantive examination in the grant of quality patents. The Delegation proposed that the INN assigned by the WHO should be included in the patent specification when the applicant was fully aware of said INN, so that the examiner could easily access the details such as the structural formula, molecular formula, therapeutic use and pharmaceutical action of the molecule. 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. Hence, 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. The Delegation further stated that national IP policy of India was focused on enhancing access to healthcare, food security and environmental protection among other sectors of vital social, economic and technological importance, as well as on fulfilling the obligations under the TRIPS Agreement and keeping sufficient safeguard for public health by adopting the TRIPS flexibilities. The Delegation then thanked the Secretariat for the preparation of document SCP/30/6 and welcomed WIPO´s efforts in organizing multiple initiatives towards capacity building and encouraged the continuation of such efforts. In particular, the Delegation proposed that courses targeted at entrepreneurs from the so-called start-ups as well as SMEs, who already had good knowledge of IP, be organized, especially with respect to negotiation of licensing agreements or commercialization aspects. The Delegation noted that the government of India had initiated a vast number of initiatives to promote the start-up community, including fee reduction, expedited examination etc. Moreover, in order to take forward the “National IPR Policy”, the government of India had formed a professional body named “Cell for IPR Promotion and Management (CIPAM)”, which regularly conducted IP awareness workshops and seminars in collaboration with industry organizations, academic institutions and other stakeholder across the country. In addition, the Delegation noted that the national IP training institute “Rajiv Gandhi National Institute of Intellectual Property (RGNIIPM)” located at Nagpur was conducting various IP awareness and training programs round the year and also a WIPO Summer School course in collaboration with WIPO.

161. The Delegation of the Russian Federation noted the importance of having access to information on the status of patents and licenses in the health sector in order to properly organize a government procurement and to take decisions about what would be needed to produce medicines and vaccines and what could be purchased. The Delegation stated that the Rospatent had taken an initiative to set up a register of the details of patents granted on medicines as well as to consider possible infringements of those patents and the possible arrival of generic medicines on the market. The Delegation believed that that initiative would be helpful to rightholders and patent applicants in providing the appropriate documentation to the patent office as well as governments and other interested parties. The Delegation expressed its support to the proposal made by the Delegation of India and to continue further research on the issue as part of the Committee’s future work.

162. The Delegation of Switzerland thanked the Secretariat for the excellent work in the preparation of the session including the sharing session on capacity building, related negotiating licensing agreements as well as all documents produced. In its opinion, the documents provided a valuable source of information on most important topics in the patent field such as inventive step or the emerging technologies. The Delegation aligned itself to the statement made by the Delegation of Canada on behalf of Group B in the area of patents and health. The Delegation supported a work program based on the proposal of Argentina, Brazil, Chile and Switzerland in document SCP/28/10 Rev. regarding a regular update on publicly accessible databases on patent status information. The Delegation noted that transparency on the patent status of medicines and vaccines was a long-standing demand of stakeholders and that access

to easily accessible and understandable patent status information was crucial for legally sound decisions, such as the procurement of health technologies or the freedom to operate. It further noted that such need for transparency on the patent status had again been expressed during the World Health Assembly. As the IP specialized UN body, the Delegation believed that WIPO was the competent authority to address that issue. In its opinion, there were major challenges in creating transparency on patent status information. Further to the Delegation´s interest in the progress of the MedsPal and Pat-INFORMED and first experiences with the use of such platforms, the Delegation stated its interest in learning more about the US Orange Book, focusing on its part as a source of information on the patent statutes of medicines, during the next session of the SCP.

163. The Delegation of Brazil thanked the Secretariat for preparing document SCP/30/6, which encouraged it to continue the work in that area. The Delegation stated that Brazil was fully committed to initiatives that facilitated access to medicines. In its view, transparency of information was crucial, as discussions in WHO Assembly had shown. Therefore, Brazil together with Argentina, Chile and Switzerland had put forward the proposal contained in document SCP/28/10 Rev., which aimed to ensure access to relevant and comprehensive patent information. The Delegation noted that having publicly accessible databases of patent information status contributed to a better alignment between IP, trade and health. That promoted the public disclosure of innovation and encouraged the dissemination of technical knowledge and was also widely used in government procurement procedures. The Delegation stated that it would be useful to continue discussions on the topic through further information exchange sessions, as the review of existing research on patents and access to medical procedures would be presented at the subsequent SCP session. The Delegation stressed its strong commitment to the improvement of public health and access to medicines. It recalled that Brazil took part in the negotiation that resulted in the Doha Declaration on TRIPS and Public Health, a major contribution to the international community to the topic. It noted that Brazil was of the belief that respect for IP and efforts to ensure access to quality medicines went hand in hand. In conclusion, the Delegation stated that although significant gaps persisted in access to healthcare around the world, access to medicines was a multi-faceted issue that required constant work. Thus, it was the responsibility of Member States to continue working together to develop a balanced and effective international patent system that encouraged and rewarded innovation and which was supportive of public policy objectives.

164. The Delegation of France expressed its support to the statements made by Group B and the EU. In order to continue improving access to information relating to patents on medicines, the Delegation expressed its hope that the Secretariat continue to increase its cooperation with the WHO and encourage the IFPMA and private partners to continue working on the Pat-INFORMED initiative by also expanding the coverage of the database to other areas of medical care and improving the number and quality of data provided to the system.

165. The Representative of the WHO informed the Committee that, during the seventy-second World Health Assembly held in May 2019, WHO Member States adopted a resolution on “Improving the transparency of markets for medicines, vaccines, and other health products,” contained in document WHA72.8. She stated that the specific recommendations to Member States and the WHO Director-General that aimed to improve pricing transparency, also included a request to the WHO to continue supporting the existing efforts for determining patent status of health products and promoting publicly available user-friendly patent status information databases for public health actors. In doing so, the WHO Secretariat was requested to work with other relevant international organizations like WIPO and stakeholders to improve international cooperation, avoid duplication of work, and promote relevant initiatives. The WHO welcomed the WIPO-hosted initiative Pat-INFORMED, a collaborative initiative between WIPO, IFPMA and 20 research-based biopharmaceutical companies. She noted that, however, because the database was aimed at helping governments make more well-informed decisions

about procurement options, the WHO would like to support and engage in further discussions about how such important initiative could be further developed for use by public health actors, such as national procurement agencies. As stated during the launch of Pat-INFORMED, the WHO had some recommendations for improvement, such as the inclusion of publicly accessible information on patent applications which was relevant for procurement decisions. Furthermore, she noted that the resolution urged Member States, in accordance with their national and regional legal frameworks, to facilitate improved public reporting of patent status information and marketing approval status of health products. The WHO welcomed the collaboration agreements that some national or regional patent offices had already signed with the MPP to update their patents and licenses database, MedsPaL, and encouraged other Member States to support that important initiative. She finally expressed the WHO´s interest in continued development and improvements of MedsPaL.

166. The Representative of OAPI expressed his view that LDCs were having serious difficulties in accessing some types of medical treatments. He expressed OAPI´s support to the proposal made by the Delegation of India which, in his view, would expand databases and make it possible for those who were in a position to request licenses to do so, but it would also help some of the Member States of OAPI to actually use the TRIPS flexibilities that were available to them.

167. The Representative of TWN reiterated that the involvement of IFPMA in the Pat-INFORMED initiative raised serious concerns about conflict of interest, as the database might be designed to further the commercial interest of the originator companies that held the patents rather than to advance public health. She noted that the International Generic and Biosimilar Medicines Association (IGBA) had also raised that issue in a letter to the Director General of WIPO, dated 6 February 2019. She stated that the information provided in the databases was not verified and complete since, for example, information about rejected and withdrawn patent applications, pre- and post-grant oppositions, voluntary or non-voluntary licenses was not provided. In her view, the databases had targeted procurement agencies but with incomplete and compromised information. She also raised concerns that Pat-INFORMED could unnecessarily delay patient access to more affordable medicines and lead to patent linkage. Therefore, TWN considered essential that Member States and WIPO contribute to maintain a database with full, complete and verified information on patents, including information about patent applications filed, rejected, withdrawn, patents granted and any pre- and post-grant oppositions pending and infringement suits as well as licenses issued. She continued by stating that national and regional patent laws and practice should ensure an optimal implementation and use of the TRIPS flexibilities, by ensuring broad exceptions and limitations and implementing the LDC pharmaceutical exemptions and avoiding the TRIPS-plus provisions and practices. In her opinion, the TRIPS-plus provisions, which in some countries had caused an increase in the prices of medicines by more than 800 percent, threatened the financial sustainability of government public health programs. Finally, the Representative urged patent offices to bear in mind that decisions they made had a direct impact on whether or not people in their countries had access to medicines, since as the US Federal Trade Commission had stated, the patent office should function as a steward of public interest and not as a servant of patent applicants.

168. The Representative of KEI noted that there was a renewed interest in relation to compulsory licensing and public non-commercial use, even by high-income countries. He particularly mentioned two examples that had taken place in the UK and the Netherlands where the concept of compulsory license had been explored. He reported that in order to improve access to cystic fibrosis treatment in the UK, which according to The Economist, cost 104,000 British pounds per year, the option to request a compulsory license had been considered by the Members of the Parliament. In the Netherlands, a Committee had been assigned to explore the granting of compulsory licenses. With regard to possible future work,

the Representative proposed that the 2014 WIPO study on “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” contained in document CDIP/14/INF/12 be presented at thirty-first session of the SCP under the agenda item patents and health. In relation to the Secretariat’s review of the existing research, the Representative proposed that the International Bureau include in its review a 2005 WHO-UNDP publication entitled “Remuneration guidelines for non-voluntary use of a patent on medical technologies”. In conclusion, the Representative noted that the 2019 World Health Assembly had passed Resolution WHA 72.8 for improving the transparency of markets and vaccines and other health products and reiterated KEI´s interest in WIPO’s trilateral cooperation to focus on supporting the implementation of such Resolution by addressing questions like how to address the lack of transparency for patent landscapes and new cell and gene therapies and also what should be done to have better information sharing over the litigation over patent validity and scope.

169. The Representative of MSF expressed her support to the continuation of the discussion on patents and health at the Committee as well as discussions on transparency and other initiatives for the use of TRIPS flexibility. She noted that transparency of patent status had been further re-enforced by the WHO Resolution passed by the World Health Assembly to continue supporting the existing efforts for determining patent status of health products and promoting publicly available and user-friendly databases on patent status. However, she also noted that there were limitations on some of the voluntary mechanisms for publishing patent status such as Pat-INFORMED, as it was based on the collaboration between WIPO and IFPMA. In her view, Pat-INFORMED should be designed in a way that it would avoid conflict of interest, give access not only to procurement agencies but also to other stakeholders and contain key information on patents. In her opinion, it should be clarified how such initiative and the collaboration between WIPO and patent offices fit within WIPO´s mandate of promoting transparency on patent status such as through its own database of PATENTSCOPE. In her view, initiatives to improve transparency of patent status of health products needed to adopt a holistic approach taking into account a number of factors that could have impact on the legal status of patents, such as the stringent application of the patentability criteria in the examination procedure, opposition and invalidation processes at the national level, which were critical to stop the ever greening strategy of obtaining multiple patents on a given health product, the existence of licenses, etc. She noted that including that information in the databases would facilitate the entrance of generic medicines in the market. In relation to the future work of the Committee, the Representative proposed that a further analysis on the concrete examples and illustration of the possible impact of the interpretation of the requirement of inventive step on generic competition and drug prices be considered, as it would enhance the mainstreaming of the health perspective in the patent law administrative practices. In addition, she proposed that a further discussion on the intersections between the voluntary licensing practices and the government led initiative of using compulsory licenses would be helpful. In particular, she stated that it would be helpful to discuss some of the concrete types of voluntary license terms that could potentially restrict competition and restrict the use of flexibilities by government as well as the concrete mechanisms that the government could adopt to prevent those abusive licensing practices from happening. Finally, she also proposed that a possible update of the WIPO website on opposition and administrative revocation mechanism be carried out.

170. The Representative of MPP stated that MPP was continuously improving the MedsPaL database by adding new features and new products that she would be interested in sharing in the subsequent sessions of the SCP. She noted that the MPP had already thirteen collaboration agreements around MedsPaL in place with regional and national patent offices. In particular, she noted that collaboration agreements had been recently signed with Peru’s INDECOPI and with the Eurasian Patent Office (EAPO). She noted that through those collaboration agreements, the patent offices agreed to work with the MPP and provide legal

patent status data for a selected number of essential medicines in order to facilitate access to that information. She then stated the MPP´s interest in exploring collaborations with more offices and invited interested parties to approach her during the session.

171. The Delegation of the United States of America expressed its support to the statement made by Group B. It recalled that the Committee had agreed that the next session of the SCP would feature a sharing session from representatives of various initiatives providing publicly accessible databases on patent status information concerning medicines and vaccines. It stated that two initiatives that might be included in such endeavor were MedsPaL and Pat-INFORMED. The Delegation also submitted, for consideration by Member States, having a speaker to discuss two US-based databases: (i) the Orange Book, which included data on approved drug products with therapeutic equivalent evaluations; and (ii) the List of Off-Patent, Off-Exclusivity Drugs without Approved Generics. It noted that the Orange Book identified drug products approved on the basis of safety and effectiveness by the United States Food & Drug Administration, or FDA, and also listed patents that were associated with approved drug products. Further, to facilitate Orange Book accessibility, the FDA had created the Electronic Orange Book or EOB, an online version of the Orange Book. It explained that the EOB served as a valuable online resource for health care professionals and allowed interested parties to search for generic equivalents of approved drug products and patents associated with drug products and any pertinent products. In addition, the Delegation noted that the FDA also maintained a separate list of approved products that were no longer protected by patents or exclusivities and for which the FDA had not been able to approve a generic version through the abbreviated approval process. It continued that such list was published by the FDA in 2018 with the aim of improving transparency and encourage submission of generic applications. The Delegation expressed its hope that an insight from the FDA Orange Book and the FDA's List of Off-Patent, Off-Exclusivity Drugs without Approved Generics would contribute to the objectives of the proposal outlined in document SCP/28/10 Rev.

AGENDA ITEM 9: CONFIDENTIALITY OF COMMUNICATION BETWEEN CLIENTS AND THEIR PATENT ADVISORS

172. Discussions were based on document SCP/30/7.

173. The Delegation of Canada, 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/30/7 and those Member States that submitted replies to the questionnaire. The Delegation stated that patents were increasingly filed and granted in various jurisdictions, and noted that the issues surrounding the protection of the communication between patent advisors and their clients were 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-border 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 further stated 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. 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.

174. The Delegation of Croatia, 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/30/7 on confidentiality between clients and their patent advisors. 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, which would aim at providing the same protection to communications with foreign patent advisors and those with national patent advisors under the international law. 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. Such confidentiality did not, in the view of the CEBS Group, impede the implementation of the requirement of sufficiency of disclosure. The Delegation expressed its opinion that the Committee should continue working on providing a further understanding of the difference systems in the field of confidentiality of communications between client and patent attorneys, among all WIPO Member States for the benefit of the clients. 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.

175. The Delegation of Romania, speaking on behalf of the European Union and its Member States, thanked the Secretariat for preparing document SCP/30/7 and the Member States that had provided updated information. The Delegation stated that a non-legally binding instrument to allow cross-border confidentiality would be beneficial to all WIPO Member States. The Delegation noted that such potential soft law instrument should aim at providing the same protection to communications between a client and its foreign patent adviser as that awarded to the communications between the client and its national patent adviser. Further, such instrument should be without prejudice to existing national legislation and should ensure optimal flexibility. The Delegation hoped that the discussions in the SCP on the topic would lead to a better understanding of the different systems in the field of confidentiality of communications between clients and patent attorneys among WIPO Member States for the benefit of all clients.

176. The Delegation of China thanked the Secretariat for the document prepared on the topic of confidentiality of communications between clients and their patent advisors, which allowed Member States to have a better understanding of the topic. The Delegation reiterated that the 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.

177. The Delegation of Iran (Islamic Republic of) expressed its appreciation to the Secretariat for preparing document SCP/30/7 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 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.

178. 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 in order to have an invention to be protected in the global market, a confidentiality-based communication between the patent advisor and the client was most important. 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 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.

179. The Delegation of India reaffirmed its views expressed in previous 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-patent 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 patent attorney could be protected through a non-disclosure agreement.

180. 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/30/7). The Delegation noted the difficulties that patent advisors and clients could face in cross-border 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 lack of confidentiality could however affect the quality of legal advice and, in consequence, also have an impact on the patent prosecution and the quality of the patent as well as in the outcome of litigation. The Delegation expressed its support to continuing an exchange on practices on the topic for a better mutual understanding and clarification of misunderstandings. It then highlighted that the Committee had established a range of valuable documents in relation to the client-attorney privilege issue that served as an important source of information and data for governments, stakeholders and other interested parties. The Delegation recalled that since the twenty-first session of the Committee, where invited speakers had shared their experiences on the confidentiality issues, there had been changes of law in several jurisdictions with respect to the protection of professional secrecy. Therefore, the Delegation proposed that as a follow up, a sharing session of Member States and practitioners, including patent attorneys and in-house counsel, be organized with respect to their experiences and the recent developments in policy and practice, including the code of conduct of patent attorneys and related regulatory rules, or the distinction between the privilege and confidentiality as well as court cases. The Delegation also 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-border 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 and it would also 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.

181. The Delegation of Canada aligned itself with the statements made by the Delegation of Switzerland and by its Delegation on behalf of Group B on the agenda item. The Delegation supported the continuation of work on the topic of confidentiality of communications between clients and their patent advisors, particularly in the context of cross-border issues. The Delegation was of the view that a study by the Secretariat on possible non-binding approaches to cross-border privilege issues or a sharing session by Member States and practitioners on their experiences and recent developments regarding the relevant policy and practice, such as recent legislative developments and court cases, codes of conduct for patent agents, establishment of regulatory bodies, the nature of and benefits of a client privilege, etc., could help provide important context on the issue for the Committee and Member States. The Delegation also noted that Canada had made legislative changes to introduce a communications privilege for the clients of patent agents and was currently in the process of establishing a code of conduct to regulate the patent agents and to ensure that the privilege was protected. The Delegation expressed its interest to present such developments in a future sharing session of the Committee.

182. The Delegation of Japan noted 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. Further, it noted that when creating an improved system that better protected confidentiality, it was quite helpful for all Member States to understand and learn about the laws, regulations, court cases, and experiences of other Member States. Therefore, the Delegation expressed its appreciation to the Secretariat for preparing the useful working documents SCP/29/5 and SCP/30/7. In the Delegation´s view, the SCP was a suitable and important forum to understand the current situation in each Member State and a place to learn from each other. Furthermore, the Delegation noted that the attorney-client privilege issue also needed to be addressed from a cross-border perspective. To that end, the Delegation believed that the Committee should continue discussions to explore the possibility of creating an international framework in the future, which could be accepted by a large number of countries.

183. The Delegation of Australia aligned itself with the statement made by the Delegation of Canada on behalf of Group B. The Delegation noted that in Australia the majority of patent applications came from applicants located outside of Australia and that many foreign applicants used the services of a patent attorney in their own country. It stated that excluding communication with a foreign patent attorney was a significant issue as it was not always desirable or practical for applicants to limit their request for advice to Australian patent attorneys. It noted that in 2013, the IP Laws Amendment (Raising the Bar) Act 2012 that extended privilege to overseas attorneys who were authorized to provide IP advice, had entered into force. The Delegation expressed its support to continued work on cross-border issues related to client-attorney privilege and welcomed the suggestion made by the Delegation of Switzerland.

184. The Delegation of Ireland thanked the Secretariat for preparing document SCP/30/7. The Delegation aligned itself with the statements made by the Delegation of Romania on behalf of the European Union and its Member States and the Delegation of Canada on behalf of Group B. It noted that in Ireland, there was a provision for patent advisers' privilege with cross-border application. It continued that in Ireland, there was a growing number of small companies and university start-up companies with very valuable IP rights that were increasingly trading at a global level. Further, it stated that the Irish Patent Office was responsible for the regulation and registration of patent advisors in Ireland, and also had the power to dismiss someone from the register for any form of malpractice so that the profession itself remained strictly controlled. In conclusion, the Delegation echoed the statements made by the Delegations of Switzerland and Canada regarding future work on cross border aspects.

185. The Delegation of the United Kingdom aligned itself with the statements made by the Delegation of Canada on behalf of Group B and by the Delegation of Romania on behalf of the EU and its Member States. In particular, the Delegation highlighted the close relationship that existed between the topic and prosecution and litigation procedures as well as its importance to the patent attorney profession and their clients. The Delegation expressed its enthusiasm to continue the conversations under the agenda item in subsequent sessions of the Committee, for example, as proposed by the Delegations of Switzerland and Canada.

186. The Delegation of Brazil thanked the Secretariat for preparing Document SCP/30/7, which, in its view, showed that there was a great variety of rules and obligations in each Member State. It noted that, whereas in some Member States specific procedures on confidentiality and IPRs applied, in others, the laws on the topic were of a general nature, and in some other Member States, different laws applied at the level of State jurisdiction. Due to such variety of approaches, the Delegation expressed its belief that Member States would profit from continuing sharing of experiences in the SCP in order to increase predictability in the area. Thus, the Delegation was of the opinion that the update of the dedicated website "Confidentiality of Communications between Clients and Their Patent Advisors" was the next right step that should be taken by the Committee. It noted that, after that, the SCP could then analyze if a soft-law approach was desirable in such delicate subject.

187. The Representative of JPAA congratulated the Chair on her election. The Representative noted that, for the JPAA, the so-called called attorney-client privilege was a very important legal concept. In his view, the Committee should continue the discussion on that matter with the participation of all Member States. He stated that the attorney-client privilege was not a tool to conceal important prior art from the patent office, but it served to protect important trade secrets of client entities from forced disclosure to third parties so that the clients felt reassured and was able to disclose their trade secrets to their patent advisors in order to receive proper advice. The Representative continued by stating that in Japan, professional representatives 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 further stated

that once information was made publicly available in one country, it was impossible to restore the information as secret in other countries, especially taking into account the strength of international communication networks. Therefore, JPAA was of the view that there was a substantial risk when conducting business in a country where confidentiality was not appropriately protected, and that that could be a major factor to constrain the economic activities of such a country, and as a consequence, put such countries in a disadvantaged position compared to others where confidentiality was protected. 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. In conclusion, the Representative stated that a soft law approach was the best way of advancing the discussions on the issue.

188. The Representative of AIPPI thanked the Secretariat for the work that it had carried out on the important issue being discussed. The Representative stressed that granting confidentiality to communications between clients and their patent advisors was an important issue that affected the daily interactions between patent advisors and innovators all over the globe. He noted that different systems and laws at the national level had led to a lack of clarity as to if and when cross-border communications between a patent advisor and their client were privileged. He further noted that such lack of clarity was exacerbated, as businesses became increasingly international and international patent filings continued to rise. In his view, the differences between the concept of confidentiality (privilege) between clients and their attorneys and the general concept of confidentiality also led to potential confusion and lack of clarity. The Representative continued that innovators of all types and, particularly, individual inventors and SMEs without significant IP experience, as well as innovators in jurisdictions without local access to international IP expertise, required access to professional advice to ensure that they received the protection to which they were entitled under the law. He further noted that the unique nature of international patent filings, and the lack of a reliable privilege in the international context, made the necessary full and frank communications difficult or impossible. Thus, the confidentiality privilege directly implicated numerous issues, including both patent quality and equal access to the international patent system. In consequence, he noted that AIPPI fully supported the proposed continued work on the topic, including specifically the proposal made by the Delegation of Switzerland to hold a sharing session that would provide concrete examples of the various issues raised by confidentiality (privilege) between clients and their attorneys in the cross-border context. He stated that AIPPI was ready to support such undertaking from the practitioner and right-holder perspectives and believed that a sharing session would provide an excellent basis for greater understanding and further discussion on the topic.

189. 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-border issue in the field of patents. Therefore, the Representative supported further work at the Committee on the topic.

190. The Representative of TWN stated that the right to confidentiality or privilege to patent attorneys was not provided by the Paris Convention or the TRIPs Agreement, but it was governed in each country by the applicable national laws or, in common law countries, through court precedence. Further, the Representative noted that even under such laws, there were exceptions to the protection of confidentiality, for example, in cases where disclosure was required by a court of law, when disclosure was necessary by reason of applicable legal accounting or regulatory requirements, when it was required by an regulatory authority having jurisdiction over the receiving party, when the information had to be disclosed for customers or for the purpose of sub-licensing, etc. The Representative then noted that it would not be feasible to come to a conclusion of creating a legal instrument at the international Level in

relation to cross-border aspects of confidentiality of information between clients and patent advisors. She then stated that the disclosure requirement was one of the fundamental requirements in patent law and therefore patent offices should make sure that the application met such 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. In conclusion, the Representative emphasized that the issue of confidentiality did not fall within substantive patent law.

191. The Representative of FICPI recognized the importance of the protection of IP advice to allow a client to have frank, full, honest and uninhibited communications with their IP advisors in order to be able to obtain comprehensive advice in confidence on their requisition and enforcement of IPRs from IP advisors nationally and transnationally. The Representative then noted that economy was increasingly globalized and thus providing cross-border recognition of privileged advice was crucial. In the view of FICPI, that would also improve the equality of access to IP systems and advice on the international level, which was particularly important for SMEs that might not have an in deep understanding of the IP system. Furthermore, they might be dependent on a very limited number of IPRs in their business which was often conducted on an international level. The Representative noted that FICPI would certainly be pleased to provide expertise and to share practices and examples for any sharing sessions in order to clarify the context and the importance of the confidentiality (privilege). Therefore, the Representative supported the proposals presented particularly by the Delegations of Canada and Switzerland as well as by Group B and the EU and its Member States.

192. The Representative of epi thanked the Secretariat for preparing document SCP/30/7 and all the Member States that provided updated information. The Representative deemed client-attorney privilege as a necessity to counterbalance the discovery in litigation in common law jurisdiction. He noted that the public policy reason why such privilege for communication between clients and legal advisors existed was that the privilege was in the interest of justice, because a client should be able to discuss his matter openly and freely without worrying that what was discussed with the adviser or the adviser's response might at a later stage be used against her/him. The Representative stated that if the client and legal advisor feared that such communication might later be exposed in court, then information would be hidden to advisors. He continued that the European Patent Convention (EPC) in Article 134a and related rules, provided European patent attorneys with attorney-client privilege in proceedings before the EPO in respect to communication between professional representative and the client. In conclusion, the Representative expressed epi´s opinion that it would be beneficial if the law related to the client-attorney privilege was harmonized at an international level. Therefore, epi supported the continuation of the discussion of the topic within the SCP.

193. The Representative of OAPI noted that around 90 percent of patent applications it received came from abroad and when the applicant was not from a Member State of OAPI, it was necessary to recur to an IP adviser or other person approved by OAPI. The Representative stated that patent advisers or attorneys acting before OAPI were obliged to respect internal rules of procedures adopted by the Council of OAPI that regulated the profession within the Member States with regard to the relationship between the client and the patent adviser. He continued that if attorneys/advisers did not respect the obligation to confidentiality of communications, they would be penalized and even excluded from the profession in certain cases. In OAPI´s view, ensuring confidentiality in exchanges between the clients and their patent adviser or attorney was extremely important because it could highly affect the IP rights of the client.

AGENDA ITEM 10: TRANSFER OF TECHNOLOGY

194. Discussions were based on document SCP/30/8.

195. 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/30/8). The Delegation also thanked 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 further stated 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 750 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 that, in addition, the CDIP had been considering technology transfer, including three proposals by Member States and/or projects 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.

196. The Delegation of Croatia, speaking on behalf of the CEBS Group, thanked the Secretariat for the preparation of document SCP/30/8. The Delegation also thanked 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 practices in patent law provisions that contributed to effective transfer of technology and looked forward to having interesting discussions. Further, the Delegation acknowledged the 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 utilization of technological solutions would be able to boost development. The Delegation then 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 supported those countries that call for avoiding any duplication of work, bearing in mind coverage of the technology transfer in the CDIP.

197. The Delegation of Romania, speaking on behalf of the European Union and its Member States, thanked the Secretariat for the preparation of the excellent document SCP/30/8 and the Member States that provided updated information. The Delegation noted that technology transfer had the potential to create win-win situations in international economic relations and therefore it was an issue of great importance for the EU. The Delegation pointed out that as shown in document SCP/20/10 two out of five listed regional platforms for technology exchange were situated in the EU and hosted by the European Commission servicing all Member States and stakeholders. However, the Delegation stated that, considering that the CDIP produced an excellent overview of the work that WIPO was performing in this area, the EU was of the view that the SCP avoids duplicating the efforts of the CDIP. The Delegation nonetheless reiterated

its support to continue updating the WIPO webpage on technology transfer regarding information on national, regional, international technology exchanged and technology licensing platforms.

198. The Delegation of China thanked the Secretariat for the preparation of document SCP/30/8. 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 further stated that China had taken a number of measures in promoting fair technology transfer, such as establishing operational platforms and introducing open licenses in the amendment of 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 would seek solutions. The Delegation proposed that the Secretariat 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.

199. The Delegation of Brazil thanked the Secretariat for preparing document SCP/30/8 on effective transfer of technology, including sufficiency of disclosure. The Delegation stressed that the SCP was the right forum for Member States to have conversations on that topic, especially with regard to the aspect of sufficiency of disclosure and its considerable impact on transfer of technology. The Delegation expressed its belief that sufficient disclosure in the patent registration stage was fundamental for the quality of patents. It noted that a patent request should be transparent enough to enable the reproduction by a person skilled in the art without further need of consultations with the patent previous owner, after the protection for a patent expires. In the Delegation´s opinion, a balanced system driving knowledge and technology transfer that led to innovation was based on the relation between technological innovation and its disclosure to the public, since without sufficient disclosure on patent applications, such cycle would be impaired. In that sense, while document SCP/30/8 provided useful information on national legislations, Brazil believed that a further step was required. The Delegation noted that a higher standard for the quality of patents demanded not only the knowledge on different patent laws, but also analytical awareness of actual patent requests. Finally, the Delegation stated that the depth achieved in the study done by the Secretariat on inventive step could be used as a reference on the issue of sufficiency of disclosure.

200. The Delegation of the Dominican Republic thanked the efforts of WIPO and the Korean Funds-in-Trust of WIPO for its invaluable support to technology transfer in the Dominican Republic through their Applied Technology Competition Projects which posed challenges to the community to find solutions in the public domain through the use of patent databases. The Delegation expressed its view that such projects promoted the use of the patent system as a tool for the technology transfer as well as incremental innovation.

201. The Delegation of South Africa thanked the Secretariat for preparing documents SCP/29/6 and SCP/30/8. The Delegation noted that the South African technology transfer legislation, the Intellectual Property Rights from Publicly Financed Research and Development Act, as implemented by the national IP management office, had undergone Ministerial review to amend the legislation. The Delegation stated that the legislation essentially ensured that IP emanating from publicly financed research and development was identified, protected where appropriate, utilized and commercialized for the benefit of the people of South Africa. It continued that the legislation mandated that all 37 publicly funded institutions within South Africa should have a Technology Transfer Office (TTO), which should develop and implement policies for disclosure, commercialization and benefit sharing arrangements, attend to all aspects of statutory protection of IP, and attend to all aspects of IP transactions and the commercialization of the IP.

The Delegation also noted that the legislation further provided for finding mechanisms in the form of TTO support to fund human capacity and training as well as an IP fund where institutions were entitled to up to fifty percent rebate for the cost incurred for the statute of protection and maintenance of IPRs. It further stated that, similar to Australia, South Africa also provided for an R&D tax incentive program to encourage investment in research and development. Finally, the Delegation noted that the information contained in documents SCP/29/6 and SCP/30/8 provided a rich source of information from which the Delegation would draw when amending the legislation. In conclusion, the Delegation agreed with statements made by the Delegations of China and Brazil, and supported the continuation of discussions on the agenda item in the SCP.

202. The Delegation of Iran (Islamic Republic of) stated that transfer of technology was a significant subject in the agenda of the SCP as the Committee could play an important role in understanding and addressing opportunities and challenges for enhancing free and efficient flow of technologies and promoting science by holding discussion and sharing information. The Delegation thanked the Secretariat for preparing document SCP/30/8 on the patent law provision that contributed to effective transfer of technology, including efficiency of disclosure, and noted that the document contained invaluable information on legal provision and practical aspect of the topic from different national legislation. With regard to sufficiency of disclosure, the Delegation noted that such requirement could potentially play a basic role in national innovation systems, as it was a crucial component of transfer of technology and of the proper functioning of the Patent System. The Delegation reiterated its view that the SCP was the relevant forum to discuss and share views on the role of patent systems on technology transfer and dissemination of knowledge. Therefore, bearing in mind the differences between the subject of transfer of technology in the CDIP and SCP, the Delegation supported that the work on transfer of technology be maintained in the agenda of the SCP.

203. The Delegation of Japan expressed its appreciation to the Secretariat for its great efforts in preparing documents SCP/29/6 and SCP/30/8. The Delegation expressed its belief that the documents were very informative and useful in understanding the patent law provisions that contributed to effective transfer of technology. The Delegation was convinced that developing a landscape in which IP rights could be appropriately protected was vital for promoting technology transfer. In its view, such a landscape would encourage motivation for eliminating the barriers to transferring and disseminating technology. It noted that if IP rights were not properly protected, private companies that might developed a new technology could be discouraged from transferring them, and therefore that might hinder technology transfer to developing countries. In addition, the Delegation stated that other means such as providing financial support and developing the positive business landscape would also contribute to such end.

204. The Delegation of the United Kingdom aligned itself with the statements made by the Delegation of Canada on behalf of Group B and by the Delegation of Romania on behalf of the EU and its Member States. The Delegation stated that an effective IP system was essential to knowledge exchange between businesses and universities. It noted that patents helped universities to secure business partners and funding but they were also vital for commercialising ideas. The Delegation continued that the UKIPO provided a whole suite of tools for universities and business wanting to make the most of their IP. The Delegation recalled that the Lambert Toolkit was created in 2005 to support university-business research collaboration by providing a set of model agreements; and that the IPO commissioned a report in 2013 to review the impact of the Toolkit and identify any useful additions, which resulted in an update to the ToolKit in 2016 to include new model agreements covering the “split IP clause” and knowledge transfer partnerships, and to amend the Toolkit to reflect changes in legal practices such as on bribery and corruption, data protection and state aid. Further, the Delegation noted that the Toolkit was also updated in line with the EU General Data Protection Regulations (GDPR) in 2018. It then noted that, following those updates, the IPO had recently carried out a small-scale survey to

gain insights into awareness, usage and impact of the Toolkit. In that regard, the Delegation stated that initial findings demonstrated that there was a high degree of awareness of the Toolkit amongst research organisations and that it was used for a variety of purposes, from being adapted on a case-by-case basis, to its use as a training tool. In conclusion, the Delegation stated that the IPO would continue to evaluate usage of the Lambert Toolkit and to move education resources onto a new internet platform to enable the IPO to improve data collection in order to perform more targeted impact monitoring.

205. The Delegation of France thanked the Secretariat for preparing document SCP/30/8. The Delegation expressed its support to the statements made by the Delegation of Canada on behalf of Group B and by the Delegation of Romania on behalf of the EU and its Member States. The Delegation expressed its view that the work of WIPO on the topic should be maintained. It pointed out that the French Patent Office had provided a whole series of provisions which made it possible to ensure links between business and universities. In particular, the Delegation noted that a catalogue of possible training on negotiation of licensing agreements had been proposed. The Delegation further proposed to carry out free visits, particularly for start-ups and small companies, carried out by a lawyer, an engineer and sometimes by a representative which could lead to a pre-diagnosis that would make it possible to evaluate the industrial property potential in a business and thus provide more personalized coaching by the visiting team. The Delegation also proposed to provide financing support to assist the small businesses to seek counsel and to implement low cost training programs which would allow start-ups and small businesses to design strategies for extension adapted to their goals. Finally, the Delegation noted that an online platform that allowed patentees to discuss licensing options with other patent holders was also in place.

206. The Delegation of India commended the work of the Secretariat in preparing document SCP/30/8. The Delegation stressed that the patent system was based on a *quid pro quo*. It noted that Article 29 of the TRIPs Agreement established the requirement of sufficiency of disclosure of the inventions in patent specifications by which any applicant had an obligation to comply with the requirements of sufficiency of disclosure and thereby general public could use the disclosure after the statutory period of patent protection was over and also able to make an improvement on to the patented technology. The Delegation continued that “sufficiency of disclosure” referred to adequacy of pertinent information to be provided in the patent specification to enable an average skilled person to perform the invention. It further noted that, considering the patent specification as a techno-legal document, the Indian patent law required that the patent specification fully described the invention and disclosed the best mode of performing the invention. The Delegation expressed its view that, in the absence of sufficient and enabling disclosure, the basic purpose of a patent system would be defeated and the possibility to work out the invention would be uncertain. Further, it stressed that for other provisions related to compulsory licensing, Bolar provisions, or any further research on the patent specification, the sufficiency of disclosure was also needed. The Delegation continued that in a fast-changing world of technology, the transfer of technology was vital not only for commercial or business related organizations but also for universities and research organizations. It noted that in modern times, various universities and research organizations were becoming self-sustainable and were also standing on their own IP portfolio. Therefore, the Delegation believed that a good license or assignment by an university to any company/organizations not only became a source of fund for further research for the university but the transfer of technology also gave different companies the lead in the market by way of introduction of a far better product which ultimately benefited the society at large. The Delegation continued that, depending on the availability of materials, there were also chances of cross-border transfer of technology among the business organizations. The Delegation informed that there were provisions for registration of change of proprietorship under the Indian Patents Act. It stated that the statute contained relevant provisions for recordal of license, assignment, etc. in the “Register of Patents” for a granted patent, as well as provisions for

change of name due to change of proprietorship during the prosecution of any patent application. The Delegation reiterated that under India's National IPR Policy, the Cell for IPR Promotion and Management (CIPAM) was establishing and developing Technology and Innovation Support Centers (TISCs) all over India in collaboration with WIPO. Further, it informed that the government of India had initiated several schemes to augment the IP ecosystem of India thereby creating an environment to facilitate transfer of technology in IP. In particular, it pointed out that there was a fee reduction, expedited examination provision and facilitators for filing patent applications for start-ups. In conclusion, the Delegation proposed that the Secretariat prepare a further study on technology transfer and its beneficial effect on public.

207. The Delegation of Belarus thanked the Secretariat for preparing document SCP/30/8. The Delegation also expressed its gratitude to delegations for providing information on their experiences in technology transfer. It further stated that, in order to create conditions for technology transfer, its patent office was implementing a project which provided interested parties with an opportunity to get acquainted with various objects of industrial property (including patented inventions and utility models) belonging to the national entities, and in respect of which there existed either commercial proposals, or decisions of the patent office recognizing them as promising inventions. The Delegation continued that, as of January 1, 2019, the project hosted 673 commercial offers for inventions and utility models. In addition, the Delegation stated that, in Belarus, the Republican Centre for Technology Transfer had been established. Its objectives were, in particular: (i) creation and maintenance of information databases serving technology transfer participants; (ii) providing access to international databases of technological transfer and scientific and technical information; (iii) rendering assistance to entities in development and promotion of innovative and investment projects; (iv) training of personnel in the field of scientific and innovative entrepreneurship. However, the Delegation noted that, despite the efforts made, technology transfer remained a problematic issue. The Delegation explained that the recent regional seminar organized in Belarus with the participation of WIPO also had shown that the issue of technology transfer was very relevant in all countries of the region. The Delegation stressed that there was a need for ongoing work to ensure that inventors interact with the business community. Therefore, the Delegation stated that the consideration of the issue of technology transfer in the framework of the SCP was relevant and useful.

208. The Representative of OAPI expressed his view that LDCs were having serious difficulties in accessing some types of medical treatments. He expressed OAPI´s support to the proposal made by the Delegation of India which, in his view, would expand databases and make it possible for those who are in a position to request licenses to do so. In addition, the Representative considered that it would also help some of the Member States of OAPI to actually use the TRIPs flexibilities that were available to them.

209. The Representative of JIPA noted that in the pharmaceuticals industry, it was difficult to develop new compounds because the market for patentable small molecules was becoming mature. He noted that, therefore, in order to survive, the companies were willing to exploit their businesses by acquiring other companies so as to reduce the development costs and eliminate risks. The Representative stated that technology transfer helped to complement the resources of the industry with those of the public research institutions, such as custom drug discovery and know-how, by connecting pharmaceutical companies with universities, promoting the research on new drugs/technology, and creating the foundation for the transformation of technology into new products and procedures. The Representative expressed its view that it was necessary to adopt legal regulations and programs that promoted technology transfer and new drug development worldwide. In that regard, he noted that in Japan, prior to the adoption of the 1999 Act on Special Measures for Industrial Revitalization, which was based on the US Bayh-Dole Act and enacted to improve industrial potential productivity and the efficient management of

resources, the IP originated from public research had belonged to the state and thus technology transfer had not been possible. He explained that the implementation of the Act had made it possible the transfer of useful drug discovery to pharmaceutical companies. Therefore, the Representative highlighted the importance of promoting the independency and self-management of public research so that universities can reach agreements with pharmaceutical companies and obtain additional funds.

210. The Representative of TWN stated that technology transfer included not only purchase and acquisition of equipment, but also transfer of skills and know-how on how to use, operate, maintain as well as understand the technology so that independent innovation by the cooperating parties was made possible. She noted that for developing countries, the process of accession to and use of the technology, commonly described as "camping-up", was very important in moving up the ladder to develop inventive capacities. She continued to state that IP, especially patent rights, created barriers to the transfer of technology, as they were often abused by patent owners to prevent the technology transfer on fair and equitable terms. The Representative continued that patent holders might simply refuse to license the technologies to developing countries, charge fees for protected technologies and impose onerous conditions to prevent further inventions based on the existing technologies. In her opinion, it was important that the IP regime at the national and international levels should provide safeguards to prevent the abuse of exclusive rights. She continued that, as the disclosure in the patent specification could play a big role in aiding the transfer of technology, such requirement should be included in the patent laws of developing countries in a way to ensure that the disclosure was detailed and enabling so that even a person with very ordinary skills in the art would be able to read and understand the technologies disclosed in the patent document without consulting the patent holder. However, she noted that most of the times, patent specifications did not disclose the invention sufficiently, for example in the case of patent applications including Markush formula claims. Therefore, she was of the opinion that such insufficient disclosure or non-disclosure affected the growth of local parties that wanted to use the technologies to manufacture the patented product beyond the patent term. Thus, the Representative urged developing countries to institute a higher standard on the disclosure requirement in the patent laws.

AGENDA ITEM 11: FUTURE WORK

211. 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. The Committee will discuss document SCP/30/3 (Draft reference document on the exception regarding compulsory licensing) at SCP/31. The Secretariat will prepare a draft reference document on the exception regarding prior use for discussion at SCP/32, taking into account any additional inputs from Member States for the preparation of the said draft document.

Quality of Patents, including Opposition Systems

– The Secretariat will submit, at SCP/31, a study based on paragraph 7(b) of document SCP/28/8 on approaches to the quality of the patent grant process, taking into account the issues raised during the sharing sessions on that topic, which were held during SCP/29 and SCP/30.

– The Secretariat will organize, at SCP/31, a session to share experiences and information on the use of artificial intelligence for the examination of patent applications. The Secretariat will organize a one-day information sharing session on issues related to the patentability of inventions, such as artificial intelligence software as computer-implemented inventions, the use of artificial intelligence as an aid to the creation of inventions or inventions generated independently by artificial intelligence, at SCP/32.

– The Secretariat will submit a report on its technical assistance activities relating to opposition systems and other administrative revocation mechanisms at SCP/31.

– Document SCP/30/4 (Further study on inventive step (part III)) will be kept open for further discussions by Member States at SCP/31.

Patents and Health

– The following initiatives on publicly accessible databases of patent status information concerning medicines and vaccines will be invited to SCP/31 to present an update, in accordance with document SCP/28/10 Rev.: (i) MedsPaL; (ii) Pat-Informed; (iii) Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book); and (iv) List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic.

– The Secretariat will submit, at SCP/31, a review of existing research on patents and access to medical products and health technologies, as contained in document SCP/28/9 Rev.

– The Secretariat will submit, at SCP/31, a report of the sharing session regarding the experiences on capacity building activities related to negotiating licensing agreements, which was held during SCP/30.

– The Secretariat will organize, at SCP/32, a sharing session by Member States on challenges and opportunities in relation to types of patent licensing provisions in the healthcare technologies.

Confidentiality of Communications between Clients and Their Patent Advisors

– The Secretariat will organize, at SCP/31, a sharing session by practitioners and Member States on recent developments and experiences with respect to confidentiality of communications between clients and their patent advisors, covering policy and practical issues and with a particular attention to cross-border elements.

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, for SCP/31, based on the inputs to be received from Member States and discussion within the SCP.

– The Secretariat will organize, at SCP/32, a sharing session by Member States on patent law provisions and practices that contributed to effective transfer of technology, including sufficiency of disclosure.

AGENDA ITEM 12: SUMMARY BY THE CHAIR

212. The Chair introduced the Summary by the Chair (document SCP/30/10).

213. The Delegation of India stated that it did not agree to include a sharing session on client-attorney privilege in the proposed future work program. It pointed out that client-attorney privilege was not a substantive patent law issue, and accordingly, could only be dealt with under the law of evidence. The Delegation further sought the reasons behind the exclusion of the INN issue in the future work proposal. While it reiterated the stand that India opposed attempt of harmonization of patent law in the future work, the Delegation stated that it would join the consensus.

214. The Delegation of Belarus, speaking on behalf of the CACEEC Group, thanked the Secretariat and the Chair for their work. The Delegation observed that the future work was a balanced plan of work for Member States. It however sought clarification regarding the future work on the quality of patents. Specifically, with respect to a study on approaches to the quality of the patent grant process, the CACEEC Group considered that it would include the delay in the patent grant process, which, in its view, should be discussed at the thirty-first session of the SCP. Having said that, the Delegation stated that the CACEEC Group supported the program of work.

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

216. 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 13: CLOSING OF THE SESSION

217. The Delegation of Guatemala, speaking on behalf of GRULAC, thanked the Chair for her efforts and efficiency in chairing the session, and expressed its appreciation to the Secretariat's support in preparing the documents. For GRULAC, the important agenda items were the exceptions and limitations to patent rights, quality of patents including opposition systems, transfer of technology and patents and health. The Delegation noted with pleasure that the Committee had agreed on concrete activities in those areas under future work. The Delegation stressed the importance of the sharing sessions, which were very useful for all members. The Delegation took the opportunity to wish success to all colleagues who were going to leave Geneva, including the delegate from Brazil. It noted that his work and professionalism would continue to contribute to the success of future meetings. As it was the final speech of the Delegation as a coordinator of GRULAC, the Delegation thanked the Secretariat and interpreters for all their support. It also thanked the regional coordinators, with whom it had had a great pleasure to share the work. Finally, it expressed its special thanks to the members of GRULAC for their friendship and support, which was essential for the activities of the coordinator.

218. The Delegation of Croatia, speaking on behalf of the CEBS Group, thanked the Chair and Vice Chairs for their able guidance during the thirtieth session of the SCP. The Delegation also thanked the Secretariat, interpreters and conference services. The Delegation expressed its belief that the Committee had had another enriching session, which had allowed for a very important exchange of experiences and practices. The Delegation reiterated that the CEBS Group would be ready to engage constructively in any future negotiations within the SCP, namely on the confidentiality of communications between clients and their patent advisors and the quality of patents. The Delegation expressed its appreciation to the colleagues who would be leaving Geneva for their contributions, and wish them all the best in their new lives.

219. The Delegation of China thanked the Chair and the Secretariat for their work. It also thanked the Member States and experts for sharing their experiences. The Delegation stated that the future work of the Committee was well balanced, and expressed its support to the future work. In its view, as the IP system had been facing with new challenges, the SCP was a very useful platform conducive to exchanges of views and positions of Member States. The Delegation appreciated the flexible positions expressed by delegations during the session. The Delegation expressed its hope that the future sessions of the SCP would also achieve the same successful results.

220. The Delegation of Romania, speaking on behalf of the EU and its Member States, congratulated the Chair and Vice Chairs for their able leadership and excellent way in which they had guided the Member States. The Delegation also thanked the Secretariat for the hard work carried out in the preparation of the session. It also conveyed special thanks to the interpreters for literally enabling delegates to understand each other. The Delegation noted with satisfaction that a great amount of valuable information had been shared during the week, such as during the sharing sessions organized under the topics on patents and health and quality of patents. The EU and its Member States welcomed the outcome of the session, as reflected in the Summary by the Chair. It looked forward to future sharing sessions on the topic of artificial intelligence. The Delegation reiterated its commitment in advancing the work of the SCP under all topics on its agenda.

221. The Delegation of Indonesia, speaking on behalf of the Asia and Pacific Group, thanked the Chair and Vice Chairs for their able guidance toward a successful conclusion of the SCP session. The Delegation also thanked the Secretariat for all their support and their hard work as well to ensure that the Committee had a smooth meeting throughout the week. The Delegation reconfirmed, and reaffirmed, its support to the future work included in the Summary by the Chair. It noted that the Asia and Pacific Group welcomed all agreements on future on each agenda item. The Delegation expressed its appreciation to the regional coordinators, delegations and Member States for their flexibility, and for having strived for balanced and inclusive work for the Committee.

222. The Delegation of Canada, speaking on behalf of Group B, thanked the Chair for her able and wise guidance during the week and continued commitment throughout the session of the SCP. The Delegation also thanked the Secretariat for its hard work prior to the session and during the week. Its thanks also went to the interpreters, translators and conference service for their professionalism and availability. Furthermore, the Delegation thanked the presenters and participants in the sharing sessions. Expressing its appreciation to the other regional coordinators, the Delegation stated that the Committee could count on the full support and constructive spirit of Group B delegations to continue the fruitful discussions that had been taking place at the SCP.

223. The Delegation of Uganda, speaking on behalf of the Africa Group, commended the Chair for her leadership in the work of the session. The Delegation thanked the Secretariat, interpreters and conference services for all their technical support. The Delegation thanked all

Member States and stakeholders for their efforts and constructive engagement, and representatives from IGOs and UN agencies who had made excellent presentations that had contributed to the achievement of the objectives of the SCP. The Delegation welcomed the good spirit by all regional coordinators and Member States in discussing future work of the Committee. It noted that the agreed future work maintained a balance between the interests of all Member States and stakeholders, indicating the ability of Member States to reach compromises. The Delegation looked forward with great optimism to the subsequent session of the SCP. The Delegation had no doubt that the momentum generated would enable the Committee to achieve its objectives in the near future. Before concluding, the Delegation congratulated the outgoing coordinator of GRULAC and thanked her for her excellent corroboration with the African Group. It looked forward to continued corroboration with the incoming coordinator.

224. The Delegation of Brazil pointed out the repetition of the words “at SCP/31” in the future work, quality of patents, second bullet point. The Delegation thanked the Chair for the excellent session and her efforts to guide the delegations in discussion during the week. It also thanked the Secretariat for the high quality of the documents that they had prepared for the session. Referring to the importance of exceptions and limitations, the Delegation noted the considerable progress that had been achieved under that agenda item. The Delegation considered that further work could be explored in the reference document on compulsory licensing, such as information on the judicial non-voluntary license whereby the courts refused injunction and allowed use of patented inventions subject to payment of royalty. The Delegation stated that the main examples of such license were found in the area of medical technologies. The Delegation further noted that it would also be useful to have information on use of non-voluntary license by competition authorities. Additional relevant information would be the breaking of costs of bringing new medicine to market. In the view of the Delegation, more transparency on that matter would help better understand the costs for medicines, specifically the costs of R&D, as discussed in the World Health Assembly in last May. Regarding patents and health, the Delegation thanked the organization of the sharing session regarding licensing agreements, which had been very successful. As, at the subsequent session, a further discussion about patent databases would be held, the Delegation expressed its view that information about patent validity, the legal status so-to-speak, should also be included, where possible, in those databases, making it more user friendly for end users who were not necessarily patent examiners. The Delegation looked forward to continued progress in all subjects in a balanced manner, and appreciated the constructive spirit shown by all delegations. On a personal note, the Delegation stated that he would leave Geneva, his first statement in WIPO being in the same room back in 2010 during the fifteenth session of the SCP. The Delegation noted that after ten years of IP, he continued to be humbled with the technology and knowledge involved in that subject. The Delegation expressed its pleasure to work with high-level colleagues, and looked forward to continue working with all delegates in the future.

225. 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 June 27, 2019.

226. The Committee adopted this report at its thirty-first session on December 2, 2019.

[Annex follows]

LISTE DES PARTICIPANTS/LIST OF PARTICIPANTS

I. MEMBRES/MEMBERS

(dans l'ordre alphabétique des noms français des États)
(in the alphabetical order of the names in French)

AFRIQUE DU SUD/SOUTH AFRICA

Jetane CHARSLEY (Ms.), Director, National Intellectual Property Management Office (NIPMO), Department of Higher Education, Science and Technology, Pretoria

Verushka GILBERT (Ms.), Deputy Director, Legal International Trade and Investment, International Trade and Economic Development Department, Ministry of Trade and Industry, Pretoria

Mandla NKABENI (Mr.), First Secretary, Permanent Mission, Geneva

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Lucie BERGER (Ms.), First Secretary, Geneva

III. ORGANISATIONS NON GOUVERNEMENTALES/NON-GOVERNMENTAL ORGANIZATIONS

Association asiatique d'experts juridiques en brevets (APAA)/Asian Patent Attorneys Association (APAA)
Catherine Eunkyeong LEE (Ms.), Co-Chair, Patents Committee, Seoul
Kazuo YAMASAKI (Mr.), Member, Patents Committee, Tokyo

Association européenne des étudiants en droit (ELSA International)/European Law Students' Association (ELSA International)
Hatice KOCAEFE (Ms.), Brussels
Federico LO BIANCO (Mr.), Brussels
Andrej ŽERJAL (Mr.), Brussels
Jure ZUPET (Mr.), Brussels

Association interaméricaine de la propriété industrielle (ASIPI)/Inter-American Association of Industrial Property (ASIPI)
Matías NOETINGER (Mr.), Tesorero, Buenos Aires

Association internationale pour la protection de la propriété intellectuelle (AIPPI)/International Association for the Protection of Intellectual Property (AIPPI)
Jonathan P. OSHA (Mr.), Observer, Zurich

AUTM
Marc SEDAM (Mr.), Chair-Elect, Durham, New Hampshire

Centre d'études internationales de la propriété intellectuelle (CEIPI)/Centre for International Intellectual Property Studies (CEIPI)
François CURCHOD (M.), chargé de mission, Genolier

Chambre de commerce internationale (CCI)/International Chamber of Commerce (ICC)
Ivan HJERTMAN (Mr.), European Patent Attorney, Commission on Intellectual Property, Stockholm

Civil Society Coalition (CSC)
Susan ISIKO STRBA (Ms.), Fellow, Geneva

Confédération des entreprises européennes (BusinessEurope)/The Confederation of European Business (BusinessEurope)
Bettina WANNER (Ms.), Head, Intellectual Property Advocacy and Strategy, Monheim

CropLife International/CropLife International (CROPLIFE)
Tatjana SACHSE (Ms.), Legal Adviser, Geneva

Fédération internationale de l'industrie du médicament (FIIM)/International Federation of Pharmaceutical Manufacturers Associations (IFPMA)
Luca DEPLANO (Mr.), Policy Analyst, Geneva
Grega KUMER (Mr.), Head of Government Relations, Geneva

Fédération internationale des conseils en propriété intellectuelle (FICPI)/International Federation of Intellectual Property Attorneys (FICPI)
Jérôme COLLIN (Mr.), Chair, CET3 Group, Paris
Kim FINNILÄ (Mr.), CET Assistant Report General, Helsinki

Institut des mandataires agréés près l'Office européen des brevets (EPI)/Institute of Professional Representatives Before the European Patent Office (EPI)
John BROWN (Mr.), Chair, Harmonisation Committee, Munich
Francis LEYDER (Mr.), President, Munich
Filippo SANTI (Mr.), Secretary, Harmonisation Committee, Munich

Instituto Fridtjof Nansen (FNI)/Fridtjof Nansen Institute (FNI)
Morten Walløe TVEDT (Mr.), Associate Professor, Lysaker

Japan Intellectual Property Association (JIPA)
Terukazu TERAUCHI (Mr.), Chairman, Medical and Biotechnology Committee of JIPA, Tokyo

Japan Patent Attorneys Association (JPAA)
Hiroyuki KOSHIMOTO (Mr.), Member, Tokyo
Takeo NASU (Mr.), Member, Tokyo

Knowledge Ecology International, Inc. (KEI)
Thiru BALASUBRAMANIAM (Mr.), Geneva Representative, Geneva

Licensing Executives Society (International) (LES)
Stefan KOHLER (Mr.), Member of the National Board (Switzerland), Zurich

Médecins Sans Frontières (MSF)
Katy ATHERSUCH (Ms.), Senior Policy Advisor, Medical Innovation and Access, Geneva
Yuanqiong HU (Ms.), Senior Legal and Policy Advisor, Geneva
Manuel MARTIN (Mr.), Medical Innovation and Access Policy Adviser, Geneva
Pauline LONDEIX (Ms.), Consultant, Paris

Medicines Patent Pool (MPP)
Esteban BURRONE (Mr.), Head of Policy, Geneva
Andrew GOLDMAN (Mr.), Associate Counsel, Geneva
Amina MAILLARD (Ms.), Patent Information Manager, Geneva
Liudmyla MAISTAT (Ms.), Advocacy and Policy Manager, Geneva
Maria Carmen TRABANCO (Ms.), Associate Counsel, Geneva

Third World Network Berhad (TWN)
Sangeeta SHASHIKANT (Ms.), Legal Advisor, London
Prathibha SIVASUBRAMANIAN (Ms.), Legal Advisor, New Delhi

4iP Council EU AISBL (4iP Council)
Axel FERRAZZINI (Mr.), Managing Director, Brussels

IV. BUREAU/OFFICERS

Président/Chair:	Ms. Sarah WHITEHEAD (Mme/Ms.), (Royaume-Uni/United Kingdom)
Vice-présidents/Vice-Chairs:	Mr. Alfred YIP (M./Mr.), (Singapour/Singapore) Ms. Grace ISSAHAQUE (Mme/Ms.), (Ghana)
Secrétaire/Secretary:	Marco ALEMÁN (M./Mr.) (OMPI/WIPO)

V. CONFÉRENCIERS/SPEAKERS

Marli Elizabeth RITTER DOS SANTOS (Sra.), Directora, Asociación Forum de Gestores de Innovación y Transferencia de Tecnologia (FORTEC), Porto Alegre

Antoine DINTRICH (Mr.), Director General, European Institute for Enterprise and Intellectual Property (IEEPI), Illkirch

VI. BUREAU INTERNATIONAL DE L'ORGANISATION MONDIALE DE LA PROPRIÉTÉ INTELLECTUELLE (OMPI)/INTERNATIONAL BUREAU OF THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO)

Francis GURRY (M./Mr.), directeur général/Director General

John SANDAGE (M./Mr.), vice-directeur général, Secteur des brevets et de la technologie/ Deputy Director General, Patents and Technology Sector

Marco ALEMÁN (M./Mr.), directeur, Division du droit des brevets, Secteur des brevets et de la technologie/Director, Patent Law Division, Patents and Technology Sector

Tomoko MIYAMOTO (Mme/Ms.), chef, Section du droit des brevets, Division du droit des brevets, Secteur des brevets et de la technologie/Head, Patent Law Section, Patent Law Division, Patents and Technology Sector

Aida DOLOTBAEVA (Mlle/Ms.), juriste, Section du droit des brevets, Division du droit des brevets, Secteur des brevets et de la technologie/Legal Officer, Patent Law Section, Patent Law Division, Patents and Technology Sector

Marta DIAZ POZO (Mlle/Ms.), juriste adjointe, Section du droit des brevets, Division du droit des brevets, Secteur des brevets et de la technologie/Associate Legal Officer, Patent Law Section, Patent Law Division, Patents and Technology Sector

Qi Jun KWONG (Mlle/Ms.), stagiaire, Section des conseils législatifs et de politique générale, Division du droit des brevets, Secteur des brevets et de la technologie/Intern, Legislative and Policy Advice Section, Patent Law Division, Patents and Technology Sector

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