

Standing Committee on the Law of Patents

Twenty-Eighth Session
Geneva, July 9 to 12, 2018

REPORT

adopted by the Standing Committee

1. The Standing Committee on the Law of Patents (the “Committee” or the “SCP”) held its twenty-eighth session in Geneva from July 9 to 12, 2018.
2. The following Member States of WIPO and/or the Paris Union for the Protection of Industrial Property were represented: Algeria, Argentina, Australia, Austria, Azerbaijan, Belarus, Benin, Bolivia (Plurinational State of), Brazil, Burkina Faso, Canada, Chile, China, Colombia, Costa Rica, Côte d’Ivoire, Croatia, Czech Republic, Democratic People’s Republic of Korea, Denmark, Djibouti, Dominican Republic, Ecuador, Egypt, Estonia, Finland, France, Gabon, Germany, Ghana, Greece, Guatemala, Holy See, Honduras, Hungary, India, Indonesia, Iran (Islamic Republic of), Ireland, Italy, Japan, Kazakhstan, Kenya, Kuwait, Latvia, Lebanon, Lithuania, Malawi, Malaysia, Malta, Mexico, Morocco, Mozambique, Niger, Nigeria, Norway, Oman, Pakistan, Panama, Paraguay, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Saudi Arabia, Senegal, Seychelles, Singapore, Slovakia, South Africa, Spain, Sweden, Switzerland, Tajikistan, Thailand, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Uganda, Ukraine, United Arab Emirates, United Kingdom, United States of America, Uruguay, Viet Nam, Yemen, Zimbabwe (92).
3. Representatives of the following intergovernmental organizations took part in the meeting in an observer capacity: African Regional Intellectual Property Organization (ARIPO), European Patent Organization (EPO), Eurasian Patent Organization (EAPO), European Union (EU), Patent Office of the Cooperation Council for the Arab States of the Gulf (GCC Patent Office), South Centre (SC), United Nations (UN), World Health Organization (WHO), World Trade Organization (WTO) (9).

4. Representatives of the following non-governmental organizations took part in the meeting in an observer capacity: Asian Patent Attorneys Association (APAA), CropLife International (CROPLIFE), European Law Students' Association (ELSA International), Fridtjof Nansen Institute (FNI), Health and Environment Program (HEP), Institute of Professional Representatives Before the European Patent Office (EPI), International Association for the Protection of Intellectual Property (AIPPI), International Federation of Intellectual Property Attorneys (FICPI), International Federation of Pharmaceutical Manufacturers Associations (IFPMA), International Intellectual Property Commercialization Council (IIPCC), Japan Intellectual Property Association (JIPA), Japan Patent Attorneys Association (JPAA), Knowledge Ecology International, Inc. (KEI), Médecins Sans Frontières (MSF), Medicines Patent Pool Foundation (MPP), National Inventors Hall of Fame, Third World Network Berhad (TWN) (17).
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/27/10 Prov.2.); "Revised Draft Agenda" (SCP/28/1 Prov.3); "Report on the International Patent System: Certain Aspects of National/Regional Patent Laws" (SCP/28/2); "Reference Document on Exception Regarding Acts for Obtaining Regulatory Approval from Authorities (Second Draft)" (SCP/28/3); "Addendum: Reference Document on Exception Regarding Acts for Obtaining Regulatory Approval from Authorities (Second Draft)" (SCP/23/3 Add.); "Further Study on Inventive Step (Part I)" (SCP/28/4); "Updated Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents" (SCP/28/5); "Report on WIPO's Technical Assistance Activities in Respect of Enhancing Patent Examiners Capacity" (SCP/28/6); "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); "Proposal by the Delegations of Brazil, Canada and Switzerland" (SCP/28/9); "Addendum to Document SCP/28/9 (Proposal by the Delegations of Brazil, Canada and Switzerland)" (SCP/28/9 Add.); "Proposal by the Delegations of Argentina, Brazil and Switzerland" (SCP/28/10).
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); and "Proposal by the Delegation of Canada" (SCP/26/6).

8. The Secretariat noted the interventions made and recorded them. This report summarizes the discussions on the basis of all observations made.

AGENDA ITEM 1: OPENING OF THE SESSION

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

10. Mr. Marco Alemán, (WIPO), welcomed the participants on behalf of the Director General, and acted as Secretary to the SCP.

AGENDA ITEM 2: ADOPTION OF THE AGENDA

11. The SCP adopted the revised draft agenda (document SCP/28/1 Prov.3).

AGENDA ITEM 3: ADOPTION OF THE DRAFT REPORT OF THE TWENTY-SEVENTH SESSION

12. The Committee adopted the draft report of its twenty-seventh session (document SCP/27/10 Prov.2), as proposed.

GENERAL STATEMENTS

13. The Delegation of Indonesia, speaking on behalf of the Asia and the Pacific Group, expressed its confidence in the experience and leadership skills of the Chair, and also expressed its appreciation for the hard work done by the Secretariat towards the preparation for the meeting. The Delegation noted that, even if the Paris Convention and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) had set minimum international standards of patent protection, the patent law remained essentially territorial and governments had flexibility to formulate their domestic patent laws. The Delegation stressed that maintaining that flexibility remained critical for policy planners to craft or amend domestic patent laws in accordance with national development priorities and social and economic realities. The Delegation continued that the TRIPS flexibilities allowed governments, and especially in countries with limited resources, the necessary policy space to meet their health needs and, at the same time, to foster innovation. The Delegation further stated that the SCP played important role in creating a balance between the rights of patent owners and the larger public interest, particularly in the area of public health, technology transfer and patent flexibilities. The Delegation stated that its Group would constructively participate and contribute towards a productive discussion on those issues. The Delegation looked forward to the information exchange on opposition and administrative revocation mechanisms, the information exchange on cooperation between patent offices in search and examination, the sharing session with respect to enhancing examiners capacity, particularly in small and medium-sized offices, the information exchange on publicly accessible databases on patent information status and data on medicines and vaccines. Further, the Delegation expressed its interest in experiences of Member States in implementing the confidentiality of communication between clients and their patent advisors as well as the sharing session on patent law provisions that contributed to effective transfer of technology. The Delegation hoped that the information exchange sessions and the sharing sessions of the SCP would provide guidance for improving and further enhancing the efficiency of the patent system in a manner sensitive to the diverse needs of members of the Committee. The Delegation thanked the Secretariat for preparing

document SCP/28/2, and stated that the update of the SCP website based on feedbacks received from members of the Committee should be continued. The Delegation further stated that it looked forward to the discussion on exceptions and limitations to patent rights. The Delegation thanked the Secretariat for preparing documents SCP/28/3 and SCP/28/3 Add. The Delegation looked forward to the presentation of the draft reference document and hoped that work on the draft would be continued until completion. The Delegation looked forward to the discussions on inventive step issues (document SCP/28/4) and technical assistance relating to enhancing examiners capacity (document SCP/28/5). With regard to patents and health, the Delegation wished to take the opportunity to draw the attention of the Committee to the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines (UNHLP Report). The Delegation noted that the Report had specifically explored the policy incoherence between intellectual property, trade and human rights, and made a number of recommendations in that regard. The Delegation continued that some of those recommendations were specifically addressed to WIPO and were directly relevant to the subject of the sharing session on patents and health. The Delegation stated therefore that the Asia and the Pacific Group wished to request the SCP to initiate those exploratory discussions based on that important Report. Further, the Delegation took note of the Proposal by the Delegations of Brazil, Canada and Switzerland (document SCP/28/9), and stressed the importance of considering the role of the patent system in promoting the development of new medical products and advancement of health technologies. In that regard, the Delegation looked forward to the discussion on that proposal. The Delegation drew attention of the Committee to the fact that the Protocol amending the TRIPS Agreement would enable developing countries with insufficient or no manufacturing capacities in the pharmaceutical sector to import cheaper generic medicines produced under compulsory licensing. The Delegation highlighted that that Protocol finally came into force on January 23, 2017. Referring further to paragraph 6 of the Doha Declaration, which stated that "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement", the Delegation noted that that amendment gave legal certainty that medicines could be exported at reasonable prices to satisfy the needs of the countries without or with limited pharmaceutical production capacity. The Delegation hoped that the Committee would also consider a work program to support the Members' commitment and bring that important measure into force in accordance with the mandate of the Committee and WIPO. Further, the Delegation supported the idea that the SCP should have discussions on the opposition systems. The Delegation further emphasized that the Committee should give equal prominence to that issue in the work of the SCP as it did to the issue of quality of patents. In particular, the Delegation was of the view that there should be a work program on opposition systems that would comprise a questionnaire or a survey on different kinds of opposition mechanisms available in various countries, the procedures and modalities for their use, constraints in their use, and how such systems could be strengthened and constraints could be removed. The Delegation was of the opinion that the SCP should agree on a common understanding of the term "quality of patents". Specifically, the Delegation questioned whether the term meant efficiency of patent offices in processing patent applications, or the quality of patents granted, ensuring that the offices did not grant patents of questionable validity. In that regard, the Delegation requested the Secretariat to provide regular information to Member States on the outcome of patent applications in different jurisdictions and on the outcome of opposition procedures. Further, the Delegation took note of the proposal made by the Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom (document SCP/28/8) and looked forward to the discussions on that proposal. Finally, the Delegation expressed its hope that the Committee would achieve productive outcome.

14. The Delegation of Lithuania, speaking on behalf of the Group of Central European and Baltic States (CEBS Group), thanked the Secretariat for preparing the session. The Delegation was pleased to note that Member States had agreed on the balanced future work during the previous session that had led to a balanced work program of the twenty-eighth session. The

Delegation looked forward to continue discussions on quality of patents and expressed its hope that those discussions would be supported by Member States. Further, the Delegation stressed the importance of the proposal made by the Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom (document SCP/28/8). In addition, the Delegation expressed its belief that the work on the topic of client-patent attorney privilege should lead to higher quality of patent examination process and that discussion could contribute to a more predictable patent framework. As regards the discussions on exceptions and limitations to patent rights, patents and health as well as on technology transfer, the Delegation was of the view that the patent system had to ensure innovations and that the work of the SCP had to remain within the Committee's mandate. With regard to future work, the Delegation expressed its willingness to underline the non-exhaustive list of the issues. The Delegation emphasized that the fact-finding work was important for the CEBS Group during the twenty-eighth session of the SCP. Further, the Delegation expressed its belief that harmonization of the substantive patent law remained the priority for the future work. In conclusion, the Delegation stressed the importance of the Committee and expressed its readiness to engage in the discussions in a constructive manner.

15. The Delegation of Morocco, speaking on behalf of the African Group, expressed its confidence in the experience and leadership skills of the Chair and also expressed its appreciation to the Chair for its guidance in the Committee. Further, the Delegation thanked the Secretariat for the preparation of the twenty-eighth session of the SCP. In addition, the Delegation underlined the importance and significance of the SCP's role as a multilateral forum which enabled Member States to discuss fundamental issues. The Delegation pointed out that the work of the SCP was essential for the development and balanced use of the patent system and that it could play a significant role in the achievement of socio-economic development of Member States, particularly in developing countries and least developed countries (LDCs). The African Group looked forward to the information exchange sessions under items 6 to 9 of the agenda. The Delegation expressed its hope that those sessions would help to improve the effectiveness of the patent system, taking into account, in particular, the interests of developing countries and LDCs. The Delegation took note of document SCP/28/3 on exceptions regarding acts for obtaining regulatory approval from authorities and thanked the Secretariat for the preparation of the study. The Delegation was of view that exceptions and limitations are an integral part of a solid patent system, especially since they established a balance between general interest and the rights of patent holders. In particular, the Delegation pointed out that document SCP/28/3 enabled Member States to have a clearer understanding of those exceptions and limitations as well as a better understanding and explanation of those exceptions and limitations to patent rights. Further, the Delegation noted that the discussions on patents and health remained crucial in order to promote a more balanced patent system. Therefore, the Delegation pointed out that that issue became a priority for the African Group. In that regard, the Delegation recalled the Sustainable Development Goals (SDG Agenda 2030). Specifically, SDG Goal 3 aimed at ensuring healthy lives and promoting wellbeing for all at all ages. The Delegation thanked the Delegations of Canada, Brazil and Switzerland for their proposal contained in document SCP/28/9. However, in that regard, the Delegation recalled the proposal contained in document SCP/24/4. In particular, the Delegation was of view that that document was an excellent basis for discussion on policy priorities of public authorities in the area of public health and it gave a solution for international challenges in terms of access to affordable medicines and health care. Further, the Delegation supported the idea that the SCP should have discussions on the opposition systems which was an important issue in Agenda Item 6. The Delegation further emphasized that the Committee should give equal prominence to that issue in the work of the SCP as it did to the issue of quality of patents. In relation to Agenda Item 9 on transfer of technology, the Delegation highlighted the need to carry out additional studies on the role of sufficiency of disclosure in the context of transfer of technology. Finally, the Delegation highlighted the importance it attached to the work of the Committee.

16. The Delegation of Switzerland, speaking on behalf of Group B, expressed its appreciation to the Chair for its guidance in the Committee. Further, the Delegation thanked the Secretariat for the preparation of the twenty-eighth session of the SCP, including the documents for discussion, the four sharing sessions and the informative session. The Delegation expressed its appreciation of the efforts and willingness of all Member States during the previous session that had led to a balanced work program. The Delegation hoped that such constructive spirit would prevail during the twenty-eighth session. The Delegation expressed its willingness to contribute to the work of the Committee in a fruitful manner and to work towards a positive outcome that reflected the interests of all Member States. Further, the Delegation stressed the importance of the SCP, which was the only multilateral forum on patents. With that regard, the Delegation noted that the SCP should carry out its work by engaging in technical discussions on issues of substantive patent law in line with its mandate. Further, the Delegation also believed that discussions during the Committee as well as the future work should be beneficial to the real world, including IP offices, innovators, practitioners and other users of the patent system. The Delegation therefore pointed out that the Committee's work on the quality of patents and on the confidentiality of communication between clients and their patent advisors served that purpose. The Delegation attached considerable importance to advancing work on those topics. In relation to the topic of work-sharing and collaborations on the subject of inventive steps, the Delegation mentioned various proposals that had been made on the subject by the Delegations of Canada, Denmark, the Republic of Korea, Spain, the United Kingdom and the United States of America. The Delegation was of the view that the information gathered in the questionnaire on the cooperation between IP offices in search and examination clearly demonstrated the positive impact of cooperation in the area of search and examination on the validity and the quality of granted patents worldwide. The Delegation added that the evaluation of the inventive step was essential for the patent system, and therefore, a deep understanding of the patentability requirement was critical. In that connection, the Delegation noted that different regional groups had declared interest in further studies and exchanges on that topic. The Delegation was of the view that the success of the various patent programs and regional work-sharing arrangements showed that that topic was not only of interest to industrialized Member States but was of interest to all Member States. Further, the Delegation pointed out the importance of quality of patents. In particular, the Delegation believed that the Committee should build on the importance of the work on technical topics, as was mentioned by many Member States, because it would lead to a higher quality of patents during the national patent examination process as well as granted patents. Further, the Delegation thanked the Secretariat for further study on inventive step (document SCP/28/4). In that regard, the Delegation looked forward for further work on that topic. In addition, the Delegation pointed out that it looked forward to the presentations on the proposal made by the Delegation of Spain (document SCP/28/7) as well as on the proposal made by the Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom (document SCP/28/9). Further, the Delegation pointed out that the work on the confidentiality issues between clients and their patent advisors would also contribute to that purpose. In its opinion, the protection of confidentiality might impact the quality of the patent protection process and the quality of the patent to be issued. Further, the Delegation pointed out that the users of the patent system had expressed their need to work in a trustful environment throughout the entire patent prosecution process, including cross-border situations. Taking into account the differences in patent protection provisions, the Delegation believed that the convergence of approaches in the form of a soft law would contribute to a predictable, more qualitative patent framework. In that regard, the Delegation stated that Group B was ready to engage in the discussions and to work on other issues related to exceptions and limitation to patent rights, patents and health as well as technology transfer. Further, the Delegation highlighted that during the discussions, the interests of all relevant stakeholders, including the broader public and right holders, should be

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

17. The Delegation of El Salvador, speaking on behalf of the Group of States of Latin America and the Caribbean (GRULAC), stated that the extensive experience of the Chair would help to guide the discussions and exchange of information in the Committee. Further, the Delegation noted that the Chair had the support of its Regional Group to make headway with the different issues that should be discussed in the SCP. Additionally, the Delegation thanked the Secretariat for its excellent work in preparing the meeting and the published documentation. The Delegation stated that the activities of the Committee were highly important as they dealt with issues of substantial impact for the development of all Member States. Further, the Delegation pointed out that substantive issues such as exceptions and limitations to patent rights, patents and health and the transfer of technology were matters of special importance for its Group. The Delegation stressed the importance of advancing work on the quality of patents, because the Delegation believed that the work on that topic was crucial for access to new technologies, in general and technologies linked to health, in particular. Therefore, the Delegation looked forward to the discussions under Agenda Item 6. With regard to Agenda Item 5 on exceptions and limitations to patent rights, the Delegation thanked the Secretariat for documents SCP/28/3 and SCP/28/3 Add., and expressed its hope to continue discussions in that regard. With regard to Agenda Item 7, the Delegation highlighted the proposals contained in documents SCP/28/9, SCP/28/9 Add. and SCP/28/10. With regard to transfer of technology, the Delegation reiterated the importance of that topic for developing countries and LDCs. In particular, the Delegation continued to support information exchange sessions. Finally, the Delegation expressed its confidence in the productive and fruitful work of Committee.

18. The Delegation of Austria, speaking on behalf of the EU and its Member States, thanked the Secretariat for preparing the meeting. The Delegation was committed to continue the success of the previous session of the SCP, in constructively discussing and advancing on the five main topics of the agenda, and in deciding on the future work of the Committee. The Delegation stated that its Group was ready to engage in those discussions in a constructive manner on the basis of the agenda. In relation to the agenda of the SCP, the Delegation noted that it had been decided that that session of the SCP would further elaborate and discuss the non-exhaustive list of issues that had been discussed in the SCP during the previous sessions on a fact-finding basis. However, the Delegation emphasized that the harmonization of substantive patent law should be seen as the means and a long term aim of the SCP. With regard to the future work of the Committee, the Delegation stressed the importance of fact-finding work and discussions during the SCP. The Delegation felt that a work program of the twenty-eighth session should provide opportunities for all Member States to make steps forward on important issues. In particular, the Delegation stressed the importance of advancing work on the quality of patents, because the Delegation believed that the work on that topic would be of interest of Member States across the spectrum of development. The Delegation was keen to continue discussions on the topic of confidentiality of communications between clients and their patent advisors, as convergence of differing provisions would be of benefit to users of the patent system. On patents and health, the Delegation expressed its belief that any further work in that area should reflect a balanced approach, taking into account the various factors of relevance to patents and health. At the same time, the Delegation wished to recall that they could not go beyond the mandate of the SCP and WIPO, and that the discussions about factors of access to medicines other than patent protection should be left to more appropriate fora. With regard to discussions on the future work of the Committee, the Delegation expressed its hope that the Committee would agree on a balanced work program for future sessions. The Delegation reiterated the importance of retaining the delicate balance

between the topics discussed in the SCP. In particular, the Delegation pointed out that mutual understanding would enable Member States to create a beneficial work program for future sessions. The Delegation remained committed to the work of the Committee and looked forward to a constructive session.

19. The Delegation of China noted that it had always attached a high importance to the role of intellectual property in stimulating innovation, technology and economic development. In that regard, the Delegation reaffirmed its firm position to protect intellectual property. The Delegation stressed the importance of the SCP and, in particular, mentioned that the Committee remained a very important platform for discussions in relation to the international patent system. Therefore, the Delegation expressed its hope that with common efforts of all Member States, the patent system would play a better role in stimulating innovation, economic, social and technological development. The Delegation was pleased to see the efforts made by Member States in previous sessions of the Committee in order to maintain continuous development of the work of the SCP. In that regard, the Delegation thanked Member States as well as the Secretariat for the hard work during previous sessions. The Delegation remained committed to make progress with the discussions and information sharing sessions, particularly in relation to patents and health and technology transfer. In that regard, the Delegation stated that those topics were of vital importance for striking appropriate balance between the interests of right holders and the general public. The Delegation was also of the view that those discussions would help to realize the social value of a patent system. Further, the Delegation pointed out that they would assist Member States to further deepen their understanding and to learn about the work of other members in that regard. Finally, the Delegation stressed that due to differences among Member States, it was necessary to show more flexibility in taking into account the interests and the needs of all different parties on those topics in order to move forward. In conclusion, the Delegation expressed its hope to have fruitful discussions in order to advance the discussions with the SCP.

20. The Delegation of Tunisia supported the African Group's statement delivered by the Delegation of Morocco. The Delegation congratulated the Chair and the Secretariat for preparing the session and in particular for preparing document SCP/28/3. The Delegation acknowledged the progress made during previous sessions of the Committee on patents and health and transfer of technology. The Delegation thanked the Secretariat for the update of the SCP electronic forum in relation to certain aspects of national and regional patent laws. As regards the implementation of exceptions and limitations to patent rights into national laws, the Delegation pointed out constraints faced by developing countries and LDCs in making full use of patent flexibilities. In that regard, the Delegation expressed its willingness in applying those exceptions and limitations in order to access affordable and essential medicines for public health purposes. The Delegation therefore supported the African Group's statement that had underlined the use of patent flexibilities in the field of health by developing countries and LDCs. Further, the Delegation noted that access to medicines should not be a privilege but the right for everybody. The Delegation pointed out that it was also vital to achieving the aim of the SDG Agenda 2030 to ensure healthy lives and promote wellbeing for all at all ages. Finally, the Delegation stressed the important role of the SCP in that regard.

21. The Delegation of Iran (Islamic Republic of) expressed its fullest cooperation and constructive engagement in the course of the Committee's deliberations. The Delegation thanked the Secretariat for preparing the session, and aligned itself with the statement made by the Delegation of Indonesia on behalf of the Asia and Pacific Group. Further, the Delegation pointed out that the deliberation of the Committee in past years provided an appropriate platform for Member States to share ideas and experiences in an inclusive and constructive manner, despite the existence of different visions and priorities. The Delegation further noted that the agenda of the SCP included issues that covered essential areas for all Member States. In that connection, the Delegation pointed out that the discussions on the topic of exceptions

and limitations, patents and health and technology transfer were significant in promoting economic, social and cultural progress for all countries through technological innovation. The Delegation recalled the importance of the SCP's contribution in implementing the SDG's recommendations. The Delegation further noted that extensive and in-depth exchange of information on the issues under the agenda items of the SCP would assist Member States to further deepen their understanding, to learn from each another, and to improve domestic legislation and practices. With regard to Agenda Item 7 on patents and health, the Delegation recalled the SDG Agenda 2030. Specifically, SDG Goal 3 aimed at ensuring healthy lives and promoting wellbeing for all. The Delegation also took note of document SCP/28/5 on the disclosure of International Nonproprietary Names (INN) in patent applications and/or patents. The Delegation thanked the Delegations of Canada, Brazil and Switzerland for their proposal contained in document SCP/28/9 and expressed its willingness to realize that proposal. In addition, the Delegation expressed its hope that the SCP would agree a more ambitious work plan in line with the proposal of the African Group for a WIPO work program on patents and health (document SCP/24/4). In particular, the Delegation noted that patent flexibilities were imperative for developing countries and LDCs to streamline their social, economic development priorities in their overall intellectual property policy making process. The Delegation therefore welcomed document SCP/28/3. The Delegation was of the view that the SCP should continue its work in that regard in order to create a useful reference tool for Member States in the process of designing their patent law and policies. Further, the Delegation noted that the patent system should contribute effectively in fostering innovation for the broader human and social development in all countries by facilitating transfer of technology. Consequently, the Delegation expected the Committee to discuss the key issues of how patents could be a barrier to the transfer of technology and expressed its hope to see progress in that area. The Delegation also looked forward to the sharing session on transfer of technology. Finally, the Delegation reiterated its belief that the international harmonization of patent law, given the variations in levels of social, economic and technological developments, and significant differences between approaches and objectives among national patent laws, would not benefit the Member States. In conclusion, the Delegation expressed its hope that the Committee would make significant progress in advancing discussions on issues of particular relevance to the common interests of the Member States.

22. The Delegation of India aligned itself with the statement made by the Delegation of Indonesia on behalf of the Asia and Pacific Group. The Delegation noted that WIPO had an enormous responsibility in ensuring a right balance between innovations and socio-economic development. The Delegation believed that the TRIPS flexibilities had made a significant advance for individual Member States to design their domestic patent laws. Therefore, the Delegation noted that it was not in a position to support the process of harmonization of patent law. Further, the Delegation was of the view that quality of patents was the most essential element of the patent process. In that regard, the Delegation mentioned that the patent examination process as well as opposition systems played a vital role. In particular, the Delegation was of the view that a well-defined opposition system added value to the process of the patent examinations and helped to ensure quality in patent claims. Further, the Delegation expressed its appreciation that the Committee scheduled the discussions on the important issues under the agenda item on patents and health. The Delegation also expressed its appreciation for the UNHLP Report on access to medicines. The Delegation was of view that Member States should comply with Article 27 of the TRIPS Agreement in order to avoid ever-greening of patents and to support public health priorities. In that context, the Delegation welcomed the proposal made by the Delegations of Brazil, Canada and Switzerland (document SCP/28/9). Further, the Delegation welcomed the sharing session on the subject of transfer of technology. In its view, a significant progress on the subject of transfer of technology and its connection with the patent system had been made. On the subject of confidentiality of communications between clients and their patent advisors, the Delegation believed that that question was not a substantive patent law issue and should be governed by the law of

evidence. Finally, the Delegation looked forward to the sharing sessions and information exchange sessions on the various agenda items. The Delegation remained committed to a constructive and participative discussion on those issues in the twenty-eighth session of the SCP.

23. The Delegation of Egypt supported the statement made by the Delegation of Morocco on behalf of the African Group, and thanked the Secretariat for preparing the session. The Delegation stated that patents should not be used to obstruct access by some countries to modern technology. Further, the Delegation noted that the role of the patent system was to promote development of technological progress. The Delegation conferred that patents must play a positive role in improving public health and balancing the rights of inventors and public interest. Therefore, the Delegation was of the view that WIPO must play its role as an agency within the United Nations in order to fulfill the sustainable development, particularly in public health. The Delegation appreciated the efforts of the Secretariat in preparing the document regarding constraints of developing countries and LDCs in making full use of patent flexibilities, in particular, in relation to Article 27 of the TRIPS Agreement. In particular, the Delegation was of the view that WIPO should provide additional information regarding the essential medicines list as well as information about their prices. Further, the Delegation stressed the importance of quality of patents. In that regard, the Delegation looked forward to further improvements in the quality of drugs, patent examination and patent specifications and standards of drug registration. In particular, the Delegation stressed that a patented drug should always involve an inventive step. In addition, the Delegation stressed the importance of the capacity of patent examiners in different national offices to improve their skills in that regard. Further, the Delegation noted the importance of exceptions and limitations to patent rights and their effect on public health. In particular, the Delegation welcomed one single document which contained a list of all exceptions and limitations. Further, the Delegation supported the African Group's proposal on patents and health. The Delegation was of view that the Committee had not made progress in that regard. In addition, the Delegation took note of the proposal made by the Delegations of Brazil, Canada and Switzerland (document SCP/28/9) and expressed its hope that that proposal would make a positive contribution to the Committee's discussion.

24. The Delegation of the Republic of Korea expressed its appreciation for the Chairs' excellent leadership and expertise. Further, the Delegation thanked the Secretariat for preparing the session of the SCP. The Delegation stated that the SCP was one of the important committees for Member States to engage in substantive, fruitful discussions on technical issues in relation to patent law and international cooperation. In particular, the Delegation noted that the SCP provided the opportunity to discuss important issues, such as exceptions and limitations to patent rights, quality of patents, technology transfer as well as patents and health. Further, the Delegation expressed its hope for balanced patent system in order to effectively recognize and protect intellectual creations of inventors. In particular, the Delegation expressed its belief that so-called social innovation would positively influence the lives of people. Finally, the Delegation expressed its hope for fruitful discussions, and stated that it was ready to engage in those discussions in a constructive manner.

25. The Delegation of Brazil thanked the Chair, the Vice-Chairs as well as the Secretariat for preparing the session. The Delegation supported the statement made by the Delegation of El Salvador on behalf of GRULAC. The Delegation expressed its willingness to reach a consensus on a balanced work program which would help to fulfil the main objectives of the patent system such as the promotion of economic, social and cultural progress for all countries through technological innovation. The Delegation expected that the sharing sessions would be very productive and would help to enhance the mutual understanding on the various topics of the agenda, including opposition systems, patents and health, confidentiality between clients and their patent advisors and technology transfer. As regards the exceptions and limitations to patent rights, the Delegation stated that they were essential to promote a better

balance between the interests of the patent holders and the interests of society. The Delegation was of the view that such balance contributed to strengthening the credibility of the intellectual property system and encouraged its wider acceptance as an important tool for the promotion of innovation, creativity and development. In that connection, the Delegation especially welcomed the second draft reference document regarding exception on acts for obtaining regulatory approval from authorities (document SCP/28/3). The Delegation also welcomed additional exchange of views on quality of patents and opposition systems. In its view, knowledge sharing on that matter would contribute to the mutual understanding of patent laws and procedures for the benefit of all Member States. The Delegation therefore thanked the Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom as well as of Spain for their proposals. On patents and health, the Delegation expressed its belief that innovation, bolstered by the patent system, had produced a number of important technologies that had improved health outcomes worldwide. The Delegation further stated that innovation was also vital to achieving the aim of the SDG Agenda 2030 to ensure healthy lives and promote wellbeing for all at all ages. It further stated that while the extent of the needs differed between countries, it was as much an agenda in the richest countries in the world as it was in least developed countries. The Delegation stated that the SCP was the most appropriate forum for Member States of the United Nations to discuss and try to find ways to ensure that the patent system provided the most meaningful contributions to public health priorities. In that regard, the Delegation supported proposals contained in documents SCP/28/9, SCP/28/9 Add., and SCP/28/10. In its view, those proposals could accommodate the diverse viewpoints of Member States as well as contribute to the development of a balanced and effective international intellectual property system. In addition, the Delegation supported the proposal of the African Group on patents and health, contained in document SCP/24/4. Further, the Delegation wished to stress that pursuing a better alignment between IP, trade and health policies was an ongoing, endless process. The Delegation encouraged other Member States to develop a balanced and effective international patent system which promoted and rewarded innovation in a manner supportive of public policy objectives. The Delegation was convinced that those objectives were mutually reinforcing. Finally, the Delegation looked forward to meaningful discussions in the sharing sessions, and expressed its willingness to have an open dialogue with all Member States.

26. The Delegation of Côte d'Ivoire expressed its gratitude to the Chair for his commitment and professionalism. The Delegation thanked the Secretariat for the quality of the documents prepared for the session. The Delegation aligned itself with the statement made by the Delegation of Morocco on behalf of the African Group. The Delegation noted that the SCP played an important role in the restoring of balance within the global system of intellectual property. In that regard, the Delegation pointed out that Member States should reach mutually beneficial agreements, especially, in relation to patents and health. Further, the Delegation noted equal importance of all topics of the agenda. Finally, the Delegation expressed its hope that a consensus and successful results would be reached by the Committee at its twenty-eighth session.

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

27. The Secretariat presented document SCP/28/2.

28. The Delegation of Lithuania, speaking on behalf of the CEBS Group, thanked the Secretariat for preparing document SCP/28/2. In particular, the Delegation expressed its appreciation for hard work, done by the Secretariat, that allowed to keep the SCP Electronic

Forum up-to-date. The Delegation pointed out that the SCP Electronic Forum was an important source of information that highly contributed to better awareness in relation to different aspects of regional and national patent laws.

29. The Delegation of Switzerland, speaking on behalf of Group B, thanked the Secretariat for the preparation of document SCP/28/2. In addition, the Delegation also thanked Member States that provided input on changes in their national patent laws. The Delegation pointed out that the regularly updated SCP Electronic Forum website was an important source of information. In particular, the Delegation was of the view that the data contained in the SCP Electronic Forum provided insights into various patent legislations and it contributed to a better understanding of the international patent system.

30. The Delegation of Austria, speaking on behalf of the EU and its Member States, thanked the Secretariat for preparing document SCP/28/2 and updating the SCP Electronic Forum. The Delegation thanked the Delegations of Australia, Bosnia Herzegovina, the Dominican Republic, Kyrgyzstan, Morocco, the Philippines and the Eurasian Patent Organization for their input, based on which the SCP Electronic Forum website had been updated. The Delegation believed that the website served as a useful reference in the SCP discussions and a good basis for better understanding certain aspects of national and regional patent laws. Consequently, the Delegation considered that it was important to keep such tool up-to-date.

31. The Delegation of Belarus thanked the Secretariat for updating the SCP Electronic Forum and preparing the session. The Delegation noted that the SCP Electronic Forum was a unique source of information on issues of national and regional patent laws. Further, the Delegation presented changes in the patent legislation of Belarus. In particular, the Delegation noted that methods of medical treatment had been excluded from patentable subject matter. In addition, pre-clinical and clinical trials were not considered as patent infringement under the amended law. Finally, the Delegation expressed its hope that successful results would be reached by the Committee at its twenty-eighth session.

32. The Delegation of Mexico thanked the Secretariat for preparing the session. The Delegation informed the Committee on recent legislative changes on patents and utility models. Among others, divisional patent and utility model applications will be published, the term for submitting observations related to the accomplishment of articles 16 and 19 of the Mexican Industrial Property Law will be reduced from six to two months, and the files of patent and utility model applications will be open to the public. Further, the Delegation stated that the aim of those changes was to establish the highest international standards in the area of intellectual property. Finally, the Delegation reported that recent legislative changes were available at the WIPO Lex Database.

33. The Delegation of Ireland reported on changes in their national patents law. In particular, the Delegation noted that substantive examination had been introduced into legislation. Further, the Delegation noted that further change would allow observations by third parties to be made during the application process. In conclusion, the Delegation pointed out that those amendments had been introduced with a view to enhancing the quality of national patents in Ireland.

34. The Delegation of South Africa thanked the Secretariat for preparing the session. Further, the Delegation noted that in accordance with recent legislative changes, a depository system for patents had been replaced by a substantive examination system.

35. The Delegation of Germany thanked the Chair and the Secretariat for preparing the meeting. The Delegation looked forward to the discussions on quality of patents and patents and health. Further, the Delegation provided an up-date regarding amendments to the German Patent Law. In particular, the Delegation noted that a new amendment enabled the German Patent and Trade Mark Office (DPMA) to reproduce works protected by copyright and to make those works available to the public for the purpose of examination of the state of the art. In addition, the Delegation stated that authors of those works had been entitled to remuneration. The Delegation was of the view that that amendment would facilitate the work of patent examiners and enhance the quality of patents.

36. The Delegation of the Dominican Republic thanked the Secretariat for preparation of the session as well as for updating the SCP Electronic Forum in relation to the legislation of the Dominican Republic. Further, the Delegation stated that recent changes in the legislation were not legislative changes but had primarily an administrative focus.

37. The Representative of the EAPO thanked the Secretariat for preparing the meeting. Further, the Representative provided updates on recent changes in relation to sufficiency of disclosure. In particular, the Representative stated that sufficiency of disclosure became an independent ground for patent revocation. Further, the Representative mentioned that the EAPO accepted third-party observations concerning the patentability of an invention in a patent application.

38. The Delegation of Ukraine thanked the Secretariat for preparing the session and, in particular, document SCP/28/2 on certain aspects of national/regional patent laws. The Delegation also expressed its gratitude to the Secretariat for updating the website of the SCP and stressed the importance of the SCP work. In relation to changes envisaged in the legislation of Ukraine, the Delegation noted that should new amendments be adopted, it would inform the WIPO Secretariat and the Committee.

39. The Representative of the GCC Patent Office informed the Secretariat that it had prepared a revised law that contained a number of elements touching upon the quality of patents. In particular, the Representative noted that a number of issues, such as the publication of patents and patent revocation were taken into account. The Representative expressed its hope that those changes would promote the quality of patents within the GCC.

AGENDA ITEM 5: EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

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

41. The Secretariat made a presentation on document SCP/28/3. The presentation is available at:
http://www.wipo.int/edocs/mdocs/scp/en/scp_28/scp_28_a_e_l_reference_document_wipo.pdf.

42. The Delegation of Indonesia, speaking in its national capacity, noted that document SCP/28/3 was very useful for all Member States and thanked the Secretariat for preparing the document. In particular, the Delegation stated that document SCP/28/3 provided a comprehensive description of the regulatory review exceptions as well as its policy objectives and goals. Further, the Delegation noted that exceptions and limitations to patent rights was one of the important issues of the agenda. The Delegation looked forward to further development of document SCP/28/3. Finally, the Delegation expressed its hope for having a similar draft reference documents in relation to research exception and compulsory licensing.

43. The Delegation of Switzerland, speaking on behalf of Group B, thanked the Secretariat for the preparation of document SCP/28/3 and for its presentation. The Delegation recognized that innovation in all technological fields was fostered by an effective patent system where a delicate balance between the interests of the right holders and that of the wider public was maintained. The Delegation believed that the current system of intellectual property fully integrated the balance between private and public interests. The Delegation pointed out that exceptions and limitations were part of national and international patent systems. The Delegation recognized that the use of exceptions and limitations was at times appropriate in specific circumstances. The Delegation stressed that the use of exceptions and limitations, in a way that undermined the incentives provided by the system of patents, could 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, which included expert studies, questionnaires, seminars, and Member States contributions, including practical experiences and case studies. The Delegation referred to the extensive documentation found on WIPO's website. The Delegation observed that such valuable references were available to any country that considered its domestic legislative arrangements and sought to adjust them according to its special needs and priorities. Therefore, the Delegation believed that the discussions and work under Agenda Item 5 had produced sufficient information for reflections on the implementation of exceptions and limitations.

44. The Delegation of Morocco, speaking on behalf of the African Group, noted that countries have flexibility to design national patent laws in accordance with the economic realities and levels of development of the individual Member States. The Delegation reiterated the importance that they attached to the issue of exceptions and limitations to the patent rights. In particular, the Delegation noted that exceptions and limitations enabled developing countries to design their national patent laws in accordance with their level of development. The Delegation was of the view that the SCP had not made substantial progress on the subject of exceptions and limitations to patent rights. In particular, the Delegation noted that a work program for developing countries had not been approved. In that regard, the Delegation supported the proposal made by the delegation of Brazil regarding exceptions and limitations to patent rights (document SCP/19/6). Further, the Delegation thanked the Secretariat for the preparation of document SCP/28/3 and for its presentation. The Delegation was of the view that document SCP/28/3 provided a review of the policy and opinions, objectives, and the scope of the regulatory review exception. In particular, the Delegation noted that that document contained specific examples of how the exception had been implemented in various national and regional laws as well as the results of its implementation, and challenges faced by Member States in implementing the exception. In that regard, the Delegation believed that document SCP/25/3 provided valuable information for interested Member States and helped them to design their national patent laws in accordance with best practices. Finally, the Delegation encouraged WIPO to use that document in the area of technical and legislative assistance for Member States. In conclusion, the Delegation looked forward to further discussions on that agenda item.

45. The Delegation of Austria, speaking on behalf of the EU and its Member States, thanked the WIPO Secretariat for preparing document SCP/28/3 on the exception to patent rights regarding acts for obtaining regulatory approval from authorities. The Delegation was of the view that that document was a good basis for further discussions on exceptions and limitations to patent rights. Further, the Delegation highlighted the broad information and resource space from which the document had benefitted. The Delegation observed that, as noted in the introduction, the primary source of information for the preparation of the reference document was collected through SCP activities as well as inputs made by Member States and regional patent offices. The Delegation believed that it affirmed the significance of the SCP and its work. In particular, the Delegation specified that the examples of some countries included in the second draft were very helpful in order to understand different legal practices in that regard. In

particular, the Delegation specified that it provided challenges faced by Member States in implementing the exception. As to the challenges faced by Member States in implementing such exception, the Delegation noted that it appeared that those challenges were mostly related to uncertainty about the scope of the exception in the national laws and lack of awareness about that exception among potential users. The Delegation also noted that such challenges could be addressed by relevance and carefully targeted awareness raising and training activities. The Delegation expressed its interest to learn more about various legal approaches of implementing the exception. The Delegation concluded that it did not appear to be a specific need for normative work at the international level concerning the regulatory review exception at that stage. The Delegation expressed the support of the EU and its Member States for initiatives which contributed to the Committee's knowledge and understanding of the topic of exceptions and limitations, in general, and regulatory review exception, in particular. The Delegation reiterated the utmost importance of striking an appropriate balance on the work of exceptions and limitations to patent rights and on the legal standards used to determine whether an invention complied with the patentability criteria, such as novelty, inventive step, and industrial applicability. Further, the Delegation stated that only the right balance between the interests of the right holders and the general public guaranteed that the patent system was beneficial to economies of Member States. In conclusion, the Delegation expressed its hope to have fruitful discussions in order to advance the discussions of the SCP.

46. The Delegation of China thanked the Secretariat for the considerable work. As regards document SCP/28/3, the Delegation noted that that document provided a very useful guideline. Further, the Delegation noted that according to the Chinese Patent Law, acts for obtaining regulatory approval from authorities was not considered as a patent infringement. The Delegation stated that the implementation of that provision had produced very positive impact. Further, the Delegation stated that the work of the Secretariat in that regard was very important in order to improve national and regional patent laws. The Delegation believed that exceptions and limitations represented, in most of the countries, very important legal provisions, since they struck a balance between the public interest and the rights of patent holders. Finally, the Delegation supported further discussions on document SCP/28/3 which could serve as a reference document for all Member States.

47. The Delegation of Iran (Islamic Republic of) believed that exceptions and limitations to patent rights played a fundamental role in supporting the appropriate balance of the patent system, as they provided a balance between the interests of the public and those of the rights holders. Further, the Delegation noted that exceptions and limitations to patent rights had a direct and indirect link to the sustainable development goals and played an important role in the social and economic development. The Delegation took note of document SCP/28/3 and expressed its appreciation to the Secretariat for preparing that document. The Delegation believed that the document provided valuable examples of full use of the scope of the regulatory review exception at national and regional levels. The Delegation further considered that such document would assist Member States to have a clearer picture of such exception and a better understanding of how to implement it and benefit from it. Further, the Delegation aligned itself with the statement made by the Delegation of Indonesia on behalf of the Asia and Pacific Group and requested the Secretariat to use that document in its technical and legislative assistance provided to WIPO Member States. The Delegation further observed that in the health sector, the empirical evidence showed that the Bolar exception had contributed directly to the reduction of prices of medicines and medical devices, since it prevented the artificial extension of the patent protection and undue delay in the commercialization of generics and biosimilars. Therefore, the Delegation concluded that the regulatory review exception had helped to increase societal welfare without violating in any way the legitimate rights of patent holders. Finally, the Delegation expressed its hope for future work in that regard and looked forward to a similar draft reference documents in relation to other exceptions and, in particular, compulsory licensing.

48. The Delegation of Lithuania, speaking on behalf of the CEBS Group, thanked the Secretariat for the preparation of the second draft reference document on exception to patent rights regarding acts for obtaining regulatory approval from authorities. The Delegation noted that the SCP had already carried out fundamental work in the area of exceptions and limitations, including expert studies, questionnaires, seminars and case studies. Further, the Delegation noted that factual information included in the second draft was a good source of different legal practices. In addition, the Delegation mentioned Section 6 of document SCP/28/3 in relation to challenges faced by Member States in implementing the exception. In that regard, the Delegation was of the view that uncertainty in relation to the scope of the exception in the national laws provided an indication of the need of training activities. Furthermore, the Delegation believed that there was no specific need for normative work at the international level concerning the regulatory review exception at that stage. The Delegation favored an approach where appropriate balance was achieved between the interests of right holders and the general public on work on exceptions and limitations to patent rights and on the legal standards used to determine whether an invention was patentable, such as novelty, inventive step and industrial applicability. The Delegation looked forward to hearing the views of other participants on that issue.

49. The Delegation of Brazil commended the Secretariat for the elaboration of the second draft reference document on exceptions and limitations to patent rights contained in document SCP/28/3 and SCP/28/3 Add. The Delegation noted that exceptions and limitations were an integral and necessary part of a strong and healthy patent system. The Delegation reminded all members that a basic tenet of the patent system was that legislation should provide incentives that led to new discoveries and inventions, while ensuring that those incentives were not overly restrictive and did not create barriers to innovation and the dissemination of knowledge. The Delegation believed that it was under such framework that the role of exceptions and limitations should be addressed. The Delegation stated that all Member States had the legal and moral obligation to pursue the best balance between the interests of the IP right holders and the interests of society as a whole. The Delegation was of the opinion that preserving such balance was the best way to safeguard the legitimate interests of IPR holders. The Delegation was of the view that in that regard, the regulatory review exception, known as the Bolar exception, played an important role in ensuring the realization of that balance, especially by ensuring that the market power granted by a patent did not create anti-competitive externalities. In the Delegation's view, the structure of the document was balanced and reasonable. In addition, the Delegation stated that Brazil had provided additional contributions to document SCP/28/3. As for the future program, the Delegation believed that compulsory licensing should be addressed by the SCP. The Delegation further observed that in the health sector, the empirical evidence showed that a balanced and thoughtful use of compulsory licensing had contributed directly to the reduction of prices of medicines and medical devices. Therefore, the Delegation concluded that compulsory licensing had helped to increase societal welfare without violating in any way the legitimate rights of patent holders. The Delegation was convinced that it would provide guidance for Member States to adopt and implement more balanced and effective patent laws, conducive both to public policy objectives and to the promotion, transfer, and dissemination of technology.

50. The Delegation of Tunisia thanked the Secretariat for preparing documents SCP/28/3 and SCP/28/3 Add. In addition, the Delegation expressed its willingness to have further updates on that subject. Further, the Delegation looked forward to having new documents on other exceptions and, in particular, compulsory licensing. The Delegation noted that the SCP was the most appropriate forum for Member States to discuss those issues and try to find ways to ensure a right balance between the interests of right holders and the general public. Finally, the Delegation aligned itself with the statement made by the Delegation of Morocco on behalf of the African Group.

51. The Delegation of Chile thanked the Secretariat for the preparation of document SCP/28/3 and for its presentation. The Delegation stated that the implementation of that provision had produced very positive influence on the entry of generic medicines into the market without delay. Further, the Delegation noted that, in Chile, the public health authority was responsible for substantive examination of each request for regulatory approval exception filed in Chile. In addition, the Delegation noted that, in some cases, there was the possibility to request a regulatory approval through a simplified process, without providing certain documents. Finally, the Delegation encouraged WIPO to use the reference document in the area of technical and legislative assistance for Member States.

52. The Delegation of Romania thanked the Secretariat for the preparation of documents SCP/28/3 and SCP/28/3 Add. Further, the Delegation explained how that exception had been implemented into the legislation of Romania. In particular, the Delegation stated that that exception in Romania referred only to the medicinal products for human use. Further, the exception applied to authorization for marketing approval in Romania or in one of the EU Member States. Finally, the Delegation noted that the national agency of medicinal products in Romania was responsible for implementation of that exception.

53. The Delegation of India referred to the history of the discourse on exceptions and limitations in the SCP. Further, the Delegation stated that the SCP should focus on the use of some exceptions, such as compulsory licensing, parallel imports, government use and the Bolar exception, which were extremely important from the perspective of accessibility and affordability of medicines. As regards document SCP/19/6, the Delegation expressed its belief that the development of the patent system and the use of patent rights should operate in a balanced and sensible manner. In addition, the Delegation noted that it should meet the objective of providing protection for the moral and material interests of inventors and at the same time should meet the objective of promoting the enjoyment of human rights of other members of the society as well. Further, the Delegation attached great importance to the work of the SCP. In particular, as regards the current SCP session, the Delegation mentioned the importance of such agenda items as exceptions and limitation to patent rights, patents and health as well as transfer of technology. In relation to those issues, the Delegation reaffirmed its view expressed in the previous sessions of the SCP. Finally, the Delegation considered that patent rights could not be absolute, since public policies also implied the companies' obligations to benefit public at large. The Delegation therefore believed that those rights and obligations should balance each other. Finally, the Delegation thanked the Secretariat for preparing document SCP/28/3.

54. The Delegation of the Russian Federation thanked the Secretariat for preparing the session and, in particular, document SCP/28/3. The Delegation was of view that that document was very useful, because it contained legal provisions that had been adopted in the legislation of different countries. Further, the Delegation expressed its willingness that the SCP would continue to work on that issue. As regards future work, the Delegation noted that another reference document on how governments used that exception would be useful as well. The Delegation expressed the importance of the provisions on compulsory licensing, in particular, in the pharmaceutical industry. The Delegation pointed out that on June 1, 2018, for the first time in the Russian Federation, the Moscow Arbitration Court granted a compulsory license for pharmaceutical products as a court of first instance. In addition, the Delegation expressed its hope that the decisions of higher courts would be as favorable as the decision of the Moscow Arbitration Court. Finally, the Delegation looked forward to further discussions on exceptions and limitations to patent rights.

55. The Delegation of Argentina expressed its gratitude also to the Secretariat for the organization of the SCP meeting and the preparation of the documents. The Delegation believed that exceptions and limitations to patent rights were essential to provide the countries the norm setting space to be able to promote development and their national objectives. The

Delegation thanked the Secretariat for the preparation of document SCP/28/3 and for its presentation. The Delegation noted that such document compiled valuable and detailed information on a relevant issue for all the countries. Finally, the Delegation noted that document SCP/28/3 was very useful for all Member States.

56. The Delegation of Senegal aligned itself with the statement made by the Delegation of Morocco on behalf of the African Group and thanked the Secretariat for preparing document SCP/28/3. The Delegation encouraged WIPO to use that document in the area of technical and legislative assistance for Member States. The delegation was of the view that exceptions and limitations contributed to a balanced patent system taking into account the interests of right holders and the general public. Finally, the Delegation looked forward to having new documents on other exceptions and, in particular, compulsory licensing.

57. The Delegation of the United States of America thanked the Secretariat for the preparation of document SCP/28/3 and for its presentation. The Delegation was of the view that that document was a useful reference on how countries around the world utilized the provisions related to acts for obtaining regulatory approval from government authorities. Further, the Delegation stated that it could also be a good reference document for governments in order to update their patent systems. Finally, the Delegation looked forward to similar documents with respect to the issues contained in document SCP/16/3 on exceptions and limitations to patent rights.

58. The Representative of KEI commended the work of the WIPO Secretariat in preparing document SCP/28/3. The Representative observed that the document provided a detailed overview of the policy objectives that engendered the creation of the regulatory review exception and a comprehensive insight into its application in 71 countries. The Representative considered that, importantly, such document also described the challenges faced by countries in its implementation. Further, the Delegation mentioned that document SCP/28/3 cited a study produced for the European Commission, which estimated that the extension of the regulatory review exception to cover any medicines and marketing authorizations in any country would benefit the European pharmaceutical industry by reducing legal costs, such as freedom to operate studies, validity opinions, patent oppositions, and costs of infringement proceedings. As regards future work, the Representative requested the Secretariat to conduct a study on the implications of Article 27.3(a) of the TRIPS Agreement on the patentability of gene and cell-based therapies.

59. The Delegation of Switzerland, speaking on behalf of Group B, mentioned that any future work in relation to Agenda Item 5 should be conducted in a balanced matter, taking into account not only the interests of the general public but also the interests of the right holders. In addition, the Delegation stated that future work in that regard should be based on the extensive factual documentation and should contain contributions from Member States. Further, the Delegation pointed out that future work that would prejudice the outcome and represent a one-size-fits-all approach would not be acceptable. As regards a topic for the next reference document, the Delegation proposed: "Use of Articles on Foreign Vessels, Aircrafts and Land Vehicles".

AGENDA ITEM 6: QUALITY OF PATENTS, INCLUDING OPPOSITION SYSTEMS

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

61. The Delegation of Switzerland, speaking on behalf of Group B, thanked the Secretariat for the further study on inventive step as well as the SCP members that provided inputs to the study. The Delegation stated that the inventive step was a core patentability requirement and a

crucial factor for the quality and strength of the issued patents and of the patent system in general. The Delegation continued that the determination of inventive step was based on many specialized concepts, such as “prior art” and the “person skilled in the art”. The Delegation stated that the study on inventive step, contained in document SCP/22/3, and the sharing session on examples and cases relating to the assessment of inventive step held during the twenty-fifth session of the SCP, showed the complexity of the topic, the similarities, as well as some differences in the evaluation of that patentability requirement in various countries and regions. The Delegation noted that similar evaluation approaches could often lead to different results in different jurisdictions. The Delegation noted that documents SCP/28/4, SCP/28/7 and SCP/28/8 provided further important information on the practices of national and regional patent offices. The Delegation continued that, in the previous sessions, a large number of delegations from various regions had expressed their support for further work on inventive step. Noting that, as a matter of substantive patent law, inventive step was clearly within the mandate of the SCP, the Delegation expressed its belief that work on that topic would help examiners of patent offices of all Member States to improve their knowledge and skills to conduct an appropriate assessment of that important patentability requirement. Consequently, the Delegation wished to see the work to be continued on inventive step based on the proposal made by the Delegation of Spain (document SCP/24/3) in relation to the secondary indicia, selection inventions and the assessment of inventive step in the chemical sector. The Delegation requested the Secretariat to continue that study and to rearrange the information in a country-by-country format. The Delegation was of the view that it would help to find easily the relevant information. In addition, the Delegation pointed out that avoiding the use of hindsight by examiners was an important issue. In that regard, the Delegation requested the Secretariat to explore that topic in detail. Finally, the Delegation took note of documents SCP/28/7 and SCP/28/8.

62. The Delegation of Austria, speaking on behalf of the EU and its Member States, reiterated its support and commitment for advancing work of the Committee on the topic of quality of patents and inventive step. The Delegation noted that the concept of inventive step belonged to the heart and center of the patent system. In that regard, the Delegation thanked the Secretariat for providing a further study on inventive step and acknowledged the high quality of document SCP/28/4. In particular, the Delegation stated that that document would help to gain a better understanding of how each Member State understood the term “quality of patents”, in general, and “inventive step”, in particular. Further, the Delegation stated that, although there were various approaches in defining the term “quality of patents”, and that the meaning of the term might be different for each stakeholder in different contexts, there nevertheless appeared to be a similar understanding on the main issues. The Delegation was confident that the findings of documents would prove useful in carrying out the Committee’s work in the area of quality of patents. The Delegation requested further studies on inventive step, as suggested in document SCP/19/5 and SCP/24/3. The Delegation looked forward to discussions on common general knowledge and its combination with the state of the art as well as to juxtaposition and hindsight analysis. The Delegation continued encouraging the widespread use of work sharing and expressed its view that the information exchange session, such as the one scheduled for that session, would encourage more Member States to learn about, and participate in, such work sharing programs. Further, the Delegation noted that a better common understanding of opposition and administrative revocation mechanisms would lead to a more streamlined patent system. As regards future work, the Delegation reiterated its support for advancing work in the Committee pursuant to the proposals made by the Delegation of the United States of America, (documents SCP/19/4 and SCP/23/4), and by the Delegations of the Republic of Korea, the United Kingdom and the United States of America (document SCP/20/11), as well as earlier proposals concerning the “quality of patents” made by the Delegations of Canada and the United Kingdom (document SCP/17/8), by the Delegation of Denmark (document SCP/17/7), and by the Delegation of the United States of America (SCP/17/10). The Delegation expressed its commitment to advance work program on “quality of patents”, which would reflect key

elements of those proposals. Finally, the Delegation supported proposals contained in documents SCP/28/7 and SCP/28/8. The Delegation looked forward to constructive discussion on that agenda item.

63. The Delegation of Lithuania, speaking on behalf of the CEBS Group, reiterated its strong support to advancement of the work on the topic of quality of patents. The Delegation stated that the topic was at the core of the patent system. The Delegation noted that inventive step was an important part of the patent law and that proper evaluation of inventive step was a guarantee of a high quality patent system. The Delegation expressed its belief that all Member States would benefit from elaborating on understanding the concept of inventive step. The Delegation thanked the Secretariat for the preparation of document SCP/28/4 as well as Member States for their inputs. In particular, the Delegation noted that that document provided information on how Member States evaluate an inventive step. Further, the Delegation looked forward to the information exchange session and expressed its belief that it would enhance cooperation between patent offices in search and examination. The Delegation looked forward to discussions on documents SCP/28/7 and SCP/28/8, and welcomed further work in that regard. In conclusion, the Delegation reiterated its support to the proposals made by the Delegation of the United States of America (documents SCP/19/4 and SCP/23/4), and the Republic of Korea, the United Kingdom and the United States of America (document SCP/20/11 Rev.), as well as earlier proposals concerning the quality of patents made by the Delegations of Canada and the United Kingdom (document SCP/17/8), the Delegation of Denmark (document SCP/17/7), and the Delegation of the United States of America (document SCP/17/10). The Delegation looked forward to constructive discussion on that agenda item.

64. The Delegation of Morocco, speaking on behalf of the African Group, noted the importance of the issue of quality of patents and opposition systems. Further, the Delegation noted that the issue of opposition systems has not been sufficiently discussed in the recent SCP sessions. In that regard, the Delegation stated that the SCP should give equal consideration to opposition systems. The Delegation noted that the term “quality of patents” meant not only the quality of patents itself but also the quality of a patent grant process within the intellectual property office. The Delegation therefore considered that quality of patents had a close connection to patentability requirements and examination process. The Delegation noted that one of the fundamental characteristics of national and regional patent laws was that such laws were based on the concept of territoriality, and that patentability criteria in various countries were different. Therefore, the Delegation pointed out that quality of patents should be determined through the national patent laws. The Delegation was of the view that while the main aim of the SCP in that regard should be improving the quality of patents, it could not be addressed simply through the exchange of information sessions among intellectual property offices, since examination and opposition practices of intellectual property offices were not free from mistakes. Further, the Delegation mentioned that given the different levels of development, human resources, technical resources and various limitations in developing countries and LDCs, it was unlikely that some harmonization on that term would be achieved. Therefore, the Delegation was of the view that the best way to achieve quality of patents was retaining experienced patent examiners. Consequently, the Delegation stated that WIPO should increase its technical assistance and capacity building for patent examiners.

65. The Delegation of Iran (Islamic Republic of) took note of document SCP/28/4 and extended its appreciation to the Secretariat for preparing the document. Noting that divergent responses had been provided to the Questionnaire on the Term “Quality of Patents” and Cooperation between Patent Offices in Search and Examination, the Delegation was of the view that there was no common understanding on the term “quality of patent” among Member States. The Delegation was of the opinion 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. The Delegation considered that despite its importance, quality of patents should be left to the regulations at the national level and discussed and decided by national authorities, taking into account the national priorities of each specific country. The Delegation reiterated its position that such topic should not be construed as a tool for harmonizing patent law or for norm setting in the future. In addition, the Delegation expressed its belief that such understanding was in accordance with Article 27.1 of the TRIPS Agreement. In the view of the Delegation, the quality of examination needed to be improved substantially in conformity with the national policy objectives of each country. Furthermore, the Delegation observed that experience sharing might improve the quality of patents and also skills and technical expertise of patent officers through bilateral and regional cooperation between patent offices, as the responses to the questionnaire had indicated. Further, the Delegation took note of documents SCP/28/7 and SCP/28/8. The Delegation aligned itself with the position of the Asia and the Pacific Group with regard to equal prominence to the topic of opposition systems in the future SCP work program. In conclusion, the Delegation encouraged the Secretariat to focus on capacity building, such as development of databases, search tools, and similar instruments, including technical assistance and staff training for developing countries in order to enhance quality of patents.

66. The Delegation of Portugal thanked the Secretariat for further study on inventive step. The Delegation considered that study very important for all Member States and intellectual property offices in order to understand inventive step as a patentability criterion. The Delegation noted that it was very important to improve the quality management system of each national intellectual property office. The Delegation supported the proposal by the Delegation of Spain (document SCP/28/7). It was of the view that that proposal would help Member States to understand the real impacts of new technologies on the patent system. In addition, the Delegation supported the proposal by the Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom (document SCP/28/8). The Delegation reiterated its support and commitment for advancing work on quality of patents and for all the proposals that would improve the quality management system of each national office.

67. The Delegation of India reiterated its statement with regard to a study presented in document SCP/22/3 entitled "Study on Inventive Step". In particular, the Delegation noted that that document as well as document SCP/28/3 should not be construed as a tool for harmonization of the concept of inventive step. As regards to quality of patents, the Delegation noted that the essence of the patent system was transparency and disclosure. Therefore, the Delegation was of the view that inviting the general public in patent granting process would enhance transparency and quality of patents. In addition, the Delegation pointed out that it was essential to provide a mechanism whereby only good-quality patents were granted. The Delegation noted that a patent that had been granted after undergoing opposition proceedings would have higher credibility in terms of meeting the patentability requirements. The Delegation added that unnecessary patenting would restrict competition and therefore, lead to high prices. Consequently, the Delegation was of the view that opposition systems should form an integral part of the agenda item of quality of patents. In conclusion, the Delegation stated that the SCP was a very valuable forum for the useful exchange of views in relation to various patent-related issues, and quality of patents was one of the most important issues.

68. The Delegation of China thanked all Member States for their inputs in relation to quality of patents. The Delegation noted proposals contained in documents SCP/28/7 and SCP/28/8. The Delegation expressed its willingness to actively participate in discussions with regards to quality of patents. The Delegation was of the opinion that the issue of quality of patents was related to innovation, examination of patent applications, use of patents and patent protection. The Delegation noted that the definition of the term "quality of patents" was complex and that it could be measured by referring to several aspects, such as inventive step and the description of an invention. Further, the Delegation stated that the State Intellectual Property Office

of China (SIPO) was implementing the project aiming at improving the overall quality of patent examination and patents. In addition, the Delegation noted that the SIPO had already created a system for control and monitoring of patent examination. With regard to work sharing, the Delegation suggested that, in addition to cooperation among patent offices, the Committee focus its work on capacity building, such as the development of databases, search tools and similar instruments, technical assistance to developing countries, enhanced search and review, staff training and exchange in order to strengthen capacity building of intellectual property offices. The Delegation noted that the SIPO collaborated with more than 26 Member States and regions in that regard.

69. The Delegation of Brazil welcomed document SCP/28/4 as well as the exchange of views on the topic of “quality of patents”. The Delegation stated that knowledge sharing activities on that matter contributed to enhancing the mutual understanding of patent laws and procedures benefitting all Member States. The Delegation stressed that, for Brazil, patents of high quality were key to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare. The Delegation continued that, notwithstanding Brazil's position, the Member States' responses to the questionnaire had suggested that the term “quality of patents” had different meanings in relation to different factors, which was an expected and rather positive outcome, given the different stages of economic and social development of WIPO's membership. The Delegation noted that such results were in line with Article 27.1 of the TRIPS Agreement which did not define the patentability requirements, giving the governments enough room of maneuver to define and apply those criteria according to their needs and priorities. The Delegation stated that those needs and priorities were not static and that they changed over time. The Delegation continued that reaching a common definition for substantive patent criteria would encroach on the ability of Member States to attain national policy objectives of the intellectual property system. The Delegation emphasized that the protection of IP was not an end in itself but a means to further economic and social development. The Delegation was convinced that the policy space provided by the TRIPS Agreement could and should be used to meet public policy objectives without jeopardizing in any way the rights of patent holders. The Delegation reiterated that IP offices could greatly benefit from cooperation and knowledge sharing in the areas of capacity building, transparency measures and information technology tools, including access to patent database and specialized scientific publications which were fundamental for the elaboration of a comprehensive report on the prior art. The Delegation welcomed exchange of views on those areas and remained open to other suggestions on the topics. As regards document SCP/28/7, the Delegation was of view that that document contributed to the discussions in the SCP. The Delegation stated that the SCP work in that regard should not duplicate the work of the Committee on Development and Intellectual Property (CDIP). In addition, the Delegation took note of document SCP/28/8. In conclusion, the Delegation expressed its readiness for further collaboration in that regard.

70. The Delegation of the Republic of Korea stated that quality of patents was a key factor in effectively creating innovative technologies, protecting the right of an inventor and improving efficiency of patent administration by the government. The Delegation considered that collaboration between patent offices in the search and examination process, in other words, work sharing, was one of the efficient tools to promote and guarantee quality of patents. The Delegation therefore supported the proposal made by the Delegation of the United States of America on the study of work sharing (document SCP/23/4) as well as proposal by the Delegation of Spain concerning studies on inventive step (document SCP/24/3). In addition, the Delegation supported the proposals contained in documents SCP/28/7 and SCP/28/8.

Sharing session on opposition and administrative revocation mechanisms

71. The Delegation of Spain made a presentation on the opposition procedure which was provided in the Spanish Patent Law 24/2015. The presentation is available at: http://www.wipo.int/meetings/en/details.jsp?meeting_id=46439.

72. The Delegation of Colombia requested a clarification from the Delegation of Spain as regards to: (i) whether the oppositions filed with the Spanish Patent Office had resulted in delay in patent granting process; and (ii) how the Office had dealt with the opposition where requests had not been substantiated and the information submitted by the opponents were not relevant.

73. The Delegation of Spain responded to the Delegation of Colombia that pre-grant oppositions could indeed lead to a delay in the grant of a patent. The Delegation clarified that, depending on each case, the opposition procedure might take more than a year, or even 15 months if the opposition would go through the appeal process. The Delegation hoped that while, in general, the Office had granted patents fairly rapidly, that was one of the reasons for the introduction of a post-grant opposition. As regards the second question, the Delegation stated that documents submitted in the opposition requests were checked as regards to whether they were relevant to the case or not. The Delegation stated that they were aware that competitors would often try to oppose a patent, but they would not necessarily have good grounds for doing so.

74. The Delegation of Japan made a presentation on the patent opposition system in Japan. The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_28/scp_28_b_opposition_japan.pdf.

75. The Delegation of the United Kingdom stated that while there was no opposition system as such in its country, there were similar systems on which it wished to inform the Committee. The Delegation stated that the Patents Opinion Service had been launched in 2005 to help businesses to resolve patent disputes by providing a quick and affordable assessment relating to the validity or infringement of patents. The Delegation further stated that, such an opinion, although nonbinding in nature, could assist in resolving disputes before they escalated into litigation before the courts. The Delegation continued that, even when litigation was unavoidable, an opinion could help the parties to better focus their cases, and thus save time and money. The Delegation informed the Committee that the cost of filing the opinion was 200 pounds and the duration of the process was three months. The Delegation further stated that, in October 2014, the Patents Opinion Service was expanded so that opinions could be issued in respect of all aspects of patent validity, including subject matter excluded from patentability and sufficiency of disclosure. It was also expanded to cover questions of infringement and validity in respect of Supplementary Protection Certificates. The Delegation further stated that, in addition, where an opinion was issued indicating that the patent was not novel or lacked an inventive step, the UK IPO could start the process of revoking that patent. In the context of the current discussion concerning opposition systems and other administrative revocation and invalidation mechanisms, the Delegation wished to note that those changes made it easier for third parties to obtain an opinion from the UK IPO concerning the validity of a patent and introduced the power for the office to revoke a patent where such an opinion found the patent to lack novelty or inventive step. Further, the Delegation stated that there were also opportunities throughout the pre-grant process for third parties to provide observations on the patentability of a particular application before it was granted. The Delegation noted that while the UK IPO examiners would evaluate the application themselves and come to a reasoned decision on its allowability with respect to UK law, such third party observations could provide examiners with valuable information, which could help inform their decisions. The Delegation stated in conclusion that information on such systems could be found in UK IPO's website.

76. The Delegation of the United States of America wished to highlight three post-grant proceedings that took place at the USPTO: *inter partes* review, post-grant review (PGR), and the transitional program for covered business method patents (CBM). The USPTO's Patent Trial and Appeal Board administered those proceedings which allowed third parties to challenge the validity of a patent. The Delegation stated that, *inter partes* review was an administrative trial proceeding conducted by the Patent Trial and Appeal Board to review the patentability of one or more claims but only on the basis of novelty or obviousness and only relying on evidence based on patents and printed publications. The Delegation continued that the procedure was available starting nine months after patent grant or reissue, for as long as a patent was in force. The Delegation noted that there was no such time limitation for issued patents under their previous first-to-invent system. The challenger had to meet a high burden of proof to prevail in those types of proceedings. As regards the PGR, the Delegation stated that it was a separate administrative trial proceeding in which a patent might be challenged before the Board on broader grounds, such as subject-matter eligibility, novelty, obviousness, or any deficiency in the disclosure. Any type of evidence might be provided by the challenger. The Delegation further stated that the PGR process began with a third party filing a petition within nine months after the grant of the patent or issuance of a reissue patent. The Delegation stated that under PGR, the challenger had to meet a lower burden of proof to prevail. Further, as regards to the transitional program for CBM, the Delegation stated that it was an administrative trial proceeding for reviewing patentability in a claim of a covered business method patent. The proceeding employed the standards and procedures of a post-grant review. CBM was statutorily scheduled to sunset on September 16, 2020. The Delegation stated that the definition of what qualifies as a "covered business method" was narrow, so not all business methods could be challenged in a CBM review. The Delegation wished to highlight that those three proceedings were aimed at ensuring that the U.S. patent ecosystem was populated with high-quality patents. The Delegation stated that the PGR and CBM proceedings allowed for any prior art or deficiency not previously considered to be raised post-grant before an expert body of administrative patent judges at the USPTO for a limited time after grant. Further, the Delegation stressed that none of those proceedings should be characterized as "opposition proceedings". They could not be used to oppose the grant of a patent but rather provide a simpler path than litigation to review the validity of an issued patent if specific conditions were met. The Delegation noted that in the United States of America, such proceedings were more properly characterized as "re-examination systems".

77. The Delegation of Switzerland, speaking on behalf of Group B, stated that opposition and administrative revocation systems were an essential part of the patent prosecution process and that many Member States included such systems into their national patent laws. The Delegation further stated that some instruments allowed third parties to invoke possible arguments against patentability of the invention concerned, and others provided mechanisms to submit prior art documentations. The Delegation stated that those mechanisms supported the IP Office's work and could enhance the quality of the granted patents. Further, the Delegation noted that any opposition and administrative revocation systems needed to be accompanied by the right of a patent applicant to be heard. The Delegation welcomed the sharing session, which allowed the Committee to learn more about the various mechanisms and experiences with their application in different countries and regions.

78. The Delegation of China stated that opposition and revocation mechanisms were closely related to the quality of patent, and were relevant to the balance between the interests of patent right holders and those of the general public. Further, the Delegation wished to share its experience with regard to that matter. The Delegation stated that China had adjusted its opposition and revocation mechanisms twice through the amendments to the Patent Law. China's Patent Law, which had been adopted in 1984, had provided for a pre-grant opposition mechanism, stating that any person might submit his observations on an application which had not been in conformity with the provisions of the Patent Law within three months from the

publication of the application, so as to ensure that patent rights would not be granted to non-compliant applications. The Delegation noted that while the provision had been designed to guarantee the quality of patent, the outcome had not seemed to meet the intended objectives. In particular, the Delegation explained that, after its implementation, the number of oppositions filed had been as small as less than 1% of the published patent applications. Postponing the granting of all patents for three months for such a small amount of oppositions had not been conducive to the sufficient protection of the right holders' interest. In addition, some people had taken advantage of that procedure to impede the granting of patents, thus impairing applicant's interest. The Delegation continued that, to speed up examination and better protect applicants' interests, China had changed its pre-grant opposition procedure to a post-grant revocation procedure in the first amendment to the Patent Law in 1992. The new provision had stated that any person might request the Patent Office to revoke a patent which had not been in conformity with the provisions of the Patent Law within six months from the date of granting the patent. After six months from the date of publishing the grant of the patent, any person might request the invalidation of the patent. The Delegation stated further that removal of the pre-grant opposition procedure had achieved desired results, yet the revocation procedure had also been problematic in a way. The Delegation explained that the nature of the revocation procedure had been basically the same as that of the invalidation procedure, and the effects could also be realized through the latter. Therefore, the procedures had been redundant and complicated. In order to streamline the procedures and further improve the patent system, China had removed the revocation procedure in its second amendment to the Patent Law in 2000. Thus, only the invalidation procedure had been retained in China's Patent Law for the purpose of making it as simple as possible for the general public to challenge the validity of patent granting, thus balancing between the interests of the general public and those of the patent right holders. The Delegation further informed the Committee that China was making its fourth amendment to the Patent Law, and they were examining relevant systems to study how to further improve the quality of patent. The Delegation stated that they would further refine the relevant systems based on their practical needs.

79. The Delegation of the Czech Republic stated that in its country the legal framework related to technical solutions such as patents, utility models and supplementary protection certificates regulated both observations on compliance with the patentability and post-grant dispute procedures. The Delegation stated that, pursuant to Section 32 of the Czech Patent Act, any person could file the written observations on the patentability of the subject matter after the publication of the particular patent application. Persons who had submitted observations did not become a party of the patent application procedure; however, the patent applicant was informed of any observation submitted. The Czech IP Office would take a submitted observation into consideration when carrying out the substantive examination of the patent application. The Delegation continued that, pursuant to Section 23 of the Czech Patent Act, a patent might be revoked in total or in part, if subsequently the invention did not meet the requirements of patentability; or if it was not disclosed in a manner sufficiently clear and complete in the patent to be carried out by a person skilled in the art; or if the subject matter of the patent extended beyond the content of the patent application as filed or if the subject matter of the patent granted on the divisional application extended beyond the content of the patent application as filed; or if the extent of the protection arising from the patent was extended; or if the patent holder had no right to the patent. The Delegation further stated that the request for revocation of a patent could be filed by any person without proving a legal interest. It could be filed after the patent was granted, within the period of validity, at any time. The request could be also filed after the lapse of the patent but with the proof of a legitimate interest. Revocation of the patent would have a retroactive effect to the date on which the patent became valid, and when it was published in an official bulletin of the Czech IP Office. Further, the Delegation informed the Committee about the system of cancellation of a utility model. Specifically, the Delegation stated that according to Sections 17 and 18 of Act No. 478/1992 of September 24, 1992, on Utility Models, the registration of a utility model could be cancelled, in

total or in part, if its technical solution did not qualify for protection under Sections 1 and 3 of the Act (i.e., the novelty, mere professional skill, industrial applicability, and subject matter that did not fall under the following: those contrary to public interest, plant and animal varieties and biological reproductive materials, and production processes or work activities); the subject matter of a utility model was already protected by a patent with effects on the territory of the Czech Republic or utility model enjoying earlier priority; or the subject matter extended beyond the content of the application as filed. The Delegation continued that the request for cancellation of a utility model could be filed by any natural or legal person without proving a legal interest after registration of a utility model within its entire period of validity at any time. The request could be also filed after lapse of the utility model but with the proof of a legitimate interest. The Delegation further stated that cancellation of the utility model had the effect of the utility model not being registered in the register. It was published in an Official Bulletin of the Czech IP Office. The final decisions of the Czech IP Office could be reviewed by the Court. Finally, the Delegation informed the Committee that in 2017, five requests for revocation of patents and 16 requests for cancellation of utility models had been filed.

80. The Delegation of Mexico thanked all the delegations which intervened during the sharing session on opposition and administrative revocation mechanisms. The Delegation noted that such experience sharing allowed the Committee to learn about various international practices that sought to make the patent system more efficient. In that regard, the Delegation wished to provide information on the administrative invalidation mechanism provided in the Industrial Property Law (IPL). In particular, the Delegation stated that the IPL provided for an administrative invalidation procedure after the granting of the patent, either *ex officio* or on request by any person with a legitimate interest. The invalidation request was submitted directly to the Mexican Institute of Industrial Property (IMPI), which had the legal authority to deal with the procedure. The Delegation stated that according to the law, a patent could be invalidated on the following grounds: (i) it had been granted contrary to the provisions governing the requirements and conditions for granting patents laid down in Articles 16, 19 and 47 of the IPL, which established what was considered patentable subject matter, as well as the documentation and information that must accompany the application; (ii) the patent had been granted in violation of the provisions of the law in force at the time; in such a case, the legal representation of the patent applicant might not be challenged; (iii) the application had been abandoned during processing; (iv) the patent had been granted by a serious error or mistake, or it had been granted to persons who were not entitled to it. The Delegation further noted that this administrative invalidation procedure made the system transparent and guaranteed due process to interested parties. The Delegation stated that, for that reason, it believed that such invalidation mechanisms benefited and strengthened a patent system and improved the quality of patents in the interest of innovation and society. The Delegation also wished to report to the Committee that its legislation provided a mechanism where, after the publication of the patent application and prior to the substantive examination, any person not involved in the procedure could submit comments and documents that he or she considered relevant to the patentability of the invention. The Delegation noted that such a mechanism opened up the possibility of enriching prior art information, which the examiner might evaluate during the substantive examination. The Delegation stated that, while such a mechanism was not an opposition procedure as such, it did share the purpose of the opposition procedure, which was to improve the quality of patents granted by taking account of general public knowledge. In conclusion, the Delegation stated that the issue of “quality of patents” was of the utmost importance to Mexico and, therefore, it was most willing to continue to discussing it, as well as other related issues in the Committee.

81. The Delegation of the Dominican Republic thanked the delegations which had intervened and shared their experiences on the opposition and administrative revocation mechanisms provided in their respective countries. Further, the Delegation stated that in the Dominican Republic, during the pre-grant phase, after the publication of the patent application,

third parties have the opportunity to file for observations, pursuant to Article 21 of Law No. 20-00 on Industrial Property. Those observations were notified to the applicant so that they could submit comments, arguments or documents as appropriate, within 60 days from the receipt of the observations. The Delegation stated that the observations and their comments should be taken into account in the substantive examination of the application. The Delegation further noted that the observations did not stop the granting process. In addition, the Delegation stated that the procedure for post-grant cancellation, established by Article 34 of Law No. 20-00 on Industrial Property, could be initiated by any interested party.

82. The Delegation of France stated that its country was in the process of implementing the opposition system. The users of the system were being consulted and certain parameters for such future procedure should be defined. In particular, the Delegation stated that the grounds for filing an opposition request would be “traditional” ones, including the requirements for patentability and the addition of new matter going beyond the original disclosure. The timeframe during which an opposition might be filed would be nine months after the publication of the issuance of the patent. Any person would be entitled to file an opposition. The opposition fee would be 750 Euros. An appeal against the final decision of the opposition body would be possible at the Court of Appeal in Paris. The Delegation further stated that, in terms of the duration of the procedure, they were envisaging a duration which would be between 12 and 18 months, and there would also be the possibility of having an oral procedure. The Delegation expressed its hope that such a procedure would be put into place by the end of 2019.

83. The Representative of APAA stated that opposition procedures had been implemented in many jurisdictions. The Representative stated that, in Asian countries, the opposition system had been widely used for enhancing the quality of patents. The Representative stated that, speaking from experience in Japan, it had had a longstanding pre-grant opposition system until 1993, then, the post-grant opposition had been introduced, and in 2003, the opposition system had been abandoned. The Representative continued that the post-grant opposition system which was appreciated as an easier measure for challenging the validity of granted patent had been reintroduced in 2015. Turning to the experience in the Republic of Korea, the Representative stated that in that country it was found that the invalidation trial, which was a fully *inter partes* administrative revocation system, had been complementary to the opposition system, but that the opposition system could not be fully substituted by the invalidation trial. The APAA was of the view that the opposition system was beneficial for all stakeholders: for third parties, the opposition was a measure for challenging validity with less burden, and for patent offices, the opposition complemented substantive examination to improve the quality of patents. The Representative also noted that even for patent holders, the opposition was a good opportunity for reinforcing granted patents by narrowing the patent scope, amendment or limitation. In addition, patent holders could benefit from simplified procedures, such as consolidation of multiple opposition procedures. Finally, the Representative encouraged Member States to further share experiences on opposition systems to achieve higher quality of patents.

Discussion on a further study on inventive step (SCP/28/4)

84. The Secretariat made a presentation on document SCP/28/4.

85. The Delegation of Spain thanked the Secretariat for a preparation of a further study on inventive step, contained in document SCP/28/4, as well as those delegations which made contributions to the content of the document. The Delegation was pleased to see that its insistence on the topic had resulted in two documents which would remain as reference documents for the future. Further, noting that not all the elements of its proposal had been dealt with in that document, the Delegation expressed its hope that they would be included in the documents to be presented to the following session of the SCP. Further, turning to the content of document SCP/28/4, the Delegation stated that the content of sections on “common general knowledge: its combination with the state of the art” and “combination: juxtaposition verses synergic effects” showed that offices employed a fairly harmonized approach, although there were some specificities in different jurisdictions. The Delegation found it particularly interesting the section on the “dangers of hindsight analysis”. In that regard, the Delegation noted that hindsight, by definition, affected the evaluation of practically all stages of the inventive step and that it was almost impossible to avoid its influence, despite the various methods employed to overcome it.

Sharing experiences of Member States on cooperation between patent offices in search and examination, including sharing of information concerning the corresponding foreign applications and grants

86. The Delegation of the United States of America wished to present the updates on some work sharing projects in which the United States Patent and Trademark Office (USPTO) was taking part. The Delegation first focused on the IP5 Global Dossier project. In particular, the Delegation stated that the Global Dossier was a collection of services that allowed examiners to view application data from participating IP Offices around the world, including an application’s patent family and counter-part prosecution histories from multiple countries at a single access point without having to go to each country’s individual patent office website. The Delegation continued that, under the umbrella of the Global Dossier, there were a couple of new initiatives. The first initiative – the Citation List, was in beta testing. The Delegation stated that the Citation List recorded all the references cited in the patent family of a given application and that the listing was prioritized by the most commonly cited amongst all the patent family members to the least commonly cited. The Delegation informed the Committee that they were working to improve access to the Global Dossier, as well as its data coverage, which included increasing the scope of application types provided through the file wrappers, the data range of documents available, and ensuring the completeness of the image file wrapper. The Delegation stated that, in addition, the IP5 offices were in discussions on the feasibility of providing application documents in structured text format and providing limited legal status information and mechanisms to auto populate office-specific forms and documents. Further, turning to the PCT Collaborative Search and Examination Pilot, the Delegation informed the Committee that the third phase of the pilot was launched on July 1, 2018. The Delegation stated that, under the first two pilots, applicants had received a PCT search report and written opinion, which was based on the collaboration of examiners from the European Patent Office, the Korean Intellectual Property Office (KIPO), and the USPTO. The Delegation continued that, under the third pilot, applicants would receive a search report drawn up from the collaboration of examiners from all five offices. The pilot would last two years, and the process was an applicant-driven. The Delegation noted a positive feedback received from the users of the pilot. Further, the Delegation turned to the Collaborative Search Pilot Program under which applicants would receive the work product which would be the result of collaboration of work performed by the KIPO, JPO and the USPTO. The Delegation informed the Committee that the expanded pilot had started just before the ongoing session of the SCP, and that filings under that pilot were on par with what they had in the initial pilot. Finally, the Delegation turned to the Patent Prosecution Highway (PPH) and stated that, under the PPH, an applicant who received a positive work product from one of the participating PPH offices or from one of the PCT International Authorities in their search and examination reports could receive expedited

prosecution in another participating office. The Delegation continued that, like the PCT, which was the longest-running and most successful of the work-sharing regimes, the PPH continued as the next most successful work-sharing operation. The Delegation stated that at that time there were 48 IP Offices participating in various PPH agreements around the world, and that since its inception to the end of 2017, there were PPH requests made in over 145,000 applications. In conclusion, to show the benefits of the project to the offices, the Delegation stated that the allowance rate in the PPH cases over the past 12 months in applications filed in the USPTO was at 87.8%, and that that was a result of the prosecution that had already been performed in other offices and the fact that USPTO had been able to rely on their work efforts.

87. The Delegation of Switzerland, speaking on behalf of Group B, stated that with respect to cooperation between patent offices in search and examination, the responses in document SCP/27/5 indicated that wide range of cooperation activities existed at the bilateral, regional, and international levels. The Delegation continued that document SCP/27/5 also highlighted the positive impact of cooperation in improving search, examination and the validity of granted patents. The Delegation stated that, for example, prior art found by other offices complemented the search work of examiners, particularly where prior art documents were in foreign languages. The Delegation noted that, furthermore, examiners might consult opinions on patentability of other offices, since they provided the rationale behind the decision taken by the examiners of those offices. The Delegation stated that, particularly, it was reported that small offices with limited resources benefit from other offices' search and examination reports and from cooperation on substantive examination work with other offices. The Delegation continued that, further positive impact was the reduction of the pendency period and improved efficiency in patent examination through the utilization of search and examination work conducted by other offices. The Delegation stated that the PPH program was an example of a successful model for work-sharing. In particular, the Delegation noted that, PPH allowed fewer office actions, which led to reduced costs for applicants and the offices, and that it also gave the examiners a better starting point from which to start their prior art search. The Delegation observed that, in addition, many responses referred to improving professional knowledge and competitiveness of examiners and optimization of internal processes through cooperation with others. The Delegation stated that the information exchanging session on cooperation between patent offices, including sharing of information concerning the corresponding foreign applications and grants, would further enhance their understanding on the topic. The Delegation continued that the responses provided by offices of different sizes and levels of experience clearly indicated that work sharing was effective in enhancing quality of patents and assisting offices with more limited capacities to improve their capabilities, knowledge, and competencies. The Delegation stated that they wished to see that work on the topic proceeded based on the proposals put forward by the Delegation of the United States of America, contained in document SCP/23/4, addressing, among others, how work sharing could amplify the capabilities of patent offices, and how it could improve the availability of prior art and of search histories. The Delegation reiterated that the Committee should continue carrying out work on the technical topics that would contribute to a higher quality of patent prosecution, the national original patent examination processes and of the granted patents, since many Member States place high importance on those topics. The Delegation, therefore, believed that work on the topics of work sharing and collaboration, as well as on inventive step should proceed. Further, the Delegation reminded the Committee that document SCP/18/9 included further questions on information access, process improvements and technical infrastructure development that could serve as a basis for further work on quality of patents. In addition, the Delegation wished to recall the proposal contained in document SCP/20/11 Rev. which proposed, *inter alia*, the organization of annual conferences on work sharing and collaboration. In this regard, the Delegation noted that, such annual conferences would be a productive forum for sharing experiences and best practices and that they would allow to update the Member States on new work-sharing arrangements and to identify ways to increase the usefulness of

such arrangements. Further, noting that many countries had expressed their strong interest on future work on inventive step, the Delegation expressed its support for further work on the assessment of the inventive step based on the proposal contained in document SCP/24/3.

88. The Delegation of the Czech Republic expressed its wish to share information on the cooperation of the IP Office of the Czech Republic with other offices in the field of search and examination. In particular, the Delegation stated that the Czech IP Office was taking part in several projects in terms of search and examination. At the regional level, in 2015, the IP Office had joined the EPO Utilization Implementation Project (UIP). The UIP enabled the utilization of the result of patent examination performed by the IP Offices of the IPC Contracting States in the patent procedure before the EPO. Further, the Delegation informed the SCP that the Czech IP Office had joined the PPH and signed the relevant agreements with the USPTO, the JPO, the CIPO and the Finnish Patent and Registration Office (PRH). The Delegation continued that, based on the exchange of search and examination results, the PPH offered the accelerated patent procedure to applicants. The Delegation further stated that the bilateral agreements had been signed with the IP Offices of Austria, Croatia, Hungary, Finland, Poland, Slovakia and Spain. In those offices, the patent procedure was accelerated based on the submission of the search report elaborated by the respective contracting office. In conclusion, the Delegation stated that since July 1, 2016, the IP office, as one of the branch offices of the Visegrad Patent Institute acting as the International Searching and International Preliminary Examining Authority under the PCT, performed activities as the Visegrad Patent Institute. The Delegation stated that the Institute had joined the global PPH network in January 2018.

89. The Delegation of Ireland made a presentation on the topic entitled “Challenge of Providing Patent Quality in a Small IP Office”. The presentation is available at:
http://www.wipo.int/edocs/mdocs/scp/en/scp_28/scp_28_e_cooperation_ireland.pdf.

90. The Delegation of the United Kingdom made a presentation on the topic entitled “UK IPO: Sharing of Information Concerning Corresponding Foreign Applications and Grants”. The presentation is available at:
http://www.wipo.int/edocs/mdocs/scp/en/scp_28/scp_28_f_cooperation_united_kingdom.pdf.

91. The Delegation of the Dominican Republic made a presentation on cooperation between National Office of Industrial Property (ONAPI) and other patent offices in substantive search and examination. The presentation is available at:
http://www.wipo.int/edocs/mdocs/scp/es/scp_28/scp_28_g_cooperation_dominican_republic.pdf

92. The Delegation of Spain thanked the Delegation of the Dominican Republic for referring positively to the collaboration programs offered by the Spanish Patent and Trademark Office (OEPM) since 2002. The Delegation stated that every year, several patent examinations from the South American countries, such as Argentina, Cuba, Peru and Mexico, had been trained at the OEPM. The Delegation stated that those were mentors who would be able to train other examiners when they were back in their respective offices.

93. On behalf of Argentina, the Chair thanked the Delegation of Spain for collaboration of its office with the office of Argentina and stated that the offered trainings were producing positive results.

94. The Delegation of Trinidad and Tobago stated that its office was very small comprising of five examiners in total. The Delegation recognized that the number of examiners employed could be a limitation if the small office would try to do all the work by itself. The Delegation stated that, in that regard, its office took advantage of the PPH programs. The Delegation stated that, in fact, some years ago, they had been advised to take advantage of examination reports that were compatible with the national law so that there would not have been a need to

examine every single application from scratch. The Delegation further stated that they also recognized that small offices might not have access to all of the minimum documentation that the large offices had access to. Therefore, the Delegation stated, they had established some collaboration not just with the big national offices, but also with regional arrangements such as CADOPAT. In addition, the Delegation informed the Committee that it had recently signed MOU with the National Institute of Industrial Property of Chile (INAPI) for provision of search and examinations services to augment its own examination. The Delegation noted further that for small offices wishing to keep up with the examination, there were many opportunities for collaboration with other offices having a bigger capacity. Further, the Delegation stated that they had also been cooperating with the patent offices of the Caribbean region which had no patent examiners to resolve their backlogs. In conclusion, the Delegation expressed its gratitude to those offices which had been engaged in this type of collaboration activity and commended them to continue it, because it was vital for the small offices to survive.

95. The Representative of the GCC Patent Office stated that the topic of quality of patents and work sharing were very important topics and that patent offices of GCC had been engaged in work sharing collaboration since 2016. The Representative also stated that patent offices of GCC had been exchanging data through electronic means and that the system had recently been updated. Further, the Representative stated that GCC's law, which was at the stage of that development, contained a number of elements promoting high patent quality. The Representative further noted that it also implemented bilateral cooperation with other regional patent offices as well as with its Member States.

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

96. The Chair invited delegations to elaborate on the proposals contained in documents SCP/28/7 and SCP/28/8.

97. The Delegation of Spain elaborated on its proposal contained in document SCP/28/7 to conduct studies on new technologies and patentability. In particular, the Delegation stated that in recent years there had been a dizzying technological development that would sooner or later be reflected in patent law. The Delegation noted that, as the only multilateral forum in the field, the SCP could not remain external to that reality, where the so-called "Artificial Intelligence" (AI), "blockchain", "big data", etc., were playing an increasingly important role in many areas of life. The Delegation continued that WIPO was aware of that reality, as had been demonstrated in the report published in February 2018, where 37 Intellectual Property Offices indicated how they used those new technologies in their management. Likewise, the Delegation stated that WIPO's Director General, at the opening of the meeting about that topic in May 2018, stated that efforts should be made to explore how to cooperate internationally in that regard. In addition, the Delegation recalled that WIPO had announced the creation of a webpage where all the information and resources related to the issue would be collected. The Delegation therefore believed that it was timely, appropriate and of interest for all Member States that the Committee dedicated its attention to that topic. The Delegation further stated that the so-called "blockchain" was a distributed and difficult-to-alter database technology that was already being used in the world of patents. In that regard, the Delegation stated that it would be interesting to know under what circumstances the technology could be used, as well as its advantages and disadvantages compared to the current situation. For example, to determine the content of the state of the art or as a means of proof of prior use that could be used as defense against a possible accusation of alleged infringement. With regard to AI, the Delegation stated that its use would have an impact on the search for the state of the art, with repercussions on productivity increases, which would probably make it possible to deal with the examination of a constantly growing number of patent applications. The Delegation noted that AI presented a series of problematic situations that patent law would have to address sooner or later, as the current rules were not prepared for such a disruptive change. The Delegation continued that

many arose concerning AI. For instance, as to the current legal life of patents within that sector, would it be going to remain appropriate? Would the patent system have to be amended in order to cater for these inventions? How would the requirement of sufficiency of disclosure be met? To what extent would an adequate description of the “black box” that was sometimes used to represent the “neural networks” be necessary? Who would have the right to patents on an invention that would come from an AI program? And should inventions generated by artificial intelligence be patentable? Noting that these questions had relation to the assessment of inventive step and sufficiency of disclosure and were closely linked to quality of patents, the Delegation requested the Secretariat, if possible, with the assistance of renowned experts in the field, to carry out a study or studies addressing all or some of the aspects raised in points 6 to 8 of its proposal to be presented at the thirtieth session of the SCP. With reference to the decision of the CDIP in document CDIP/21/8 Rev. to address the topic “Intellectual Property and Development in the Digital Environment” at the twenty-third session of the CDIP, the Delegation stated that any kind of duplication should be avoided. However, the Delegation was of the view that the SCP was an appropriate forum to discuss those issues, particularly with regard to sufficiency of disclosure and inventive step.

98. The Delegation of the United Kingdom presented a proposal contained in document SCP/28/8. The Delegation believed that the proposal was a positive addition to the discussions on quality of patents. The Delegation stated that high-quality patents were incredibly important as they provided clarity and legal certainty for right holders, third parties, and society as a whole. In addition, the Delegation stated, high-quality patents incentivized innovation by providing appropriate rewards for new developments and facilitated the transfer of knowledge, ensuring granted patents were of a high quality, promoted access to new technologies, and reduced unnecessary litigation. The Delegation observed that the responses to the questionnaire on the term “quality of patents” showed a number of ways of interpreting the term. The Delegation stated that, nevertheless, it was clear that high-quality rights were important to all members of the SCP and were crucial to ensuring that the patent system worked effectively. The Delegation continued that, while it might not be possible to reach a single common definition of the term “quality”, document SCP/27/4 Rev. showed two main concepts or factors emerging from the questionnaire responses: firstly, the quality of the patent itself, and, secondly, the patent granting process within IP Offices. The Delegation further stated that, in light of that information, it felt that the Committee was in a position to pursue further work to understand those factors. The proposal contained in document SCP/28/8 from the Czech Republic, Kenya, Mexico, Singapore, and the United Kingdom focused on the second factor. In particular, the Delegation explained, it proposed activities which would help the Committee to understand the approaches taken by different delegations to ensure the quality of the patent-granting process. Noting that a number of delegations had provided some information on that topic in their responses to the questionnaire, the Delegation stressed that that indicated a keen interest amongst Member States in sharing their experiences in that area. Therefore, as an initial step, a sharing session was proposed. The Delegation stated that such a session would provide an opportunity for delegations to talk about their experiences and to learn from each other. The Delegation further stated that, as a second stage, a study on approaches to the quality of the patent grant process was proposed to be undertaken by the Secretariat based on the responses to the questionnaire on the term “quality of patents”, sharing session, and any further information provided by the Member States. The Delegation stated that the study would compile all that information and draw out key themes. The Delegation explained that the study would not make any recommendations and individual delegations could use the information in the study in a manner which would be appropriate to their individual circumstances. The Delegation anticipated that the outcomes of the activities proposed might inform additional work of the Committee. The Delegation further thanked the cosponsors of the proposal and all delegations for their input and discussions to date. The Delegation also thanked the Delegation of Spain for their very interesting proposal. The Delegation recognized that the application of IP to AI was an area of increasing importance and

agreed that there was great value in discussing that topic in an international setting. The Delegation stated that, for that reason, it was very pleased to facilitate the recent WIPO Meeting of Intellectual Property Offices on ICT Strategies and Artificial Intelligence for IP Administration. The Delegation continued that, in terms of further discussion at the SCP, it would be happy to see further work on the issue of AI, provided that would be limited to topics related to patent law.

99. The Delegation of Mexico aligned itself with the statement made by the Delegation of the United Kingdom. Furthermore, as the proponent of document SCP/28/8, the Delegation wished to emphasize the importance it attached to the issue of “quality of patents”, as it considered it to be a substantive and technical issue, which contributed to the improvement of the system as a whole. The Delegation further stated that an intellectual property system with high-quality patent examination not only ensured that innovators benefited from the protection they deserved for their developments, but also guaranteed that patents were not granted for technological aspects that were already legitimately in the public domain, thereby facilitating the dissemination of knowledge for practical application. It therefore considered it extremely important that the SCP continued to address that issue and that activities involving the exchange of information and sharing of experiences continued, together with those other activities that provided information on the practice and provisions contained in the national legislation of various Member States. The Delegation also noted that the proposal was without prejudice to the other proposals submitted under that agenda item, specifically the proposals of the Delegation of Spain, contained in documents SCP/28/4 and SCP/28/7, since they sought to address various elements that, taken as a whole, were aimed at guaranteeing the quality of patents. Finally, the Delegation wished to stress that the proposal did not attempt to include any recommendation or obligation for Member States to make modifications or inclusions in their national legislation; it was simply designed to share and collect information that Member States might, if they so wished, take into account in order to improve the effectiveness of the patent system, in accordance with their different needs.

100. The Delegation of the Czech Republic, as one of the cosponsors of the proposal contained in document SCP/28/8, wished to express its support for the work on quality of patents to be pursued as suggested in the document. The Delegation stated that the IP office of the Czech Republic was of the view that high quality search and examination was important for the high quality of patents. For that purpose, all products and processes related to the search and examination provided or carried out by the office of the Czech Republic were subject to the certification in line with the standard ISO 9001:2015. Under that agenda item, the Delegation saw a valuable opportunity to explore more the different approaches used by national or regional offices to ensure the quality of patent application procedures in its integral part, such as formality check classification, search, examination and publication. The Delegation expressed its readiness to actively contribute to that process, should the SCP agree on the future work in the direction proposed.

101. The Delegation of Australia thanked the Delegations of the Czech Republic, Singapore, Kenya, Mexico and the United Kingdom for their proposal contained in document SCP/28/8. The Delegation considered that the proposal was a logical extension from discussions at the previous session of the SCP and therefore it supported the proposal.

102. The Delegation of Chile thanked the Delegation of Spain for its proposal contained in document SCP/28/7. The Delegation noted that it was the first time that discussions on those types of topics were taking place within the Committee which represented changes of paradigms. Considering that the SCP was an ideal place to exchange good practices and experiences on the matters, the Delegation welcomed the proposal. The Delegation was of the view that holding the information session with participation of experts on those issues might be beneficial before undertaking the study by the Secretariat. The Delegation was open to work

with the Delegation of Spain to fine-tune the proposal in view of the preparation of the information session. Turning to document SCP/28/8, the Delegation welcomed the joint proposal and that the work on the quality of patents being continued. The Delegation stated that its country had responded to the questionnaire on the quality of patents, and it welcomed the fact that said information was duly reflected on the website of WIPO. The Delegation was of the view that an examination in greater details of the elements which made up the quality of patents focusing on the processes carried out by the IP offices would be useful. That would also enable the Committee to have an exchange of knowledge and ideas, according to the Delegation. On its part, the INAPI was ready to share its experiences.

103. The Delegation of Thailand expressed its support to the proposal made by the Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom, contained in document SCP/28/8. The Delegation stated that Thailand was one of the countries facing backlogs and delay in granting patents and that they had been trying to address those difficulties for many years. Therefore, the Delegation welcomed any study on different approaches adopted by the national and regional offices regarding search, examination and formality procedures, which it believed would be useful to other Member States. Regarding how Member States defined what constituted the quality of patents, the Delegation looked forward to exploring the proposal in greater detail.

104. The Delegation of the United States of America thanked the Delegation of Spain for its proposal contained in document SCP/28/7. The Delegation stated that technologies such as, AI, blockchain cryptography, Internet of Things and others were beginning to impact daily life globally and that their effect was expected to grow massively in coming years. The Delegation stated that the SCP was a great place to study how the patent system would accommodate those technological advances. The Delegation further noted the importance of focusing the inquiries on patent issues within the Committee. Those new technologies, the Delegation stated, might involve many aspects of IP which would be handled in other pertinent Committees. The Delegation expressed its belief that AI and other technologies had the potential to make the work of patent examiners more efficient and accurate and of higher quality. The Delegation was cognizant of the many questions and challenges that patent systems also had to address in deciding how and when to grant patents on those emerging technologies. With regard to the proposal by the Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom, contained in document SCP/28/8, the Delegation commended the efforts made by all to gather support for that work from such a diverse group of countries. The Delegation stated that improving the quality of patents continued to be a top priority for the USPTO. Noting that the topic was of great interest to many Member States, the Delegation stated that the quality of issued patents and of patenting processes was fundamental to ensuring that only inventions that met the requirements set forth in national legislations were granted a patent, thus protecting the balance of interest between inventors and society.

105. The Delegation of Colombia thanked the Delegation of Spain for its proposal contained in document SCP/28/7. The Delegation expressed its belief that the proposal was in full harmony with the discussions undertaken in WIPO in May where it had been shown that different IP offices had been using some form of AI, Big Data or blockchain to be able to improve their administrative efficiency. The Delegation continued that, moreover, the private developers of databases were offering their services to patent offices, which included methodologies to be able to find the state of the art through AI. The Delegation stated that a few years ago, that had made people think of science fiction but today it became a reality. Therefore, the Delegation supported the proposal from the Delegation of Spain. Regarding the proposal contained in document SCP/28/8, the Delegation stated that it was important to continue developing the proposed study. However, the Delegation wished to emphasize the fact that the quality of patents had different meanings for various Member States. The quality of patents in Colombia was understood as fulfilling the inherent patentability requirements established in the legislation.

However, the processing of the applications, procedures used by the office would also ensure the quality of patents. The Delegation further stated that several factors, including having sufficient number of examiners with capacity to process the different applications, the technical infrastructure of the office to be able to determine the state of the art, and the availability of the quality control systems, related to the quality of patents.

106. The Delegation of Spain expressed its support to the proposal contained in document SCP/28/8. The Delegation stated that the work proposed in the document would be a natural continuation of the work that had been undertaken through the questionnaire on the quality of patents. As regards to its proposal, contained in document SCP/28/7, the Delegation supported the idea expressed by the Delegation of Chile to hold an information session with participation of experts before undertaking a new study.

107. The Delegation of France expressed its support to the proposal of the Delegation of Spain contained in document SCP/28/7. The Delegation stated that AI was a crucial topic discussed in various fora such as WHO, the World Economic Forum and the Office of the High Commissioner for Human Rights. The Delegation also thanked WIPO for the seminar organized in May 2018 entitled “Meeting of Intellectual Property Offices (IPOs) on ICT Strategies and Artificial Intelligence (AI) for IP Administration”. The Delegation noted that that meeting made to realize that many offices had made significant progress in that area. As examples, the Delegation referred to machine translation, automatic allotment of classification symbols and the prior art search. Finally, while reiterating its support to the proposal of Spain, the Delegation suggested to insert the issue of tools for IP administration to the proposal which could be of interest to all offices, whatever their size was and which would help them to improve the quality of patents.

108. The Delegation of Japan thanked the Member States which had submitted document SCP/28/8, proposing to pursue work on quality of patents and the patent grant process. The Delegation stated that ensuring the quality of the patent grant process was an essential element for patent system to achieve its objectives, which was to encourage inventions and to contribute to industrial development. The Delegation was of the view that the SCP would be a suitable forum to share views and experiences of Member States and to learn from each other how to enhance the quality of the patent grant process. Further, the Delegation thanked the Delegation of Spain for submitting its proposal contained in document SCP/28/7 to conduct studies on new technologies and patentability and noted that it was an important topic. The Delegation stated that, as new technologies such as AI and blockchain arose, many had greater hopes and expectations, but at the same time, greater anxieties and concerns about how the patent system should deal with such new technologies. In its view, the SCP would be a suitable forum to share their views and experiences on that topic and to learn from each other.

109. The Delegation of Argentina thanked the Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom for their proposal contained in document SCP/28/8, and expressed its support to the proposal. The Delegation expressed its belief that the proposal would positively contribute to the discussions on that important topic within the Committee.

110. The Delegation of Singapore, as cosponsors of document SCP/28/8, wished to endorse the statement made by the Delegation of the United Kingdom and thanked the Member States which had expressed their support to that proposal. The Delegation also thanked the Secretariat for preparation of documents SCP/27/4 and SCP 27/4 Rev. which enabled the Committee to have a better understanding of term “quality of patents” and cooperation between patent offices in search and examination. The Delegation was of the view that the proposal in document SCP/28/8 complimented the work being pursued under the agenda item on quality of patents. The Delegation stressed that the topic of quality of patents remained relevant and

important as it was a shared endeavor to improve quality and confidence in the overall patent system and to provide strong protection for future endeavors. The Delegation stated that the Intellectual Property Office of Singapore had implemented the quality management system for its patent search and examination functions that conformed to the ISO 9001:2015 standards. The Delegation of Singapore looked forward to contributing in further discussions regarding national experiences and solutions to issues and concerns arising under that important topic. With regard to document SCP/28/7, the Delegation thanked the Delegation of Spain for its proposal. The Delegation stated that the concept of AI was not new and traced back to the 1950s when the field of AI research was found as an academic discipline. The Delegation continued that, the heightened interest on the topic in the recent years was believed to be triggered by three major trends: first, the widespread availability of data; second, the exponential increase in computing power; and third, the funds in that area. The Delegation stated further that, while AI was playing an increasing important role in enhancing productivity and quality, technological advances in that area were posing disruptions to the legal framework, such as the patent law. Further, the Delegation stated that the proposal by the Delegation of Spain served as a good starting point to initiate discussions on the issues surrounding AI and patents, providing Member States with relevant insights to prepare for the legal and operational challenges ahead. The Delegation continued that, as patent offices and policymakers it was important to ensure that patent regimes were ready to cater to the needs of innovative businesses and individuals. It was on that note that the Delegation of Singapore supported the proposal by the Delegation of Spain for the Secretariat to carry out the study or studies addressing the aspects raised in paragraphs 6 to 8 of the proposal. The Delegation looked forward to being engaged and contributing towards further discussions on that topic.

111. The Delegation of Nigeria stated that ensuring quality of patents was one of the core mandates of Member States and that it looked forward to some deliberation on the subject matter. The Delegation stated that the emerging technological challenges had necessitated a need to review patentable inventions, especially in the view of AI and blockchain development. The Delegation commended the Delegation of Spain for its proposal contained in document SCP/28/7. The Delegation also expressed its appreciation to the proposal by the Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom for their proposal contained in document SCP/28/8. Further, the Delegation agreed with the view expressed by the Delegation of Morocco on the need to give equal consideration to the issue of opposition systems in order to ensure quality of patents. The Delegation further called for the need of continuous capacity building of all IP offices, especially of developing countries. In particular, the Delegation stressed the need to develop and update a comprehensive database to share patent information and to improve patent search and examination mechanism.

112. The Delegation of Guatemala stated that the proposal by the Delegation of Spain, contained in document SCP/28/7, was of great importance given the topics that it dealt with. The Delegation stated that they were innovative and novel and certainly would be very useful to discuss it within the Committee. As regards the proposal contained in document SCP/28/8, the Delegation stated that the proposal could enrich the future work of the Committee and supported the constructive comments made by other delegations on the proposal.

113. The Delegation of Ecuador thanked the Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom for their proposal contained in document SCP/28/8. The Delegation stated that quality of patents was absolutely vital to ensure that inventors were incentivized and granted patents were strong. The Delegation further stated that the future innovation was guaranteed by that approach and that the patent system would ensure a balance between the rights of patent holders and the community as a whole. The Delegation supported the work to be undertaken as proposed in document SCP/28/8.

114. The Delegation of Canada expressed its support to the proposal contained in document SCP/28/8 because it was a natural extension of the work that the Committee had done on the quality of the patents. The Delegation commended the cosponsors of the proposal for coming together across regional groups to work on a common area of interest.

115. The Delegation of Iran (Islamic Republic of) stated that it commended the group of countries cosponsoring the proposal contained in document SCP/28/8, and that it saw a merit in such an approach. However, the Delegation enquired whether the scope of the proposed work would include the topic of opposition systems. As regards the proposal of the Delegation of Spain contained in document SCP/28/7, in general, the Delegation stated that it was necessary for the Committee to start discussing the issue of new technologies. However, the Delegation questioned whether the proposed study would fall under the agenda item of quality of patents or whether it would go beyond that agenda item. Therefore, the Delegation was of the view that before commissioning such a study, it would be appropriate to have an information exchange session, as had been proposed by the Delegation of Chile, to explore the different aspects of such a proposal and then decide whether to conduct such a study with regard to the quality of patents.

116. The Delegation of the Dominican Republic expressed its support to the proposal of Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom for their proposal contained in document SCP/28/8. The Delegation also expressed its support for the proposal submitted by the Delegation of Spain contained in document SCP/28/7 with regard to the carrying out of studies on patentability of new technology and artificial intelligence.

AGENDA ITEM 7: PATENTS AND HEALTH

117. Discussions were based on documents SCP/16/7, SCP/16/7 Corr., SCP/17/11, SCP/24/4, SCP/27/8, SCP/27/8 Add., SCP/28/5, SCP/28/6, SCP/28/9, SCP/28/9 Add. and SCP/28/10

118. The Delegation of Morocco, speaking on behalf of the African Group, stated that access to health, safe and affordable medicines was a fundamental component of the right to the highest attainable standard of physical and mental health and the foundation of the comprehensive realization of the right to development. The Delegation stressed that it was comprehensively encapsulated in the SDGs, TRIPS Agreement, Doha Declaration on TRIPS and Public Health, WHO, and in the spirit of the WIPO Development Agenda Recommendations. The Delegation further stated that there was little doubt that intellectual property and intellectual property rights had the potential to play an important role in advancing innovation, the dissemination of knowledge, the creation of thriving industries, including enhancing access to medicines for all. However, the Delegation noted with concern the detrimental effects that the creation of monopolies could have on public health and its contribution to advancing inequalities between developed and developing economies. The Delegation continued that the premise for the patent system was *quid pro quo*, which was designed with the intention to benefit both the patentee and the public. The Delegation stated that, however, in practice, the system did not seem to achieve what it had been intended to achieve, because countless experiences existed where patents had been cited as being barriers to the public accessing lifesaving medicines, which were under patents. The Delegation continued that, it had become apparent that the manner in which those patents had been used had tended to create exclusionary markets, inhibit competition and led to exorbitant prices for lifesaving drugs. The Delegation expressed its belief that the African Group's proposal on patents and health (document SCP/24/4) could assist the Committee to promote access to more affordable medicines as a component of progressively realizing the right to health. The proposal sought to enhance the capacities of Member States, and particularly of developing countries and LDCs, to adapt their patent regimes to make full use of the flexibilities available in the international patent system and to

promote public policy priorities related to access to health care. The Delegation stated that, as previously articulated, the proposal suggested, among other things, that WIPO should commission a study to examine the challenges and opportunities faced by developing countries and LDCs in using licenses for healthcare technologies and should accelerate its efforts in working with other relevant agencies to assist Member States to apply patentability criteria in a manner that was congruent with their developmental objectives through adoption and application of rigorous definitions of inventions and patentability that curtail ever-greening to ensure that patents were only awarded for genuine innovations, as well as support governments with the requisite expertise to apply public health-sensitive patentability criteria. The Delegation also reminded that the African Group's proposal included the request for the co-Chairs of the UNHLP to share their views on the UNHLP's objectives, findings and recommendations. The Delegation wished to once again underscore the recommendations of the UNHLP on access to medicines, which highlighted multiple barriers to accessing medicines and healthcare technologies, policy incoherencies, and shared ideas about paths forward, including specific recommendations to different UN bodies. The Delegation also noted that the UN General Assembly through its Resolution RES71/159 of 2016 had acknowledged the need for further discussions on access to medicines among Member States and all relevant stakeholders taking into account the UNHLP Report. In closing, the African Group looked forward to reaching an agreement on a more ambitious future work program on that issue, which would be transparent, balanced and progressive and aligned with the Development Agenda Recommendations.

119. The Delegation of China, with regard to the relationship between patents and health, stated that both, the strengthening of innovation, and the protection of the public's interest, were very important. Therefore, for the Delegation, studies by WIPO on that topic were very meaningful as they would help developing countries and LDCs understand the various flexibilities contained in international treaties and how to use them in practice. The Delegation further expressed its support to the proposal by the Delegations of Brazil, Canada and Switzerland and co-sponsored by the Delegation of Argentina to conduct a review of existing research on patents and access to medical products and health technologies (documents SCP/28/9 and SCP/28/9 Add.). The Delegation suggested that after the finalization of that study, there should be a follow-up information exchange activity to establish a detailed work program to advance the topic further.

120. The Representative of the European Commission, speaking on behalf of the EU and its Member States, wished to reiterate their understanding of the challenges and constraints certain countries might face in handling public health problems. The Representative stated that it remained committed to increasing access to affordable medicines and to find solutions to the world's pressing public health challenges and inequities. The Representative continued that access to safe, effective, quality and affordable essential medicines and vaccines for all was a major challenge and a key Sustainable Development Goal that they all must support. The EU continued to pursue a human rights-based approach to health. Strengthening all areas of a health system, including the availability of qualified health workers, the provision of affordable medicines and the adequate financing of the sector, was key to making progress towards universal health coverage with quality health services that were accessible and affordable for all. The quality and integrity of the pharmaceutical distribution chain was also essential to improving public health. The Representative further stated that the current innovation model, including the role of trade related to IP, had delivered consistent progress in global public health, leading to new and improved key treatments as well as much extended life expectancy, from developed to least developed countries. That model offered a variety of tools, such as incentives for innovation based on intellectual property, on public and private financing and awards or on public research. The Representative stated that such variety was necessary to address situations, where there was a functioning market and where there could be market failures. The Representative continued to believe that any further work in the area of patents and health should reflect a balanced approach, taking into account the various factors of

relevance to patents and health as for example proposed by the Delegations of the United States of America in document SCP/17/11. Further, the Representative thanked the Secretariat for the preparation of document SCP/28/5, updating the feasibility study on the disclosure of International Nonproprietary Names (INN) in patent applications and/or patents. The Representative stated that while the document provided some interesting information, they did not consider it best use of time and resources to continue work on INNs. However, the Representative wished to express its general support to transparency efforts, for example, via approaches such as the linking of existing databases, for example MedsPaL and Pat-INFORMED. The Representative also thanked the Secretariat for the preparation of document SCP/28/6 on WIPO's technical assistance activities in respect of enhancing patent examiners capacity. Enhancing patent examiners capacity (or "examining capacity" or "examiners' skills/training") in the field of health related inventions, in particular in the field of pharmaceuticals and medical devices (notably connected devices) could, the Representative stated, support further innovation and improvement of public health. The Representative supported the Secretariat in continuing its assistance and training in that respect and noted that WIPO was the international institution mandated to provide such sort of assistance. The Representative continued that the EU and its Member States noted with interest the proposal by the Delegations of Argentina, Brazil, Canada and Switzerland in documents SCP/28/9 and SCP/28/9 Add. As already stated during SCP/27, the Representative saw merit in conducting an analysis of existing research on the topic of patent protection and access to medical products and health technologies. It was of utmost importance to the Representative to keep a balanced approach to that analysis, which would take into account the promotion of innovation, as well as of its transfer and dissemination. The Representative further reiterated its past position that in order to ensure the highest quality of evidence relied on by the SCP, the report should include high quality, independent and evidence-based relevant studies, in particular studies prepared by UN organizations, such as WIPO and the WHO, as well as the WTO. The Representative also wished to emphasize that it saw the role of the potential report as a collection of information and a document supporting future discussions in the SCP, and not an outline of different policy options for WIPO. The EU and its Member States were prepared to discuss the proposal further. In conclusion, the Representative welcomed the proposal made by the Delegations of Argentina, Brazil and Switzerland in document SCP/28/10. It found merit in increasing transparency and looked forward to discussions on that proposal.

121. The Delegation of Lithuania, speaking on behalf of the CEBS Group, underlined at the outset, that the CEBS Group attached a great importance to the issues related to public health and access to medicines. However, the Delegation stated, the issue was very complex and there was no single factor that affected availability and affordability of medical care. The Delegation 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 wished to stress the need to avoid duplication with the work of other international organizations. The Delegation continued that the SCP had a mandate to discuss the issue from the perspective of the patent system, and its Group was convinced that innovation, research and development of new life saving medicines and techniques would not be possible without respecting intellectual property rights where patent protection played a very important role. The Delegation continued to believe that work in the area of patents and health should take into account various factors of relevance to patents and health, and in that respect it referred to document SCP/17/11 that contained very relevant proposals of the United States of America. The CEBS Group appreciated the work of the Secretariat on updating the feasibility study on the disclosure of INN in patent applications and/or patents provided in document SCP/28/5. The Delegation was interested to hear more from the Secretariat on if and how the existing WIPO databases and search engines, including the PATENTSCOPE, could be better employed or upgraded to serve that purpose. Noting that the CEBS Group was in favor of transparency, the Delegation stated that it had received with interest the proposal made by the Delegations of Argentina, Brazil and Switzerland contained in document SCP/28/10 and would welcome

updates from representatives of Medical Patent Pool and Pat-INFORMED on operation of those platforms, as well as discussion on existing similar initiatives. The Delegation also thanked the Secretariat for the report on WIPO's Technical Assistance Activities in Respect of Enhancing Patent Examiners Capacity set out in document SCP/28/6. The Group welcomed the fact that WIPO had developed a few programs and recourses that were available for patent offices that would be willing to enhance capacity of patent examiners and encouraged the Secretariat to continue its activities in that respect. Last but not least, the CEBS Group took note of document SCP/28/9 containing proposal of the Delegations of Argentina, Brazil, Canada and Switzerland to conduct a review of existing research on patents and access to medical products and health technologies. The Delegation stated that the CEBS Group could support the factual summary of existing research on the topic of patent protection and access to medical products and health technologies while keeping the balanced approach. However, the Delegation concluded, such review should not contain policy recommendations for WIPO.

122. The Delegation of Switzerland, speaking on behalf of Group B, thanked the Secretariat for preparing documents SCP/28/5 and SCP/28/6. Group B wished to reiterate that both innovation and access to it were equally important in the field of patents and health. The Delegation stated that innovation was in large part fostered by the patent system. The patent system was a key incentive for research and development of medical products including life-saving medicines. The Delegation noted that investment in research and development for innovative medical products had contributed to crucial improvements in public health outcomes, and IP rights had played a key role in facilitating that innovation. The Delegation stated that continuing innovation was needed to face current and future health challenges and that the protection of IP rights, including patents, served as an incentive for medicine and innovation, thereby announcing the availability of new medicine products for all. The Delegation stressed that it was in the interest of the public in all countries to have continuing research and development of safe and effective medical products. Patents as an incentive for research and development were part of the solution to the problem of availability of future medical products. The Delegation underlined that, therefore, it was important to keep in mind the whole context of patents and health and not to focus only at one specific element of it. The Delegation further quoted the WIPO, WHO and WTO Trilateral Study "Promoting Access to Medical Technologies and Innovation" which stated that "the lack of access to medical technologies is rarely due to a single isolated factor" and stated that that view had also been restated many times by experts during information sessions held during SCP meetings. The Delegation continued that the availability of safe and effective medical products was a multi-faceted problem that included different dimensions and factors. In particular, the Delegation stated that lack of access might be influenced by inadequate financing of health care, shortage or lack of access to trained health care personnel and adequate medical facilities, fragmented and unreliable processes and infrastructure, competition of innovative drugs, supply chain management, retail markups, taxes, tariffs, et cetera. The Delegation continued that, in addition to factors that increased the price of medical product, the lack of access was also a factor of a person's ability to purchase the medical product. Furthermore, requirements for local production and other factors related to whether a medical product might be sold in a country also influenced availability. The Delegation stated further that different projects or collaborations showed how the patent system incentivized innovation and served to provide available and accessible key information about patented inventions. That included projects such as the Medicines Patents and Licenses Database (MedsPal), other recently launched patent information initiative for medicines, a partnership between WIPO and the research-based pharmaceutical industry to promote the accessibility of patent information for health agencies tasked with procurement of medicines. The Delegation took note with interest the proposal put forward by the Delegations of Brazil, Argentina, Chile and Switzerland (document SCP/28/10). It also looked forward to the further information exchange session on publicly accessible databases on patent information status and data on medicines and vaccines. Further, the Delegation stated that innovation in medical products and access to those technologies was a major concern for all Member States. Group B supported work under

the agenda item “patents and health” that took 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. In that regard, the Delegation stated that, the issue of patents and health and, in particular access to health technologies, crossed into areas that were more in the realm of other specialized UN bodies, and that extensive work had already been done in that area by those organizations and other multilateral fora. Group B took note of the proposal put forward by the Delegations of Canada and Switzerland, cosponsored by the Delegations of Brazil and Argentina, and thanked those Delegations for the constructive efforts to foster the 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. In that regard, the Delegation referred to the WIPO, WHO, and WTO trilateral study “Promoting Access to Medical Technologies and Innovation” that could serve as the basis for productive discussions. The Delegation stressed that they supported a holistic view in the area of patents and health. Therefore, wished to see work proceeding in accordance with the comprehensive approach as expressed in document SCP/17/11. The Delegation further thanked the Secretariat for the Updated Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents (document SCP/28/5), and pointed out that the WIPO PATENTSCOPE search engine was a suitable tool for searching information on inventions in all technical fields, including the pharmaceutical area. Noting that pharmaceutical compounds might be searched based on chemical structures, key words, names of applicants, international patent classification and many other search criteria, the Delegation expressed its belief that the investment in those technologies was the most efficient way forward. The Delegation continued that, the search engine provided a more effective and feasible approach to searching chemical patents than a scheme requiring to report INNs which would burden the offices and users, and would be at best incomplete. The Delegation encouraged the further elaboration of the PATENTSCOPE tool and invited the Secretariat to demonstrate its functions based on concrete examples. Further, the Delegation wished to reiterate the position of its Group that the UNHLP and resulting report was not a Member State driven process, that it did not reflect the opinions of the Member States, and neither had it been endorsed by the Member States. While noting that it was prepared to discuss the issue of access to medical products in a holistic manner and in accordance with the mandate of the SCP, the Delegation stressed that UNHLP Report should not constitute the basis for that discussion. The Delegation also emphasized that any discussion and future work should take account of the wide range of views and factors affecting access to medicines.

123. The Delegation of Iran (Islamic Republic of) at the outset wished to highlight the importance of SDG 3 which was to ensure healthy lives and promote well-being for all at all ages via universal health coverage, including access to safe, effective quality and affordable essential vaccines and medicines. The Delegation stated that that was in accordance with the understanding that the right to access to health was a fundamental and basic human right. The Delegation continued that WIPO as a part of its mandate should support countries to address IP related barriers impacting on availability, affordability and accessibility of medicines, treatment and related technologies. The Delegation stated that there was no other international forum than the SCP where countries could share experiences on the use of health-related patent flexibilities. Hence the work of the SCP in that direction was quite crucial to promote the very delicate balance required for the patent system. The Delegation took note of the Updated Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents (document SCP/28/5) and appreciated the Secretariat’s efforts to prepare the document. The Delegation also appreciated the Delegations of Brazil, Canada, Switzerland, and Argentina for their proposal contained in document SCP/28/9 and expressed its willingness to work constructively in order to finalize that proposal. The Delegation also welcomed the proposal of the Delegations of Argentina, Brazil and Switzerland on a regular update on publicly accessible databases of patent status information concerning medicines and

vaccines (document SCP/28/10). The Delegation further expressed its belief that discussion on the issue of patents and health and future work program on that issue should assist countries to adapt their patent law to make full use of patent flexibilities in accordance with their public health needs in compliance with international obligations. In light of the above, the Delegation was hopeful that SCP would agree on a work plan in line with the proposal of the African Group, contained in document SCP/24/4, which offered a solution to the challenges of affordable access to health care and medicines internationally. The Delegation considered that the proposal was a timely initiative in line with the current international efforts to improve public health.

124. The Delegation of the Russian Federation stressed the importance of the discussion of the subject of access to affordable essential medicines for public health purposes. The Delegation expressed its support to the proposal submitted by the Delegations of Brazil, Canada and Switzerland to conduct a review of existing research on patents and access to medical products and health technologies (document SCP/28/9). Noting the importance of having patent status information for making informed decisions regarding procurement, licensing or production of medicines, the Delegation also welcomed the proposal of the Delegations of Argentina, Brazil and Switzerland on a regular update on publicly accessible databases of patent status information concerning medicines and vaccines (document SCP/28/10). The Delegation further informed the Committee about the ongoing initiative in its country to create a single database of active ingredients protected by patents for the purposes of preventing the infringement of rights due to early entry of generics into the market. The Delegation further stated that the issue of patents and health is closely linked to the issue of exceptions and limitations to the rights, as well as quality of patents. The Delegation wished to reiterate that it would be interesting to have an information exchange on the industrial application and sufficiency of disclosure of pharmaceutical inventions, in particular, of the selection inventions and Markush claims. In conclusion, the Delegation thanked the Secretariat for the Updated Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents (document SCP/28/5) and looked forward to the discussion of the document.

125. The Delegation of Brazil stated that the topic of patents and health was important to every country without exception. The Delegation stated that market driven research and development had produced a number of important health technologies that had improved health conditions substantially worldwide. The Delegation continued that, as a matter of fact, the world was constantly witnessing the immense contribution of science and technology to the advancement of health care. However, the Delegation noted, the patent system was not perfect, particularly in areas where the market alone might not provide adequate incentives, like, for instance, the cure of neglected diseases. The Delegation stated that according to the WHO and the World Bank, 1.7 billion people in 185 countries needed treatment and care for neglected tropical diseases. Thus, gaps and failures in addressing disease burdens and access to treatment remained a challenge in most parts of the world. The Delegation continued that, moreover, approximately 60% of the spending on health and technology R&D in developed countries had been derived from the private sector and 40% from public and non-profit sources. The Delegation stated that, in the case of diseases that heavily affected low and middle income countries, including HIV, tuberculosis and malaria, those percentages were reversed with the public sector being responsible for 60% of total R&D funding. The Delegation noted that the challenges faced in those areas were not small. Yet, they were not insurmountable. In order to tackle those challenges, the Delegation stated, Member States irrespective of their levels of development should endeavor to build consensus on proposals that would generate effective contributions to the topic of patents and health. The Delegation continued that, it was with that spirit that Brazil was cosponsoring a proposal with the Delegations of Argentina, Canada and Switzerland (document SCP/28/9), whose objective was to conduct a review of existing analysis and research concerning patent protection and access to medical products and health

technologies. The Delegation stated that the proposal would facilitate access to relevant information on the subject which would provide guidance for Member States for developed and developing countries to implement more balanced and effective patent laws. The Delegation wished to reiterate once again its strong support for the African Group's proposal on patents and health, contained in document SCP/24/4. In its view, proposals contained in documents SCP/28/9 and SCP/24/4 were complimentary, not substitutes. The Delegation expressed its confidence that a common ground could be found in the Committee and a work program on that topic put in place to the benefit of all countries, irrespective of their levels of development. Noting that Brazil was also cosponsoring the proposal contained in document SCP/28/10, the Delegation expressed its belief that the proposal would provide continuity to the presentation of the Medicines Patent Pool (MPP) made during the previous session of the SCP. The Delegation reminded the Committee that the MPP's database called MedsPaL contained important information on the patent and licensing status of selected HIV, hepatitis C, tuberculosis and other patented essential medicines in low and middle-income countries. The Delegation stated that, therefore, it was of utmost importance that MPP and similar initiatives were given the opportunity to inform and update the SCP Member States on their activities. The Delegation believed that the proposal was a small, yet important step to reduce asymmetry between profit driven innovation models and public health priorities contributing to building a more inclusive, balanced and effective patent system, a desire shared by all Member States.

126. The Delegation of India proposed the Committee to identify specific constraints in relation to the flexibilities that could be used to address public health needs and discuss the same with a view to identifying action oriented solutions. In addition, the Delegation stated that the SCP should also consider the UNHLP Report and that any review of existing research on patents and access to health technologies should be restricted to patent laws issues, such as the role of the patentability criteria, and of the patent examination system in facilitating the access to medicines and health technologies.

Sharing experiences of Member States with respect to enhancing examiners capacity, particularly in small and medium sized offices

127. The Secretariat made a presentation on document SCP/28/6.

128. The Delegation of the United Kingdom made a presentation on enhancing patent examiner capacity at the UK IPO. The presentation is available at:
http://www.wipo.int/edocs/mdocs/scp/en/scp_28/scp_28_h_enhancing_examiner_capacity_unit_ed_kingdom.pdf.

129. The Delegation of Colombia wished to make it very clear that improving the capacity of patent examiners, particularly in small and medium sized offices was vital. The Delegation further provided the following information to the Committee: the IP Office in Colombia was of a medium size in the region: it was fifth in size in terms of the number of patent applications received. Since 2006, the IP office had increased the number of patent examiners. In 2006, the Office had only 10 patent examiners, and in 2018, 50 patent examiners were employed by the Office. The Delegation further stated that the examiners in Colombia were divided principally into three sectors: pharmaceutical, biotechnological and engineering. Around 30% of examiners were covering pharmaceutical and biotechnology and about 70% of the examiners were covering the engineering areas. The Delegation stated that, over the last ten years, the Office had created the unified system of documentation and had developed the examination guidelines in order to harmonize the examination criteria. The Delegation further expressed its appreciation to the JPO for its cooperation on examiners' training. It also thanked KIPO for their participation in various MOUs with the Office of Colombia on the issue. It further thanked the EPO for related capacity building activities which had taken place over the last five years. And finally, the Delegation informed the Committee about the Inter-American Industrial property

Program (IBEPI) in which the patent offices of Ibero-America had been gathering information in order to review a training trend of the different offices in the region with the view to consolidate and strengthen the collaboration among the patent offices.

130. The Delegation of Japan, speaking on behalf of Group B, thanked the Secretariat for preparing and introducing document SCP/28/6. The Delegation also thanked the Delegation of the United Kingdom for making the useful presentation. The Delegation recognized the range of work and technical trainings undertaken by WIPO, for example, in the field of pharmaceuticals to enhance the skills and knowledge of patent examiners from developing countries. The Delegation stated that they considered WIPO to be a competent organization to deliver such trainings. The Delegation further stated that national IP offices had different strategies to address the question of training and further development of examiner's capacities, including on-the-job training approaches, long-term comprehensive training courses, or distance learning. Group B was looking forward to learning more of the different strategies employed by Member States to enhance examiner's capacities. The Delegation recognized that small and medium-sized offices might lack resources for patent examination in several areas, including insufficient number of examiners or limited technical fields that could be covered. In that regard, the Delegation stressed that an important and efficient way to enhance examiner's capacity was work sharing, as had been shown by offices of all sizes and from all regions during the discussion under the agenda item on quality of patents.

131. The Delegation of the Czech Republic wished to share experience of the Czech IP Office regarding the improvements of examiner's capacity. In particular, the Delegation stated that Czech IP Office was a medium-sized one. In 1963, the Czech IP Office established its own IP related educational institution called the "IP Training Institute". The Institute provided a two-year distance learning which was designed for professionals in the field of industrial property, assistant patent attorneys, commercial lawyers active in the IP domain, entrepreneurs, research and development workers, students and the wider public. At the same time, each new employee of the Czech IP Office, including patent examiners, had to complete that study. The Delegation further stated that tutors were mainly IP experts working in the private sector, or the office's own experts. Participants were not only trained on regulation, protection, procedures and enforcement of the individual IP rights, but also on how to use 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 valuation or licensing. The Delegation further informed the Committee that, every year, 30 to 45 participants had applied for that distance learning. In addition, the Czech IP Office published IP related publications, such as, for example, in the field of patent law, dedicated to the international treaties in the field of patent law the European Patent Convention, the legal protection on inventions and utility models, or the patent information and search databases, et cetera. The Czech IP Office also issued the professional journal called "Industrial Property" which contained IP related articles, the information on the European legislation, the information on the latest case law, and the short actual IP related information. The Delegation further stated that examiners of the Czech IP Office regularly took part in trainings on search and examination organized by the European Patent Academy for the offices of the EPC Contracting States. They also participated in the training workshops or conferences focused on the various search and examination elements organized by the EPO, WIPO or other IP offices. As regards the number of examiners, the Delegation informed the Committee that the Czech IP Office had 35 patent examiners, of which 11 were chemists and 10 examined the patent applications related to health.

132. The Delegation of the United States of America thanked the Secretariat for preparing and introducing document SCP/28/6. The Delegation also thanked the Delegation of the United Kingdom for their training efforts. The Delegation stated that the USPTO supported technical assistance to developing countries and LDCs with respect to examiners training. The Delegation stated that over the years, the USPTO had provided a number of examiner training

programs on search and examination procedures, both at its headquarters and in various countries. The USPTO continued to provide training and support of technical assistance and capacity building for small and medium-sized offices through its Global Intellectual Property Academy. The Delegation stated that patent programs were designed to focus on a wide range of topics relating to national and international application processing, including administration, budgeting, operational procedures and examination procedures. The Delegation informed the Committee that, in 2017, the USPTO had provided training for representatives from IP offices from numerous countries, including Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam, Argentina and Turkey. The Delegation also stated that the USPTO offered online training materials through its website.

133. The Delegation of China thanked the Delegation of the United Kingdom for its presentation. The Delegation believed that those activities would help the Committee to strengthen technical assistance and capacity building of examiners. The Delegation stated that over the last few years, SIPO had been cooperating with other IP offices in that area. The Delegation further informed the Committee about the funds-in-trust established between China and WIPO. The Delegation stated that SIPO had organized a lot of seminars and training courses in order to share its experiences and expertise with other countries. For instance, the Delegation stated, it had organized a seminar on IP management with the ASEAN countries. SIPO had also collaborated with WIPO in the organization of seminars and courses for training on management and marketing of IP. Further, the Delegation stated that, in 2017, SIPO had organized training courses for 90 interns on IP. The Delegation expressed its hope that cooperation between SIPO and other IP offices around the world would be strengthened.

134. The Delegation of South Africa wished to share its experiences in the areas of examination and the training of examiners. The Delegation stated that, as it had mentioned earlier, South Africa had embarked on the process of amending its patent laws to make a provision for substantive search and examination, as the country was a depository system at that moment. The Delegation stated that the IP policy had been in development for the last nine years and it had been recently approved by the Cabinet. The Delegation continued that, in the anticipation for the approval of the IP policy, in 2016, the Office had recruited 20 examiners from different technology fields, including biotechnology, physics and chemistry. Those examiners, the Delegation stated, had gone through two years of training program, which partly had been sponsored by various patent offices. The Delegation further highlighted the central role that WIPO should play in the training of examiners. Further, to learn from experience of its country, the Delegation stated several examiners were dispatched to other offices to get training on the issues of novelty, inventive step, unity of invention, clarity, etc. However, the Delegation stated that it had actually not been that helpful for South Africa to train its examiners using interventions from other countries, although the trainings had been well intended, because the laws of those countries had been different from the law of South Africa. That made them think about their training strategies. Consequently, the Office had partnered with the EPO, primarily because of the similarities between the law and practice of South Africa and the EPO. The Delegation expressed its confidence that the partnership with the EPO would actually assist its Office to have a more structured program on training of examiners that would enable it to have an effective grant system in South Africa. However, the Delegation still held the view that it was primarily WIPO's role to be at the forefront of providing the technical assistance and training to examiners, particularly to the examiners of LDCs.

135. The Delegation of Uganda thanked the Secretariat for preparing document SCP/28/6. The Delegation stated that Uganda's Intellectual Property Office was a small office of about 30 staff and only three patent examiners. The Delegation stressed that the capacity of examiners was a key in ensuring that granted patents were of high quality, which was particularly important in sensitive sectors like health. The Delegation expressed further its gratitude to WIPO, SIPO, JPO, EPO, ARIPO and a number of other countries which had

provided trainings to its examiners in the areas of patent search and examination, IPC classification, preparation of search reports, and written opinions regarding novelty and inventive step. The Delegation further stated that they had also benefitted from the PCT trainings on use of work products of International Authorities in examination of PCT applications which were compliant with the Industrial Property Act of 2014. The Delegation also appreciated the distance learning courses offered by WIPO. The Delegation noted that thanks to those trainings, the Office was able to begin substantive examination in 2017, which had greatly reduced the processing time of applications for the benefit of applicants. Supporting the statement made by the Delegation of South Africa, the Delegation called for a more active role to be played by WIPO to coordinate the patent examiners trainings. In conclusion, the Delegation stated that since Uganda was endowed with both traditional and genetic resources, the Uganda's IP Office set up a traditional knowledge unit. Therefore, they awaited the completion of the Guidelines as indicated in document WIPO/GRTKF/IC/13/7, entitled "Recognition of Traditional Knowledge with the Patent System", to enable its patent examiners to handle patent applications based on traditional knowledge or evoked by using traditional knowledge in an appropriate manner.

Updated feasibility study on the disclosure of International Nonproprietary Names (INN) in patent applications and/or patents

136. The Secretariat illustrated document SCP/28/5.

137. The Delegation of Chile thanked the Secretariat for the Updated Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents. The Delegation highlighted the important role that transparency played through the incorporation of INN in patent applications and the registered granted patents. The Delegation believed that that initiative would contribute to providing more information and transparency of the system irrespective of being turned into an additional tool for offices, i.e., examiners at the time of carrying out the searches and the examination of prior art in patent application. The Delegation was convinced that more transparency was needed in the system of patents related to medicines. The Delegation explained that for that reason in Chile they were proposing to establish a mechanism to require patent applicants who were submitting a patent application for an invention containing an active ingredient incorporated into a pharmaceutical product, to indicate, if already known, the INN assigned by the WHO. The Delegation explained that if at the time when the patent application was submitted such information was not yet known, the patent applicant had to inform the Chilean Patent Office (INAPI), as soon as such piece of information was available. The Delegation specified that the same obligation during the time when the patent was in force. The Delegation was convinced that such measure should provide more information for the industrial property rights holders, government authorities and the public at large.

138. The Delegation of the United States of America appreciated the Updated Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents. The Delegation noted that that document updated the previously presented study contained in SCP/21/9. The Delegation reiterated some points which they had previously made on that topic. First and foremost, the Delegation considered that it was clear that the INN disclosure might not be feasible at the time of patent filing or even after, in certain cases. The Delegation observed that, as pointed out in the study, INN were typically not available at the time of filing for a large number of patent applications. The Delegation pointed out that that was due to the various constraints inherent in the timeline for submitting a request to the INN Secretariat. The Delegation stressed that WHO INN guidelines were also clear that applicants should not obtain an INN before all patent procedures were completed, and that a request for an INN should not occur before clinical trials had begun. The Delegation was of the view that, as supported by the results of the study, requirements to provide an INN after patent filing would

be burdensome to both patent offices and the applicants. The Delegation highlighted that with such requirements, for example, patent offices would be forced to develop and implement extensive new procedures and infrastructure for handling INN disclosures. Furthermore, the Delegation considered that some national laws might not provide a mechanism for reopening the prosecution of patents already granted, based on an INN disclosure or lack thereof. The Delegation believed that the accuracy and timeliness of an applicant's disclosure of the INN would have to be verified and patent examiners would have to be trained on the INN system and procedures. The Delegation was of the opinion that all that would place a high burden on the offices, in part due to the significant differences between the procedures of patents and INN processes. Therefore, the Delegation did not believe that a country that was a member of the Patent Cooperation Treaty, the Patent Law Treaty or other relevant bilateral or multilateral agreement would be permitted to impose that type of additional disclosure requirement in a patent application. The Delegation therefore did not support the requirement to disclose the INN in a patent application which already provided a complete and legally sufficient disclosure. The Delegation believed that such a requirement would be an additional requirement that might not be permitted under various international frameworks. The Delegation noted that the core concerns set forth by the proponents of the disclosure of the INN was that patent examiners and others were not able to conduct an adequate search and identify relevant prior art for a particular technology. The Delegation observed that documents SCP/21/9 and SCP/28/5 indicated that some patent offices seeking to search chemical and pharmaceutical inventions might experience certain difficulties due to the complexity and expense involved in prior patents relevant to those inventions. However, on the other hand, many other patent offices were currently able to routinely conduct such searches. In the Delegation's view, that highlighted the value of work sharing. The Delegation specified that, for instance, a patent office could consider the work product and include technical search history of another office when conducting its own examination of a corresponding patent application. The Delegation mentioned the PPH as an example of that cooperation. The Delegation also made the example when one office bilaterally assisted another office in conducting searches and examination of corresponding patent applications. The Delegation noted that, on the previous day, it had heard in the Committee the presentations from several offices stressing the value of cooperation between offices in searching the prior art for patent applications. The Delegation stressed that, as pointed out in document SCP/28/5, many other tools were available to offices examining applications in the field of chemistry, such as the Orange Book and the record of the Supplementary Protection Certificate (SPC). The Delegation further observed that software systems that automatically identified, extracted and indexed chemical data were also available and were being continuously improved, including some systems associated with free of charge databases. In the Delegation's view, those solutions, and in particular the software based solutions, were much more useful, practical and cost effective in assisting offices wanting to examine patent applications in the chemistry area than developing a burdensome, complex, and incomplete INN disclosure requirement. The Delegation asked the Secretariat to provide the SCP updates on their efforts to develop such IT information technology solutions within the WIPO system, such as PATENTSCOPE.

139. The Delegation of Ecuador thanked the Secretariat for document SCP/28/5. The Delegation explained that the Constitution of the Republic of Ecuador, in its Article 363(7), provided that to achieve the well-being of the population, it was obligatory for the state to guarantee the availability of, and access to, safe and effective medicines of quality, to regulate their commercialization, and to promote national production of generic medicines which corresponded to the epidemiological needs of the population. The Delegation highlighted that with regard to access to medicines, the public health interests would prevail over the economic and commercial ones. The Delegation stressed that the patent system, in turn, had a goal, on one side, to promote innovation and, on the other side, provide a mechanism for society to have access to available technological information, patented products and products produced through patented processes. The Delegation mentioned that it was important for Ecuador to

support initiatives able to identify mechanisms for an adequate use of the patent system which could bring more transparency to the patent grant procedure in relation to pharmaceutical products. The Delegation believed that that was possible through access to information in the public domain, and in particular through the simple identification of pharmaceutical products contained in patent documents. The Delegation considered that to achieve that, it was necessary to disclose, in the patent application, the greatest amount of information available concerning a given pharmaceutical product, and that information should be easy to identify. The Delegation highlighted that in order to fulfill the disclosure requirement, the patent applicant, or the patent owner, could disclose the information concerning the pharmaceutical product (patented or for which patent protection was sought), through the identification of its chemical name, manufacture name, chemical structure, number of CASs, among other parameters. The Delegation pointed out that only in few cases such identification took place by providing the INN of the pharmaceutical product. The Delegation was of the opinion that the identification of the pharmaceutical product through the INN, if already known at the moment of filing the patent application, would greatly facilitate the task of patent offices in carrying out their task of examination of patentability criteria. The Delegation further explained that the identification of an INN would enable patent offices, on the one hand, to identify in an objective and quick manner the prior art, and, on the other hand, to identify in an easier way the active substances referred to in a patent application. The Delegation highlighted that patent offices of developing countries did not have the appropriate information technology (IT) infrastructure or software in order to carry out such task. Therefore, the Delegation welcomed document SCP/28/5 and was interested in discussion that would enable the Committee to delve into that topic.

140. The Delegation of the Republic of Korea noted that, in general, national and regional patent laws required an applicant to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and the claims to be clear and concise. The Delegation pointed out that the requirements relating to the form or contents of international patent applications under the PCT applied to national and regional patent application filed within the PCT Contracting States. The Delegation believed that, in order to carry out prior art searches, the choice on parameters and strategies differed depending on the purpose of patent search and the types of information to be searched. The Delegation observed that no national or regional law required the disclosure of INN in patent applications or granted patents. However, the Delegation considered that improving the possibility to search patent documents concerning pharmaceutical substance through the use of INN key word search might potentially benefit all stakeholders. The Delegation believed that if relevant INN information was linked to corresponding patent applications, one of the potential benefits would be that the search of patents relevant to an active pharmaceutical substance on public patent databases, which were normally free of charge, might be enhanced.

141. The Representative of KEI thanked the Secretariat for its presentation of the Updated Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents. The Representative supported the remarks made by the Delegation of Chile regarding the disclosure of INN in patent applications and/or patents. The Delegation believed that such disclosure should be required when filing a patent application related to a product with a designated INN, or as soon as the INN had been designated by the WHO. The Representative observed that document SCP/28/5 prepared by the Secretariat did not identify any significant obstacles for the disclosure requirement. The Representative was of the opinion that the disclosure of INN in patent applications and/or patents would help to increase transparency of patents related to medical products. The Delegation was of the opinion that such measure was consistent with the current drive towards increased transparency related to medical products, as evidenced by the Committee's interest in publicly available patent status databases such as MedsPaL managed by the Medicines Patent Pool and Pat-INFORMED, WIPO's new partnership with the pharmaceutical industry.

142. The Representative of the WHO thanked the Secretariat for its collaboration on the Updated Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents contained in document SCP/28/5. The Delegation pointed out that the study, in its preliminary findings, showed that there were no significant hurdles to require INN disclosure in patent applications and patents as soon as INN was designated by the WHO.

143. The Delegation of the United Kingdom noted with interest the Updated Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents and thanked the Secretariat for that update. The Delegation fully recognized the importance of considering viable options for determining patentability. The Delegation aligned itself to the statements made by the Delegation of Switzerland on behalf of Group B, and the Delegation of Austria on behalf of the EU and its Member States. The Delegation shared many of the same concerns highlighted in the report. The Delegation mentioned in particular that, as the feasibility study made clear, not all INN would be known, especially before a patent was filed or before prosecution was completed. The Delegation was of the opinion that to retrospectively introduce INN into patent specifications would be a substantial time and cost burden on either the applicant or the IP office, with some additional potential complications. Firstly, the Delegation observed that not all patents would be held by the same company which brought the INN product to market. The Delegation highlighted that that added a further level of complexity as to who might actually undertake the identification and then inclusion of the INN into the patent. Secondly, the Delegation specified that not all patents might identify the active ingredients in technical terms. The Delegation provided the example regarding a chemical structure defined in its functional terms. The Delegation further noted that it might make it difficult to identify patents that specifically related to a compound and that in some cases adding an INN might result in adding new matter to a specification which had potential legal implications. The Delegation recalled that during the twenty-fifth session of the SCP, participants were receptive to the presentation on PATENTSCOPE and chemsearch, introducing a chemical sub-structure searching facility. Consequently, the Delegation welcomed a further demonstration of the PATENTSCOPE tool by the Secretariat at a future session of the SCP.

144. The Delegation of India reiterated its statement on the inclusion of INN in a patent specification which, in its view, would improve the quality of granted patents. The Delegation noted that the INN was assigned by WHO for a single, well defined, substance, but not for mixtures of substances, herbal substances or homeopathic products. The Delegation mentioned that during substantive examination, if the INN was known, an examiner could easily access some details such as IUPAC name, structure formula, molecular formula, chemical abstract services number, therapeutic use and pharmacological action of the molecule. The Delegation believed that thanks to the inclusion of INN in a patent application, granting a patent for the molecule with trivial and obvious modifications could be minimized to some extent. The Delegation emphasized that the Committee should continue to work on a feasibility study for the inclusion of INN in a patent specification, if INN was known to the applicant. The Delegation specified that such study should address the concerns raised by the Delegation with respect to the negative bias illustrated in document SCP/21/9 during the twenty-first session of the SCP. The Delegation drew the attention of the Committee, in particular, towards the negative bias showed in the document SCP/21/9 with respect to the burden on applicants for submitting the INN and evading the question of usefulness or advantage of mandatory disclosure of the INN in patent specification when the applicant was fully aware of such offset INN. The Delegation appreciated the efforts of the Secretariat in preparing document SCP/28/5 and took note of it.

Information exchange session on publicly accessible databases on patent information status and data on medicines and vaccines.

145. The Delegation of Switzerland expressed its wish to introduce the joint proposal by the Delegations of Argentina, Brazil, Chile and Switzerland, contained in document SCP/28/10. The Delegation commended the evolving collaborative spirit in the SCP. The Delegation noted that there were three cross regional proposals, i.e., the proposal of the Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom under the agenda item on quality of patents, contained in document SCP/28/8 as well as the two proposals that the Delegation was cosponsoring under the agenda item on patents and health: (i) Proposal to conduct a Review of the Existing Research on Patents and Access to Medical Products and Health Technologies, contained in document SCP/28/9; and (ii) Proposal of Argentina, Brazil, Chile, and Switzerland regarding a Regular Update on Publicly Accessible Databases of Patents Status Information concerning Medicines and Vaccines, contained in document SCP/28/10. The Delegation believed that those cross regional collaborations would contribute to trust-building between Member States and regional groups and to advance the work of the Committee. The Delegation thanked the Secretariat for its flexibility and all its efforts, including the provision of translation despite the late submission of the proposal. The Delegation stressed that information on the patent status of essential medicines had been a long standing and crucial demand for health authorities, procurement agencies and other stakeholders. The Delegation specified that those authorities required easily accessible information in order to take effective and legally sound decisions, for example, on the procurement of important medicines and on the freedom to operate. The Delegation observed that there were various challenges in accessing relevant patent information, in particular from low and middle-income countries. The Delegation mentioned that some of those challenges were mentioned in the proposal contained in document SCP/28/10, such as the lack of online searchable databases or highly technical language of patent specifications. The Delegation noted that health authorities or procurement agencies needed to be able to search the patent status in each country of interest, individually. The Delegation recalled that there were at least two instruments that were created to serve such long standing need of accurate and reliable information. The Delegation stated that MedsPaL database of the Medicine Patent Pool (MPP) provided particular benefits and advantages, which included transparency under the patent status, license agreements and data exclusivity. The Delegation specified that its design and structure allowed non-patent experts to access essential information and to understand it. The Delegation observed that there was a regular update of such database. The Delegation reminded that the MPP presented its work on the database during the previous SCP session. The Delegation further mentioned the second instrument, i.e., the joint initiative between WIPO and the research based pharmaceutical industry, Pat-INFORMED, which allowed access to important information on the status of patents on medicines in the area of cancer, Hepatitis C, cardiovascular and respiratory systems, as well as medicines and products under the WHO model list of essential medicines. The Delegation was of the view that information provided directly by the patent holder would enhance reliable access to the status of patents on medical products. The Delegation was looking forward to learn more about that database. The Delegation believed that such instrument was a prime example of how the patent system could be implemented for direct benefit of public health. The Delegation considered both initiatives could become crucial, complimentary, resources for patent information and serve to close the long standing need. The Delegation, together with the Delegations of Argentina, Brazil and Chile, proposed that the WIPO Secretariat invite on a yearly basis, the Representatives of MPP and Pat-INFORMED to inform the Committee on the advances made on those information platforms. The Delegation was of the view that the cross-regional support of the proposal demonstrated the interest to, and importance of, access to reliable information on the patent status in the pharmaceutical field. The Delegation believed that a regular update of those databases and other similar initiatives would increase the knowledge of Member States and the wider public on those important tools and provide a better understanding on their functioning.

The Delegation believed such mechanism would allow Member States to exchange opinions with the Medicines Patent Pool, Pat-INFORMED or other initiatives to improve resources and tools. The Delegation explained that the proposal included a timeline of four years, after which the Committee would decide on a follow up. The Delegation was prepared to answer any questions concerning the proposal, if there were any. The Delegation believed that the regular update could start already at the twenty-ninth session of the SCP.

146. The Delegation of the United States of America thanked the Delegations of Argentina, Brazil, Chile and Switzerland for their proposal. The Delegation agreed that receiving yearly updates from the Representatives of Medicine Patent Pool and Pat-INFORMED on their information platforms would be useful. However, the Delegation noted that due to the late date of submission of that proposal, they would need to review it further internally before coming to a final conclusion on whether the Delegation could fully support it.

147. The Delegation of Argentina, as one of the co-sponsors of the proposal, endorsed the statement made by the Delegation of Switzerland. The Delegation considered that databases such as MedsPaL and Pat-INFORMED were tools which provided a greater transparency to the patent system and facilitated the decision-making process of the health authorities enabling them to obtain information on the situation of patents on medicines. The Delegation was of the opinion that, as highlighted in document SCP/28/10, a periodical update on the progress made in the information platforms would enable the Committee to continue a constructive discussion on work in that area and exchange points of views on possible alternatives to improve its resources and tools.

148. The Delegation of the Republic of Korea observed that patents and public health were closely related to each other. The Delegation specified that there were various and different viewpoints on the relationship between patents and access to medicines and health technologies. The Delegation noted that it was of the utmost importance to have a comprehensive view on every effect of patents on access to medicines and health technologies. For that reason, the Delegation considered that it was crucial to have a sharing session during the twenty-eight session of the Committee. The Delegation was pleased to have an information exchange session on publicly accessible databases on patent information status and data, on medicines and vaccines, in order to promote mutual understanding among Member States' experiences and to share various viewpoints. The Delegation was of the opinion that it was crucial to understand the *status quo* of each Member State in order to produce a positive outcome in the area of patents and access to medicines. The Delegation hoped to participate in the discussion on that agenda item in a balanced manner. The Delegation stated that a balanced study on that issue should be conducted in order to achieve desirable outcomes. The Delegation wished that all Member States discussed with a transparent approach and an open mind.

149. The Delegation of Chile was pleased to cosponsor the proposal contained in document SCP/28/10, and thanked the Delegation of Switzerland for having presented it in an excellent manner. The Delegation further thanked the Delegations of Argentina and Brazil for the work carried out regarding that document. The Delegation fully shared the view that an improved access to information on the legal status of patents and licenses in the area of medicines and vaccines would facilitate health authorities and procurement agencies in taking their decisions. The Delegation shared also the view that there were barriers which made such access difficult, creating inevitably an obstacle for a proper access to medicines and vaccines. The Delegation stressed that that proposal involved tools which already existed, i.e. the databases of MedsPaL and Pat-INFORMED. The Delegation specified that both databases identified public information on patents related to medicines and vaccines, and facilitated patent search by health authorities and procurement agencies. The Delegation, as an active supporter of Medicines Patent Pool since its origins, and being convinced of the importance that kind of

initiatives had in relation to the patent system and access to health, believed that it was crucial that both of them had an official and regular body within the Committee to report their achievements and the challenges faced. The Delegation believed that such proposal was drafted in clear terms and did not see any obstacles which might prevent its adoption at the current session of the Committee. The Delegation urged all the members of the Committee to jointly approve that initiative.

150. The Delegation of Spain supported the statement made by the Delegation of Austria, speaking on behalf of the European Union and its Member States, on the agenda item on patents and health. The Delegation was aware of the problems and challenges that the countries of all sorts of income and regions were facing in having access to medicine. However, the Delegation believed that the fruit of research carried out in that field and protected through patents, made it possible to obtain medicines to treat diseases, such as Hepatitis C, which had been incurable for years. The Delegation hoped that the promotion of the use of the patent system would allow, in the near future, curing many diseases which were still incurable to date. The Delegation attached great importance to the item on the relationship between patents and access to medicine. Therefore, the Delegation welcomed with great satisfaction the new proposal submitted by Member States which, at least up until recently, appeared not to agree on the agenda item on patents and health. The Delegation considered the two proposals, the one contained in document SCP/28/9 submitted by the Delegations of Argentina, Brazil, Canada and Switzerland, and another contained in document SCP/28/10, submitted by the Delegations of Argentina, Brazil, Chile and Switzerland, very interesting, not only because of their content and objectives, but also due to the effort put by those delegations in order to overcome differences, which seemed to be impossible to resolve up until recently. For those reasons, the Delegation supported the proposal contained in document SCP/28/9. The Delegation believed it was essential to analyze and compile all studies on the issue of the relationship between patents and access to medicines to be carried out within WTO, WIPO and WHO. The Delegation further supported the proposal contained in document SCP/28/10 to receive annual updates on the progress made in the platforms of MedsPaL and Pat-INFORMED. The Delegation, in that latter case, wondered if it was possible to include regular information of other existing databases on that subject-matter in addition to those indicated in the proposal.

151. The Delegation of India understood that the proposal regarding a Regular Update on Publicly Accessible Databases of Patent Status Information Concerning Medicines and Vaccines, contained in document SCP/28/10, included also a yearly update before the SCP by the Representatives of MPP and Pat-INFORMED. The Delegation welcomed that proposal and expressed its wish to participate in future activities in its framework. The Delegation further believed that the proposal contained in document SCP/28/9 was balanced and welcomed discussions on it. However, the Delegation stated that the Committee should also consider the UNHLP Report while reviewing existing research on patents and access to medical technologies. Furthermore, the Delegation pointed out that such review should be restricted to patent law issues, such as the role of patentability criteria, and the patent examination system in facilitating access to medicines and health technologies, which were key recommendations of the UNHLP.

152. The Delegation of Morocco, speaking on behalf of the African Group, recalled the proposal by the African Group on the agenda item on patents and health. The Delegation stressed that for African countries, the topic of patents and health was a priority and required debates in different international fora on a comprehensive policy that would enable countries to meet the needs in the area of public health. The Delegation took note that the relationship between patents and health was a source of global concern. The Delegation recalled the African Group's proposal contained in document SCP/24/4 which was articulated around three main points: (i) a study, to be prepared by independent experts, on constraints faced by

developing and least-developed countries in making a full use of patent-related flexibilities; (ii) exchange of information amongst the Member States and experts renowned in that field; and (iii) provision of technical assistance to Member States, particularly developing and least-developed countries, taking into account the work accomplished in the framework of the two points above mentioned. The Delegation explained that such proposal also requested WIPO to set-up an international register of patents on medicines and licenses concerning those patents. The Delegation reminded the support that the proposal of the African Group had received from Member States since its presentation during the twenty-fourth session of the SCP, being a well-structured, ambitious and pragmatic proposal.

153. The Delegation of Iran (the Islamic Republic of) thanked the Delegations of Argentina, Brazil, Canada and Switzerland for their proposal contained in document SCP/28/9. The Delegation acknowledged the effort made in revising such proposal in order to reflect the feedback and comments received from the Member States during the two previous sessions of the Committee. The Delegation shared the view that that proposal was not intended to compete or replace the other work carried out under the agenda item on patents and health. The Delegation understood that the scope of such review remained limited to the mandate of the SCP and did not go beyond the discussion on the patent-related aspects to health technology. The Delegation noted that as the time period covered by the study was 2005 to 2015, it was its expectation that the report of the UNHLP and IP relevant recommendations contained therein would be reflected in the final product of the proposed work program. The Delegation further welcomed the proposal regarding the regular updates on publicly accessible databases of patent status, information concerning medicine and vaccines contained in document SCP/28/10. The Delegation recalled that its priority for future work under that agenda item was reflected into the elements contained in the proposal of the African Group under document SCP/24/4.

154. The Delegation of Indonesia expressed its wish to start with a general statement with regard to the agenda item on patents and health, to be followed by specific comments with regard to the proposals presented under that agenda item. The Delegation echoed the views that the topic of patents and health was of great importance to all Member States. The Delegation believed that providing access to essential and life-saving medicines at affordable prices was indeed in the interest of all countries. The Delegation explained that the patent system was designed to promote innovation and at the same time offer a mechanism to ensure that innovation was accessible to society. The Delegation was of the opinion that, in the context of public health, the objective of the patent system was to achieve an optimal balance between the interests of the patent holder and those of the public at large. The Delegation believed that the objective of the exercise of patents and health within the SCP was to develop a work plan for the Committee in order to inform Member States in achieving the optimal balance between granting exclusive right on inventions related to medicines and making sure that the public's access to medicines was not threatened. The Delegation considered important the discussion under that agenda item on how the Secretariat and WIPO Member States could work together in the understanding and use of TRIPS flexibilities related to public health. The Delegation further recalled the cooperation agreement for technical assistance between WIPO and WTO, which gave WIPO the mandate to offer assistance on IP-related matters which were also covered by WTO agreements. The Delegation thanked the Delegations of Argentina, Brazil, Chile and Switzerland for their proposal contained in document SCP/28/10 and the Delegation of Switzerland for its presentation. In the Delegation's view, a regular update would allow Member States to engage in a constructive discussion on patent information on medicines and vaccines and on the ongoing work in that area. The Delegation stressed that for Indonesia, finding a balanced solution to procure medicines at competitive prices was not only about furthering commercial interest through price negotiations, but also facilitating options to generic medicines procurement. The Delegation recalled that, at the launch of the Pat-INFORMED database during the 2017 WIPO General Assembly, it was made clear that the database would

identify patents that Pat-INFORMED participants had the right to enforce and might be relevant to the supply of generic products and that it could not provide and should not be seen as providing any guarantee of freedom to operate for a number of reasons. The Delegation hoped that the Committee would be able to find an agreement with regard to that proposal in a manner acceptable to all. The Delegation thanked the Delegations of Argentina, Brazil, Canada and Switzerland for the proposal on a review of the existing research on patents and access to medical products and health technologies as reflected in documents SCP/28/9 and SCP/28/9 Add.. The Delegation fully agreed that all countries shared the interest to encourage development of new and innovative medical products and health technologies, promote the transfer and dissemination of technological innovation as well as ensure timely access to advancements in medical products and health technologies at a sustainable cost to individuals and society. The Delegation was supportive of the conduct of any literature review, as long as the exercise would remain within the realm of patent law issues. The Delegation specified that it would not be within the mandate of the Committee or WIPO to review other issues relating to access to medicines such as taxes, tariffs, price control regulations, differential pricing modality, point of purchase arrangements, sustainable health financing, reimbursement systems, regional selection, use of medical products, reliable health and supply system, purchasing power and insurance coverage of patents. The Delegation was of the view that the Committee should limit itself to those factors and/or other issues. The Delegation pointed out that those further factors were to be defined clearly, in order to ensure their consistency with the Committee's mandate. It was in the Delegation's interest that any review exercise would also address the role of patentability criteria and the patent examination system in facilitating access to medicines and health technologies. The Delegation expressed its willingness to lend its support if any review would also cover flexibilities in the international legal framework related to access to medicines and application of robust patentability criteria from a public health perspective in the examination of pharmaceutical patents. The Delegation was looking forward to further discussion on that proposal and hoped that the Committee could find a solution for a review activity that would be balanced and acceptable to all. The Delegation recalled the proposal of the African Group contained in document SCP/24/4, and hoped that the Committee could start engaging in its discussion for a work program on patents and health. The Delegation understood that any other proposals submitted to the Committee were not meant to replace the proposal included in document SCP/24/4. The Delegation hoped to have a meaningful discussion and an agreed work program under that agenda item.

155. The Delegation of the United Kingdom thanked the Delegations of Argentina, Brazil, Chile and Switzerland for their proposal contained in document SCP/28/10 and for identifying the opportunity to better understand how MedsPaL and Pat-INFORMED might help to address the issues faced by countries, particularly developing and least developed ones, in obtaining relevant and comprehensive patent information on medicines and vaccines. The Delegation thus supported the proposal to invite both the Medicine Patent Pool and Pat-INFORMED Representatives to regularly update the Committee on the developments of their databases.

156. The Delegation of South Africa aligned itself with the statement made by the Delegation of Morocco on behalf of the African Group. The Delegation believed that it was within the mandate of WIPO to strike a balance between innovation and public health. In that light, the Delegation emphasized the importance of the African Group proposal contained in document SCP/24/4, as they believed that it could address some of the challenges that they were currently facing. The Delegation considered that when life-saving medicines became unaffordable to the public, a moral debate should ensue on the role that the patent might play in inhibiting access to essential and life-saving medicines. The Delegation noted that the issue of high prices for medicines was not a developing or least-developed countries issue, but rather it was a societal issue. The Delegation mentioned that, as an example, the Federal Drug Administration (FDA) in the United States of America approved in 2017 the use of a drug, Ocrevus for people with primary progressive multiple sclerosis (MS) or relapsing MS. The

Delegation explained that such medicine was game changing for people diagnosed with MS. However, the Delegation stressed that many people living with MS simply could not afford the treatment offered by that drug, since it costed 65,000 US dollars per year, which was 20% less than the average cost of medicines used to treat patients living with MS. The Delegation noted that happened in a country where there were no issues on procurement, distribution channel, infrastructure, taxes, and tariff and so forth. Therefore, the Delegation wondered how difficult it could be in developing or least developed countries. The Delegation recalled that the African Group's proposal requested the Secretariat to conduct a study on certain issues, which the Delegation believed to be of interest to all Member States, in identifying and understanding the challenges in the area of patents and public health and in incentivizing innovation in health technologies. The Delegation further mentioned that the African Group's proposal also called for technical assistance in a series of workshops, development of guidelines and information sharing. The Delegation believed that the African Group's proposal was not in any way inconsistent with the mandate of the Committee. The Delegation noted with interest the proposal of the Delegations of Argentina, Brazil, Canada and Switzerland, as contained in document SCP/28/9, to request the review of existing research on patents and access to medical products and health technologies, consistent with the mandate of the SCP. The Delegation observed that such proposal was a departure from the original proposal presented by the African Group that requested detailed studies, since that new proposal was requesting only a literature review. Despite that, the Delegation noted that there were some synergies between the two proposals. The Delegation reiterated its support to the African Group's proposal, as reflected in document SCP24/4, and encouraged the Committee to initiate the substantial work program on the African Group's proposal while considering document SCP/28/9.

157. The Delegation of Côte d'Ivoire thanked the Secretariat and the Member States who had made the proposal on patents and health. The Delegation endorsed the statement made by the Delegation of Morocco on behalf of the African Group. The Delegation noted with interest those proposals that called for further analyzing the studies which could lead to concrete solutions of that issue which was the Achilles' heel of all countries, above all the developing ones. The Delegation recognized that improvements had been made since the adoption of the TRIPS Agreement, but considered that there were still many challenges regarding the use of flexibilities under that Agreement, whose operability was uncertain and effects still difficult to prove. The Delegation believed that there was need of a strong and solid agreement on the topic of patents and health, and that would allow the Committee to move forward and to get the SCP out of the rut that it had been in for the past few years. The Delegation believed that could happen only under the aegis of international organizations like WIPO and the WHO. The Delegation was of the opinion that the African Group's proposal contained in document SCP/24/4 was a good point to start, and expressed its interest in seeing progress in that area.

158. The Delegation of Tunisia attached crucial importance to the issue of patents and health, which was a priority for it. The Delegation endorsed the statement made by the Delegation of Morocco on behalf of the African Group regarding the proposal contained in document SCP/24/4. The Delegation took note of the proposal made by the Delegations of Argentina, Brazil, Canada and Switzerland contained in document SCP/28/9.

159. The Delegation of Morocco, speaking in its national capacity, thanked the Chair for his efforts in making the discussion fruitful, the Secretariat for its work in preparing the current session of the Committee, and the delegations for their contribution. The Delegation endorsed the proposal of the African Group on patents and health contained in document SCP/24/4.

160. The Delegation of France thanked the Delegation of Switzerland for its excellent introduction of proposal contained in document SCP/28/10. The Delegation endorsed the statement made by the Delegation of Austria speaking on behalf of the European Union and its

Member States on the agenda item on patents and health. The Delegation considered that it was an important subject which should concern everybody. In that respect, the Delegation believed that the proposal contained in document SCP/28/9 was a practical proposal that would allow the Committee to move forward towards the SCP's objectives on that delicate topic. The Delegation appreciated the presentations that had been made during the previous SCP session, namely the one made by MPP on MedsPaL. The Delegation believed that a regular update of such information would be useful so that all delegations had the latest information. The Delegation suggested including in that updating exercise also other databases, as proposed by the Delegation of Spain. The Delegation expressed its support for the proposals contained in documents SCP/28/9 and SCP/28/10.

161. The Delegation of Mozambique thanked the Secretariat for all the arrangements for the meeting and commended the Chair for his manner of conducting the SCP work. The Delegation supported the statement made by the Delegation of Morocco on behalf of the African Group. The Delegation believed that the proposal by the African Group would fit all the Member States, irrespective of their regions or level of development. The Delegation explained that the Mozambique IP Code of 2015 established compulsory license as a way of balancing rights of patent holders and needs of public health. The Delegation reiterated that it was in their interest that the proposal from the African Group be taken into account.

162. The Delegation of the United States of America thanked the Delegations of Argentina, Brazil, Canada and Switzerland for their proposal contained in document SCP/28/9 on the review of the existing research on patents and access to medical products and health technologies. The Delegation believed that strong protection of intellectual property incentivized the development of life-saving drugs and encouraged their early launch, creating opportunities both for inventors and follow-on generics. The Delegation further explained that a stable and predictable patent system promoted investments that benefitted countries' economies. The Delegation was open to continuing discussions with the cosponsors of that proposal to try to find an acceptable and constructive way forward on it. However, the Delegation had some reservations regarding several aspects of such document that made it problematic for them to support it in its current form. The Delegation stated that the overarching area of interest for them was that any studies included under the review should be the result of an objective critical analysis. For that reason, the Delegation suggested that it was essential that the studies included in the proposed review should be peer-reviewed and evidence-based. The Delegation further mentioned that a second important area of interest for them was that the review should include in its scope the relationship between various non-patent barriers and availability and accessibility of essential medicines in order to indirectly distill the impact of patents on the availability and accessibility in the short term. The Delegation recalled that such language had been initially included in an earlier version of the proposal reflected in document SCP/26/6. The Delegation noted that, as previously mentioned during the Committee, the effect of various non-patent barriers to access to those medicines was pertinent to the discussion of the SCP. The Delegation was of the opinion that learning about those barriers was crucial in understanding the extent of the effect that the patent system might have. The Delegation took note that ensuring effective access to life-saving medicines was a critical issue around the world. However, the Delegation observed that, as many studies and seminars had pointed out, there were numerous factors that influenced access to medicines in a country, which should also be considered, including, among others, technical absorption capacity, government procurement, tariff and tax policies, manufacturing capabilities, and logistics and infrastructure factors. The Delegation was concerned that a current proposal might no longer capture studies that would address that important point. The Delegation had a number of other suggestions for the proposal and remained open to constructively engaging with the cosponsors of that proposal to find a way to effectively inform the SCP non-normative discussions on that topic.

163. The Delegation of Switzerland, speaking on behalf of Group B, reiterated that it supported the work carried out under the agenda item patents and health, provided that it was relevant for the SCP mandate and avoided duplication of work. The Delegation was of the opinion that the proposal of the African Group, as reflected in document SCP/24/4, contained some elements which fell outside of the scope of the Committee's mandate. The Delegation expressed its wish to provide a few illustrative, non-exhaustive, examples with that regard. The Delegation, as the first example, noted that many additional incentives listed under paragraph 12 of such proposal did not relate to the patent system. In relation to paragraph 14, the Delegation reiterated its position that, in its view, the UNHLP Report was not a Member State driven process and therefore it did not reflect the opinions of the Member States, nor had their endorsement. The Delegation further emphasized that any discussion and future work should take into account the wide range of views and factors affecting access to medicines. With respect to paragraph 15 of that proposal, the Delegation stressed that the UN Special Rapporteur had a mandate and parameters of work that were not directly relevant to the SCP discussions, being the Committee of a technical body. Therefore, The Delegation stated that Group B could not agree on paragraph 15. As a last example, the Delegation mentioned paragraph 16, where it was stated that discussions on compulsory licenses should take into account the broader objectives of the patent system. In that respect, the Delegation referred to the extensive work already carried out under the agenda item exceptions and limitations, including studies, seminars and sharing sessions on the topic. Consequently, the Delegation believed that the proposal on a workshop on compulsory licensing would lead to an unbalanced discussion.

164. The Delegation of Switzerland, speaking in its national capacity, referred to some of the comments that had been made on the joint proposal contained in document SCP/28/10. The Delegation stressed that it had been mentioned several times that other initiatives could also be included in the proposal. The Delegation referred the Member States to paragraph 9 of the proposal, where they invited Member States to discuss and approve similar initiatives, which could be included in the yearly update on the advances of the information platforms.

165. The Delegation of Japan thanked the Delegations of Argentina, Brazil, Canada and Switzerland for the submission of document SCP/28/9, the proposal to conduct a review of existing research on patent and access to medical products and health technologies. The Delegation shared the view that access to medicines was an important issue. The Delegation reiterated that the issue of access to medicine involved various factors. It explained that those factors included some other than those related to the patent system, such as national health care system, quality and quantity of medical human resources, local production capacity, access to medical facilities and distribution channels. On that point, the Delegation supported the view expressed by the Delegation of the United States of America. The Delegation further believed that financial incentives for developing new drugs encouraged more R&D activities and benefitted people around the world. Therefore, the Delegation was of the opinion that appropriately protecting Intellectual property rights was critical to providing inventors with incentives to develop innovative medicines and devices which would save millions of lives in the world. The Delegation noted that that had always been the case. The Delegation concluded that it was their conviction that such 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 effect of the patent system.

166. The Delegation of Egypt reiterated its support for the statement made by the Delegation of Morocco on behalf of the African Group on the agenda item on patents and health. The Delegation further endorsed the statements made by the members of the African Group. The Delegation noted that the African Group proposal, as contained in document SCP/24/4, included a whole set of activities that the Committee could undertake under that agenda item within the framework of its work and mandate. The Delegation specified those activities covered, among others, recommendations and studies put forth by the UNHLP Report. The

Delegation took note of the proposal made by the Delegations of Argentina, Brazil, Canada and Switzerland. The Delegation believed that such proposal was a good basis for discussion, being not far from the African Group proposal. The Delegation pointed out that all the submitted proposals were acceptable, provided they were aimed at improving the well-being of the population of all Member States, and increasing their level of health.

167. The Delegation of Canada took the opportunity to present the revised version of the proposal contained in document SCP/28/9 to the Member States and the Committee. The Delegation thanked Member States for their comments and for providing them with the opportunity to present the revised proposal at the twenty-eight session of the SCP. The Delegation was pleased to note that the Delegations of Brazil and Argentina had agreed to join Switzerland and Canada in cosponsoring the proposal. The Delegation thanked the Delegations of Argentina and Switzerland for cosponsoring their proposal and was looking forward to working with them. The Delegation further thanked Member States for the positive engagement on their proposal during the previous session of the SCP. The Delegation noted that that version of the proposal remained identical to the version that had been circulated to regional coordinators at the twenty-seventh session of the SCP, with only two minor technical changes. Firstly, the Delegation specified that paragraph 3, in its revised version, began with “what we propose” instead of “Canada proposes” so that it reflected the fact that there were multiple cosponsors. The Delegation further explained that also the timing of the review was changed in paragraph 7, so the expression “to follow the 28th session of SCP and be presented at SCP 30” replaced the terminology “commencing after SCP 27”. The Delegation stated that they were advancing that proposal in a constructive spirit and with a view to contributing to the discourse on that essential topic in a collaborative fashion in order to create a document that all Member States could find useful. The Delegation clarified that their proposal was not intended to compete with, or replace, other work carried out under the agenda item on patents and health and should be considered strictly on its own merits. The Delegation further acknowledged that there was a vigorous debate with many points of view on the relationship between patents and access to medical products and health technology. The Delegation considered that that exercise was not intended to settle that debate, but grounded on a foundation of high quality research. The Delegation stressed that that was merely intended as a literature review to summarize and collect more than a decade’s work of research into one resource that all Member States could draw from to support their respective positions. The Delegation pointed out that the report would not make any original recommendations and inclusion of any study in the report should not be understood as an endorsement of that document’s conclusions or recommendations by the Secretariat or the Committee. The Delegation highlighted that given the breadth of studies that would be captured by that exercise, the Delegation expected that all sides of the debate would be well represented in the final report. The Delegation thanked all Member States for their comments and looked forward to further discussions and collaborative work.

168. The Delegation of Nigeria supported to revisit the African Group’s proposal contained in document SCP/24/4. The Delegation considered that that proposal was the solution to the challenges faced in the field of public health.

169. The Delegation of the Dominican Republic thanked the Delegations of Argentina, Brazil, Canada, Chile and Switzerland for their proposals. The Delegation noted that medicines were essential elements in ensuring the greatest degree of public health. For that reason, the Delegation believed that research on patents and access to medical products and health technologies, as well the update of information contained in databases such as Pat-INFORMED and MedsPaL, could have positive impacts on the lives of the population. Therefore, the Delegation endorsed the proposals included in documents SCP28/9 and SCP/28/10.

170. The Representative of WHO, in relation to the proposal made by the Delegations of Argentina, Brazil, Chile and Switzerland contained in document SCP/28/10 on a regular update on publicly accessible databases of a patent status information concerning medicines and vaccines, stated that the WHO Secretariat had participated in the information session during the previous session of the SCP where it had expressed the importance of access to information regarding status of patents, licenses and patent applications around the world. The Representative noted that for the health authorities and national government procurement authorities, as well as for regional and international health agencies, it was important that such information was available in user-friendly formats to allow them to make informed and lawful decisions on the manufacturing, purchase, licensing or import of health products. The Representative congratulated the expansion of MedsPaL to all patents on essential medicines and welcomed the Pat-INFORMED initiative. The Representative looked forward to see the new Pat-INFORMED database and hoped it would include also patent applications and patents on essential biologics. The Representative expressed the wish to share with Member States that the WHO had recently published a Progress Report on Access to Hepatitis C Treatment, focused on overcoming barriers in low and middle-income countries, which included patents and license information in that field. The Representative informed that copies were made available to the members of the Committee. The Representative stated that she had followed with interest the deliberation of the Committee regarding the proposal in document SCP/28/9 to conduct a review of existing research on patents and access to medical products and health technologies. The Representative stated that if the SCP would decide on moving forward with that proposal, the WHO was ready to support the work in collaboration with WIPO and WTO in the framework of their existing trilateral collaboration and in collaboration with other relevant international organizations. The Representative informed the Committee that the World Health Assembly, during its meeting held in May 2018, had discussed two agenda items in that area: (i) implementation of the global strategy and plan of action on public health, innovation and intellectual property; and (ii) how to address the global shortage of and access to medicines and vaccines. The Representative noted that the World Health Assembly had decided to request the WHO Secretariat to elaborate a roadmap report outlining the programming of WHO's work on access to medicines and vaccines. The Representative further informed the Committee that an online Member States' consultation process on the zero draft roadmap had recently started and would run until August 16, 2018. The Representative communicated that a consultation meeting would take place in Geneva on September 10 and 11, 2018, on those activities.

171. The Representative of MPP welcomed the opportunity to provide some information regarding the Medicines Patents and License Database, known as MedsPaL. The Representative appreciated the Committee members' interest in promoting patent transparency. The Representative recalled that MedsPaL was a free platform that provided patent licensing and regulatory data exclusivity information for more than 6,800 national patent applications and medicines in over 100 low and middle-income countries. The Representative mentioned that at the request of WIPO Member States, MPP had had the pleasure to present MedsPaL at the twenty-seventh session of the SCP. The Representative specified that, as it was announced at that time, MPP had recently expanded the range of medicines included in MedsPaL from HIV, hepatitis C and tuberculosis to other medicines which included medicines for various cancers and hepatitis B, as well as some biological medicines. The Representative explained that MedsPaL included not only information on patents and patent applications, but also on licenses, both negotiated by the Medicines Patent Pool and negotiated directly between companies. The Representative highlighted that they had included information on regulatory data exclusivity which was another form of exclusivity available in certain countries in which MPP had been collecting data from national regulatory authorities. The Representative stressed that over the previous few months, MPP had continued to develop collaboration agreements with various patent offices and had signed an agreement with one additional regional patent office, namely, the African Regional Intellectual Property Office (ARIPO). The Representative pointed out that

ARIPO's accession brought the number of patent offices with whom MPP had an agreement to nine: Argentina, ARIPO, Brazil, Chile, the Dominican Republic, Ecuador, El Salvador, the European Patent Office (EPO) and South Africa. The Representative stated that through those collaboration agreements, the patent offices had agreed to work with MPP, and to provide information on the legal patent status data for a number of essential medicines in order to facilitate access to such information which was of great importance to a wide range of public health stakeholders, working to increase access to medicines in low and middle-income countries. The Representative looked forward to continued collaboration with additional patent offices and to have the opportunity to explore and discuss that possibility with a number of patent offices during the current session of the Committee. The Representative took note of the proposal from a number of WIPO Member States to invite the MPP for a regular yearly update during the winter session of the SCP. The Representative declared that, if Member States agreed on that proposal, MPP would be glad to do so and continue to engage with WIPO Member States in order provide regular updates on MedsPaL and new features as the product continued to evolve.

172. The Representative of JIPA had the pleasure to provide a statement on behalf of their association, comprising about 900 major Japanese companies as members. The Delegation made the statement in collaboration with the Japan Pharmaceutical Manufacturer's Association (JPMA), which counted 72 leading R&D oriented pharmaceutical companies, and with the support of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). The Representative believed that it was important for the Committee to agree that providing excellent medicines to a lot of patients all over the world was a mission of governments and companies in least developed and developing countries. The Representative noted that the pharmaceutical industry had developed a lot of medicines over the past century, and in particular over 550 medicines in the last 15 years. The Representative stressed that those medicines had contributed to human health and saving lives. The Representative specified that developing a new medicine implied significant costs and a long R&D period. The Representative explained that to successfully distribute a medicine to patients in a new country, pharmaceutical companies had first to bear the cost for conducting additional clinical trials to meet local requirements, obtain local regulatory approval, set-up local distribution channels, make new networks, educate health care providers about the benefits of the new products, and undertake post-marketing research and surveillance. The Representative highlighted that intellectual property rights were able to provide companies invested in launching a new medicine with an opportunity to keep creating more innovative drugs or more variable therapies for patients. Referring to a report prepared by the National Bureau of Economic Research, the largest economics research organization in the United States of America, the Representative noted that stronger patent protection accelerated new drug launches. The Representative believed that appropriate patent protection would enable pharmaceutical companies to continuously carry out R&D activity for delivering excellent medicines that would contribute to human health and saving lives in developing and developed countries. The Representative stated that, although the effectiveness of using a compulsory license had been proactively discussed, they did not believe that the problem of access to medicines could be solved by limiting patent rights, including issuing a compulsory license. The Representative pointed out that, as mentioned in document SCP/26/5, 95% of the medicines contained in the 2013 WHO model list of essential medicines, were not under patent protection in the majority of lower-income countries. The Representative observed that patents with respect of those medicines had expired or were not filed. The Representative concluded that such fact meant that there should be factors other than patent protection which were restricting access to medicine. The Representative believed that various factors other than patent protection, such as regulatory shortcomings, supply chain programs, lack of health-care financing, resulted in problems of access to medicine. The Representative further noted that, as intensely discussed at the patents and health session at the twenty-seventh session of the SCP, an affordable price was a crucial factor in order to improve access to medicine in developing countries. The

Representative stated that Japanese pharmaceutical companies strongly recognized that issue and were proactive in finding a solution to it. With that regard, the Representative expressed its wish to provide a few examples on how Japanese pharmaceutical companies were struggling with access to medicines in developing countries in order to solve that issue. The Representative illustrated that Eisai, a Japanese pharmaceutical company, believed that providing health care products at prices commensurate to the income levels of each country was very important, and had adopted affordable-pricing strategies in developing countries using various models. The Representative stressed that such company, for example, already provided receptor, a treatment for Alzheimer, in Indonesia, and Revovir, a treatment for patients with chronic hepatitis B, in the Philippines, at lower prices compared to those applied in developed countries/regions such as the United States of America, Europe and Japan, helping patients with low incomes to have access to those medicines. The Representative further mentioned that Takeda's Patients Assistance Program (PAP) used an innovative approach to increase access to some medicines in a sustainable way. The Representative reported that Takeda had currently PAPs regarding the pharmaceutical product Adcetris in countries with evolving health care systems, such as Malaysia, the Philippines and Singapore, as well as in some selected countries in Southeast Asia, Middle East, Eastern Europe, Africa and Latin America. The Representative also noted that Japanese pharmaceutical companies were actively engaged in finding solutions to the problem of neglected tropical diseases (NTDs). The Representative further introduced a few examples of Japanese pharmaceutical companies' engagement with the problem of access to medicines regarding NTDs. The Representative stated that the pharmaceutical company Astellas was participating in the Neglected Tropical Diseases Discovering Booster consortium launched by the Drugs for Neglected Diseases Initiative (DNDi), together with Eisai, Shionogi, Takeda and seven other pharmaceutical companies. The Representative specified that the purpose of that consortium was to identify lead compounds for new anti-parasitic drugs for leishmaniosis and Chagas diseases. The Representative further explained that Sumitomo Dainippon Pharma had signed an agreement with Medicines for Malaria Venture (MVV) on joint research aimed at identifying anti-malaria candidate compounds joint research. The Representative clarified that that joint research had its origins in the compound-screening program for malaria program which Sumitomo Dainippon Pharma and Medicines for Malaria Venture had been jointly conducting since 2015. The Representative recalled that both the joint research and the program had been awarded funding from the Global Health Innovative Technology Fund (GHIT). The Representative stressed that in February 2016, Daiichi Sankyo and DNDi had launched a High-Throughput Screening (HTS) Project of 40,000 compounds with the goal of discovering anti-Chagas and anti-leishmaniosis compounds, and had subsequently identified three compounds series. Based on the results obtained in March 2017, Daiichi-Sankyo had signed an agreement with DNDi to advance a Hit-to-Lead Project in order to develop derivatives from those three compounds series as leishmaniosis and Chagas disease treatment. The Representative stressed that such collaborative project had been funded through the GHIT Fund Hit-to-Lead Platform (HTLP). The Representative stated that more information on other JPMA activities related to access to medicines in developing countries was available on JPMA's website. The Representative recalled that Japan's pharmaceutical companies had been joining about 30 partnerships for developing medicines for neglected tropical diseases and worked actively in order to address the problems of access to medicines in developing countries. The Representative believed that Japanese companies' activities were contributing to improving access to medicines. The Representative further understood that, as referred to in document SCP/26/5, there should be factors other than patent protection which were restricting access to medicines. Therefore, the Representative believed that promoting R&D of medicines and the use of the patent systems could accelerate the launching of new drugs. The Representative was convinced that the patent system promoted public health in developed countries as well as in the developing ones.

173. The Representative of IFPMA expressed its wish to make three comments, given that IFPMA was mentioned in document SCP/28/10. The Representative thanked the proponents of such document and all the others members of the Committee for recognizing the great value of Pat-INFORMED, a joint initiative of WIPO and IFPMA. Secondly, while the Representative did not plan to give an update or answer some of the questions that had been raised, he mentioned that there would be a big event related to Pat-INFORMED during the 2018 WIPO General Assembly. Thirdly, the Representative confirmed that the Committee could count on IFPMA's constructive contribution to its work, and in case of any invitations, IFPMA would probably respond positively.

174. The Delegation of Switzerland expressed its wish to make some comments on document SCP/28/9. The Delegation aligned itself to the statement made by the Delegation of Canada on the proposal contained in document SCP/28/9, and was pleased that the Delegations of Argentina and Brazil cosponsored that proposal. The Delegation thanked the Delegation of Spain for its statement and for its comments on the importance of overcoming differences among delegations and defining common determinants for collaboration. The Delegation further thanked the Delegations of Argentina, Brazil, Canada and Chile for their good collaboration. The Delegation, with respect to document SCP/28/9, referred to some points in the revised proposal that they considered important. Firstly, the Delegation believed that the review of existing quality studies in the field of patents and health would benefit all Member States and the work of the SCP. The Delegation observed that there was rich research documentation and a variety of aspects and issues related to patents and health. The Delegation was of the opinion that the proposed study would shed light on the research and quality evidence related to the relationship between patents and access to medicines, and would provide the Committee with the state of knowledge needed by improving the knowledge of its participants. Considering the already existing extensive high-quality research conducted by WHO, WTO and WIPO, as well as by academic researchers, the Delegation believed that the review of such documentation was a constructive step forward before continuing or entering into further work on patents and health. In the Delegation's view, that would help the Committee in advancing its future work in a way and direction that could provide a genuine and original contribution to the state of knowledge and on the relation between the patent system and access to health technologies. The Delegation explained that the review would focus on fact-finding and research based on technical expertise. The Delegation clarified that such proposal did not prejudice other proposals under that agenda item, for example, the proposal of the African Group or the second proposal under document SCP/28/10 that the Delegation cosponsored. The Delegation explained that the resulting document of the review would not include original recommendations. The Delegations stressed that Member States were free to develop their own conclusions based on the document and define the way forward. The Delegation thanked Member States for their constructive comments and were looking forward to further discussion of the proposal with them and to address the concerns that they had expressed.

175. The Delegation of Argentina reiterated the relevance the issue of patents and health had for its country, and in particular the access to medical products and health technologies. The Delegation thanked the Delegation of Canada for the presentation of document SCP/28/9. The Delegation considered that a review of the existing research on patents and access to medical products and health technologies, as proposed in that document, would provide the Committee with factual information, without including recommendations. The Delegation believed such information would be extremely useful to improve the understanding of the topic and would serve as a basis to continue the work of the Committee in a harmonious and efficient way without duplications.

176. The Representative KEI considered that, as the Committee was discussing its work program on patents and health, it was worthwhile revisiting recent discussions on that topic within the WHO. The Representative noted that during the WHO Executive Board held in January 2018, the Delegation of the Netherlands had underscored that increased transparency on relevant data, such as innovation pipelines, pricing, market power and patents, had been unconditional for achieving the SDG 3.8. It had further noted that countries like the Netherlands had been considering the use of compulsory licensing to address the high prices of medicines. The Representative further recalled that during the WHO General Assembly held in May 2017, the Delegation of Portugal had noted that all regions of the world had faced, at different levels, insufficient access to medical products. The Representative further mentioned that in its intervention, the Delegation of Portugal had noted that in recent times, the dramatic increase of prices of new and innovative medicines had made them unaffordable to a large segment of the population also in rich countries while threatening the sustainability of health care systems. According to the Representative, the Delegation of Portugal had considered that in too many countries, prices of new medicines to treat hepatitis C and cancer, for instance, had been particularly shocking. The Representative underscored the strong support of KEI for the African Group's proposal contained in document SCP/24/4, as a sound basis for the Committee's work on patents and health. The Representative urged the SCP to schedule a presentation by experts on the legal basis of, and Member States' experiences with, the non-voluntary use of patents on medicines as a limitation to remedies available in Part 3 of the TRIPS Agreement, including cases of running royalties for infringement of medical devices and diagnostic tests and export of those products outside of the TRIPS Article 31 *bis* framework. The Representative suggested that the proposal submitted by the Delegations of Argentina, Brazil, Canada and Switzerland be expanded to address also the issues of transparency, as they related to litigation over patent validity and scope and the economic aspects of drug development and commercialization, including the costs of R&D, the prices and revenues of products as well as utilization in gaps in access for new drugs. The Representative considered that the need for greater transparency on R&D outlays was relevant for several reasons. First, the Representative was of the opinion that the only reason to grant a legal monopoly on a life-saving drug was to induce private investments in R&D. The Representative believed that if there was no reliable data on R&D outlays, including data on each clinical trial used to support the registration of a novel drug, it was not possible to evaluate the efficacy and efficiency of the patent monopoly as an incentive more properly designed, or evaluate alternatives to the monopoly, such as cash market entry rewards. The Representative considered that those alternatives to patents would be consistent with greater and fairer access to medical innovations. The Representative stated that the terms of reference of Canada's proposed work program on assessing the role of compulsory licensing and voluntary licensing mechanisms, such as patent pools, in facilitating the affordability and availability of medical products, should provide information of all cases between 2005 and 2017 where non-voluntary use of patents was allowed as a limitation on remedies, including, for example, limitations on remedies for infringement of patents on medical diagnostic tests and medical devices in the United States of America. The Representative informed the Committee that KEI had compiled an extensive catalog on countries' practices on that topic and would be glad to share the results of that research with the Committee. The Representative was of the opinion that the study should also examine the use and impact of compulsory licenses of medicines for HIV, cancer and heart disease in developing countries between 2001 and 2017. For that purpose, the Representative drew the attention of the members of the Committee to a recent study on the use of TRIPS flexibilities published in the bulletin of WHO in March 2018. The Representative concluded his intervention by drawing the Committee's attention to negotiations at the UN in New York on political declarations for tuberculosis (TB) and other non-communicable diseases. The

Representative stated that it had come to their attention that one Member State had been determined to purge all references to WTO TRIPS flexibilities and to the progressive delinkage of R&D costs from the prices of medical technologies. The Representative considered that that was a sad state of affairs, and in his view undermined the commitment to multilateralism to the detriment of a balanced IP systems and the international trade architecture.

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

177. The Delegation of Switzerland, speaking on behalf of Group B, attached high importance to the topic of confidentiality of communications between clients and patent advisors. The Delegation noted an increase in the filing of patent applications and grant of patents in various jurisdictions. The Delegation considered that the issue surrounding the protection of the communication between clients and patent advisors was strongly related to the patent application procedures as well as patent prosecution and litigation in different countries. The Delegation was convinced that such issue had a significant impact on how the patents were filed and how communications under those procedures were handled. The Delegation believed that patent applicants or owners needed to be able to receive cross-border legal advice without the risk of forced disclosure of the confidential communication received from their patent advisors. The Delegation stressed that unclear or lack of regulations in countries caused legal uncertainty and unpredictability, and affected the users of the patent system, both patent applicants and patent advisors. The Delegation observed that users of the patent system from different regions, for example, Brazil, Canada, India, Japan and Switzerland had emphasized the need to treat that subject at the international level. The Delegation highlighted that the users of the patent system could not rely on the confidentiality of their advice in cross border situations. The Delegation stated that Group B strongly expected the SCP to respond to that issue. The Delegation noted that the protection of confidentiality would not affect the disclosure of an invention. The Delegation specified that patent laws worldwide requested the disclosure of the invention in a manner sufficiently clear and complete to be carried out by a person skilled in the art. The Delegation pointed out that such patentability requirement was not compromised by the client-patent advisor privilege, neither did the confidentiality of communication between clients and patent advisors affect the level of available prior art for patent examiners. The Delegation believed that the Committee should take substantive steps to address that matter at the international level in a manner that left enough space of flexibility for Member States in light of the differences of legal systems applicable to that subject matter. The Delegation noted that the soft law approach had been proposed during several SCP meetings and should be further pursued. The Delegation reported that Group B believed that court cases in different national legal systems in the field of confidentiality of communications would provide resourceful materials for Member States and would contribute to that important discussion. The Delegation recognized that different opinions had been presented around that issue during the previous sessions of the SCP. The Delegation reiterated the invitation to all Member States to approach the problems and/or difficulties they saw in conducting such work in a more objective and precise manner in order to foster a discussion on what could be accomplished. The Delegation mentioned that, for example, Group B had suggested that a study based on the questionnaire could be conducted and that the collection of court cases should be continued so as to allow Member States who wished to provide additional relevant court cases to submit such information.

178. The Delegation of Austria, speaking on behalf of the European Union and its Member States, attached great importance to the continuation of work under that agenda item. For that reason, the Delegation was pleased to have a second sharing session on the experiences of Member States in implementing the confidentiality of communication between clients and their patent advisor through national legislation, including cross border issues. The Delegation

thanked Member States for giving the Committee the opportunity to continue the work of the twenty-seventh session of the SCP and gaining valuable insight in their national practices and court cases. The Delegation was very much looking forward to further exchanging views about that important agenda item. The Delegation reiterated its sincere interest in further steps to be taken regarding the recognition of foreign patent advisor privilege. The Delegation was convinced that the current situation, with unclear or lack of regulations in the area, caused legal uncertainty and unpredictability for patent applicants and patent advisors. Therefore, the Delegation recalled its preference for a non-legally binding flexible instrument, since in its view, that would provide advantages not only for the users of the patent system, but for all WIPO Member States. The Delegation was of the opinion that, in contrast to the current circumstance, convergence of different systems would bring significant improvement for all the participants in the IP system. The Delegation firmly believed that increasing legal certainties was beneficial for all WIPO Member States, irrespective of the level of development.

179. The Delegation of Lithuania, speaking on behalf of the CEBS Group, attached great importance to the continuation of the work under that agenda item and welcomed the decision to hold a sharing session on the experiences of Member States in implementing the confidentiality of communication between clients and their patent advisors through national legislation, including cross-border issues. The Delegation reiterated that soft law approach, which had been proposed during the previous meetings of the Committee, could be pursued and effectively applied in that area. The Delegation saw a merit in continuing the collection of the court cases, adding new jurisprudence in that area. The Delegation further stated that the CEBS Group could also support the proposal of the Group B for a study based on a questionnaire that would allow interested Member States to provide additional relevant court cases.

180. The Delegation of Iran (Islamic Republic of) recalled that the Paris Convention left the issue of confidentiality of communication between clients and their patent advisor, which was the matter of administrative and judicial procedures to national laws. The Delegation observed that a sharing session among Member States, which had been organized during the twenty-third session of the SCP, had clarified that there had been fundamentally divergent views among Member States on that issue. For that reason, the Delegation was not convinced that the issue of confidentiality of communication was a substantive patent law issue, and that the Committee should further continue discussion on that topic.

181. The Delegation of Switzerland, speaking in its national capacity, thanked the Secretariat for organizing the sharing session on experiences and court cases of Member States in implementing the confidentiality of communication between clients and their patent advisors through national legislation. While the Delegation had shared its experiences with the client-patent attorney privilege during the previous session of the SCP, it made some general comments. The Delegation noted that professional secrecy had a national character and could not be retained once a patent matter crossed the border. The Delegation stressed that the current situation at the international level showed that adequate regulation and protection of confidentiality did not exist in every country. Moreover, where it existed, the protection was not always applied to foreign patent attorneys or not to the same extent as to the domestic professionals. The Delegation highlighted that in existing laws there were wide divergences in different countries on important factors of professional secrecy protection, for example, on the scope of the protected communication between patent attorneys and their clients, or the qualification of a patent advisor. The Delegation considered that the situation was unsatisfactory with respect to legal certainty and predictability of the safeguard of sensible information and trust in the patent attorney-client relationship. The Delegation believed that a full and frank communication between patent agents and their clients was not possible under those circumstances, and that that compromised the quality of the legal advice with an impact on patent prosecution and quality of patents. The Delegation recalled its proposal on

non-binding soft law presented during the twenty-first session of the SCP, as a solution to the cross-border aspect of the client's privilege. The Delegation specified that such framework might contain general definitions of key terms, such as patent advisor or privileged information, and a minimum standard of the privilege. The Delegation clarified that such framework might serve as a template for national laws and it would provide a flexible approach that would allow the adoption of national legislations according to one country's legal background and needs. The Delegation reiterated its proposal and encouraged Member States to enter into discussions on the content of a non-binding framework which included questions on how Member States would like to define the different essential terms such as patent advisor or professional advice. However, the Delegation proposed, as an intermediate step, further in-depth research on topics such as the notion of patent advisor and the protection for in-house counsels. As to the latter, the Delegation explained that in-house counsels were considered to be a separate profession and did not enjoy the same status and protection as an independent patent attorney in several jurisdictions. The Delegation added that a further topic could be on the qualification of patent advisors, in particular if they had to be a patent attorney or if they could be also another qualified professional. The Delegation concluded that a third topic for studies could be the question on what kind of communication is protected: for example, if the communication with third parties could be also protected by such privilege.

182. The Delegation of Denmark thanked the Chair for facilitating that sharing session. The Delegation stated that confidentiality of communications between clients and their patent advisors continued to be a topic of great importance for the Danish users. The Delegation informed the Committee about the recent changes to the Danish Civil Procedure Act, since that Act had been amended in order to secure the confidentiality of communications between clients and patent advisors. The Delegation explained that Article 170 of the Danish Civil Procedures Act secured confidentiality of communications between clients and professionals in relation to professions where confidentiality was considered necessary, for example, doctors, lawyers, mediators and priests. The Delegation specified that as of July 1, 2018, Article 170 of that Act included patent advisors as defined in Article 134 of the European Patent Convention on EPO's list of European patent advisors. The Delegation clarified that currently Article 170 of the Danish Civil Procedures Act entailed that patent advisors were not required to give evidence to the court of knowledge acquired through their work. The Delegation stated that the Danish Patent Office was pleased with that recent development in the Danish legislation, as it had strengthened the confidentiality between clients and their patent advisors, taking into account the cross border aspects of that topic and its importance for the users of the patent system. The Delegation remained dedicated to discuss the topic within the international context.

183. The Delegation of China considered that the examples and relevant information provided by other Member States during the previous SCP sessions, as well as the current sharing session, were very helpful to understand in depth the agenda item on confidentiality of communication between clients and their patent advisor. The Delegation reiterated its view that the subject matter should be regulated by national laws and had to be left to each country's legislative models and traditions. In its opinion, it could not be addressed by the international patent law. The Delegation stressed that within the legislation of many Member States, and in particular in their patent laws, there was no provision about confidentiality of communication between clients and their patent advisor. The Delegation mentioned, as an example, that in China it was stipulated that the advisor could not disclose the information of the patent application, however, such rule found its basis in the Code of Conduct of those professionals and it was framed as an obligation, not as a privilege. The Delegation believed that on that topic, different legal traditions of countries should be respected and therefore let national laws to decide whether it was necessary to establish a system to protect the confidentiality of communication between clients and their patent advisor, and on which terms. The Delegation was of the view that the current stage was not yet mature for the adoption of an international framework on that agenda item.

184. The Delegation of Morocco, speaking on behalf of the African Group, thanked the Secretariat for organizing a sharing session on the experiences of Member States in implementing confidentiality of communication between clients and their patent advisors through national legislation, including cross border issues. The Delegation noted the various experiences in how some Member States implemented that subject into their national laws, including the limitations and difficulties encountered. However, it was the Delegation's view that such issue fell under the regulation of national laws on administration and judicial procedure, and thus it had some reservation against undertaking in a norm setting or further substantive work on that issue.

185. The Delegation of South Africa thanked the Secretariat for having organized a sharing session on that issue. The Delegation mentioned that one of the structural reforms of the current South African law under review was how to treat qualifications of patent attorneys. The Delegation explained that under the current South African legislation, in order to practice as a patent attorney, it was necessary to have a technical degree and a legal degree, to be admitted as an attorney before the High Court, and to undertake successfully a patent examination test. The Delegation illustrated that such system had for some time sustained the South African patent profession and enabled South Africa to have a very strong patent profession, despite the absence of substantive search and examination in the area of patents before the patent office. The Delegation recalled that South African government was in the process of introducing substantive search and examination for patent application before their national patent office. Therefore, the Delegation clarified that also the current model of patent attorney profession was under review, because it had not allowed the profession to be transformed and it had restricted access to such profession. For that reason, the Delegation stated that the government of South Africa was considering implementing a different system where also patent agents would be allowed to practice on patent-related matters, even if they would not be patent attorneys. The Delegation stressed that patent agents were not regulated by the South African Attorneys' Act which stemmed from the Constitution, and therefore, their communications would not be privileged under those circumstances. However, the Delegation specified, as that was an issue of national law, it was working on the regulation of those communications, and on whether advice given by both patent attorneys and patent agents should be privileged and protected. The Delegation believed that that was an issue to be regulated under national law and not an issue which should be the object of a norm-setting exercise within the Committee.

186. The Delegation of France endorsed the statements made by the Delegation of Austria, on behalf of the European Union and its Member States, and by the Delegation of Switzerland on behalf of Group B. The Delegation informed the Committee of a decision taken by the Court of Appeal of Paris dated November 24, 2015, in the framework of the current information sharing session. The Delegation explained that there had been two companies in conflict: one had been represented by a patent advisor, while the other by a lawyer. The Delegation specified that the lawyer had had in his possession a document prepared by a patent advisor, and thought that he could be constrained by professional secrets to which patent advisors were subject to, in relation to such document. The Delegation recalled that, according to French legislation, patent advisors were subject to absolute professional secret, which extended to consultations with their clients, professional correspondence with the clients, their peers and lawyer, notes of any meeting, and, in general, to all documents related to the professional dossier. The Delegation explained that the lawyer of the opposite side had sustained that he had not been constrained by that legal obligation, since it had only concerned patent advisors. The Delegation noted that, on that specific point, the Court of Appeals had stated that the lawyer had been also obliged to respect that obligation on professional secret when exchanging correspondence with a patent advisor. The Delegation mentioned that in France, there was no

case law on cross border issues with regard to confidentiality of information between patent advisors and their clients. However, the Delegation believed that the principle stated in the referred decision could apply also in cases involving the exchange of correspondence between a patent advisors located in different countries.

187. The Delegation of Turkey shared experiences of its country in implementing the confidentiality between clients and patent advisors, especially by emphasizing the new IP Code and Code of Conduct rules for patent and trademark attorneys which had entered into force in January 2017. The Delegation clarified that such legislation consisted of the new IP Code, which amended the previous law 5000/2003 in respect of the patent attorney profession, and the *ad hoc* regulation provided by the Code of Conduct and Discipline of Patent and Trademark Attorneys which entered into force at the same date. The Delegation specified that the *ad hoc* regulation was issued under the new IP Code. The Delegation considered that those provisions were set to have a major impact on the profession of patent attorneys as they established new rules regarding responsibilities of patent and trademark attorneys, especially from a disciplinary point of view. The Delegation explained that Article 5 of the new IP Code and Code of Conduct introduced attorney-client privilege regulation and the obligation of confidentiality of communication, according to which those attorneys were not allowed to disclose information and secrets regarding their clients. The Delegation specified that such obligation did not in any way involve a right benefitting the clients in the sense of attorney client privilege. The Delegation explained that under the new IP Code, all patent and trademark attorneys, irrespective of whether they were attorneys at law, were subject to, and punishable by, uniform rules of conduct in exercising their professional activity with peers, clients and the Turkish Patent and Trademark Office. The Delegation believed that those new pieces of national legislation provided legal certainty and predictability regarding the confidentiality of communication between clients and their patent advisors at the national level.

188. The Delegation of Japan recalled that it had expressed its views on that issue several times and its position had not changed. The Delegation believed that, in order to ensure that patent attorneys and their clients could maintain honest and frank communications, such communications had to be properly protected in every country. The Delegation was of the opinion that the SCP was a suitable and important forum for Committee's members to share their laws, regulations, code, cases and experiences on that issue so that they could understand the common situation in each Member State and also learn from each other. The Delegation further observed that the attorney client privilege issue needed to be addressed from a cross border perspective. For those reasons the Delegation believed that the Committee should continue discussions to explore the possibility of creating an international framework which could be accepted by a large number of countries.

189. The Delegation of Australia believed that free and frank communication between clients and attorneys was essential to good and clearly articulated patent applications. The Delegation considered that it was not always desirable or practical for applicants to limit their requests for advice to Australian patent attorneys. The Delegation pointed out that in Australia, the majority of patent applications came from foreign applicants who also used patent attorneys in their own country. The Delegation stressed that excluding privilege for communication with a foreign patent attorney was therefore a significant issue. The Delegation was of the opinion that, in the context of the global patent system, high quality professional representation led to well-drafted specifications, greater certainty and validity of granted patents, and most importantly, an increase in the quality of information disseminated to the public for further innovation.

190. The Delegation of the Republic of Korea fully recognized the importance of the client-patent attorney privilege, especially when it came to cross border issues, since international disputes over patent rights were globally increasing. The Delegation considered that nowadays, in order to have an invention to be protected effectively in the global market, it

was crucial to protect the confidentiality-based communication between the patent advisor and their clients. The Delegation believed that that agenda item could be effectively and desirably discussed in the SCP, even though each Member State put in place different systems into their national legislation regarding that subject matter. The Delegation was of the opinion that patent applicants' goodwill and the confidentiality of communication between them and their patent advisors should not be harmed or violated due to different patent systems. The Delegation hoped that Member States would make efforts to bring constructive results and participate in the discussions with an open mind.

191. The Representative of JPAA expressed his appreciation to the Chair for his leadership. The Representative, as he had repeatedly emphasized in previous SCP sessions, firmly believed that keeping confidentiality of communication between clients and their patent advisors was very important. Therefore, the Representative was of the opinion that the SCP should continue discussions on that subject matter. The Representative further considered that the SCP was the most appropriate forum to discuss that issue. He stressed that confidentiality between clients and their patent advisors was important in that it protected trade secrets of clients from being disclosed to third parties. The Representative observed that, as mentioned by many Member States, such confidentiality would promote frank discussion between patent attorneys and their clients and would finally lead to improved patent quality. The Representative further noted that such confidentiality was not a tool for the purpose of hiding essential prior art from patent offices. The Representative hoped that the discussion on that topic, given its importance, would continue within the SCP and that all the Member States would contribute to it. The Representative believed that a soft law approach would be a good way to address that issue.

192. The Representative of the AIPPI thanked the SCP for all its continuing efforts on that issue in the last years, including the current sharing session. The Representative noted that those efforts in the past had included doing a comprehensive review of the real problems that existed internationally, as a result of the inconsistent approach that countries had taken in respect of whether confidential communications between patent owners and their patent advisors should be protected from forced disclosure. The Representative observed that, as stated in the past, that problem was twofold. The Representative mentioned, as a first element, the lack of coverage domestically in certain countries; even if he did note that a number of countries had taken steps unilaterally within the last number of years to address the issue domestically. However, the Representative was of the view that there was still a lack of coverage internationally in certain cross-border scenarios where communications were exchanged with different agents in different countries. The Representative believed that it was timely to consider a pragmatic and harmonized solution for moving forward with the real difficulties and risks that existed internationally in terms of cross-border communications, given the progress made on the issue to date by the SCP and the development at the national level in some countries on that topic. The Representative reminded the Committee that the problem was that in many jurisdictions, patent advisors were often not lawyers, i.e., that they had highly skilled, scientific backgrounds but they did not necessarily have the legal training or qualifications. The Representative pointed out that, as a result, domestic and foreign communications between clients and non-lawyer patent advisors were often not protected from enforceable disclosure, for example, during litigation. The Representative observed that that could result in the forced disclosure of those confidential communications including, in some cases, trade secrets, to the public at large and competitors of the patent owner. The Representative observed that, in turn, the lack of protection of that communication could lead to patent owners not seeking proper IP advice or not providing with full and frank disclosure of all relevant measures, and ultimately, the goal and purposes of domestic and international patent systems would not be fully served. The Representative stressed that, as he had mentioned at the outset, certain countries had taken matters on a unilateral basis to address that problem at least domestically. For example, the Representative noted, the United Kingdom had a statutory

provision in its Patent Act which provided that communications between United Kingdom or European agents and their clients were privileged. However, the Representative believed that it was uncertain as to whether that protection would extend to cover communications with foreign agents. The Representative communicated that New Zealand, Australia and most recently Canada in 2016, had gone one step further than the United Kingdom, and their patent legislation had statutory provisions that protected communications between patent owners and their agents, both foreign and domestic ones. The Representative added that the Federal Government of Canada in April 2018 had announced that increasing the statutory protection of those communications was an action taken by the Federal Government to actually more robustly regulate patent and trademark agents in Canada and that would lead directly to the greater good in terms of serving the public interest thanks to the introduction of statutory privilege. The Representative informed the Committee that domestically, the courts of the United States of America generally recognized that communications between patent owners and their US non-lawyer agents were privileged. The Representative explained that that had been recently affirmed by the decision of the Supreme Court of Texas in 2017. The Representative further highlighted that the courts of the United States of America had also generally recognized that if a communication between a patent owner and a foreign agent was subject to protection in that foreign agent's country, that protection would be respected by the courts of the United States of America as well. The Representative mentioned that recently the United States Patent and Trademark Office (USPTO) had enacted a new rule according to which for the purpose of proceedings before the Patent Trial and Appeal Board, communication between patent agents and patent owners would be treated as privileged and that was extended to both domestic and foreign agents. The Representative pointed out that in most of those countries where that protection was provided by statutory enactment, the designation of the communication being protected or privileged was challengeable in court. The Representative further clarified that such designation was subject to the overview of the court, in order to ensure that it was properly made and served to protect against any abuse in recurring inappropriately to designating communication as confidential. The Representative stated that other jurisdictions that were also protecting communications between patent owners and their clients included Denmark, Japan, France, the Netherlands, Sweden and Switzerland; even if in some jurisdictions it was uncertain as to whether communications with foreign agents would be subject to that same protection. The Representative mentioned that procedural rules with respect to the European Unified Patent Court proposed the adoption of a rule providing that communications between patent agents and their client be privileged in the territory of the countries where the Unitary Patent System applied. For all those reasons, the Representative affirmed that AIPPI was firmly of the view that the time was appropriate for developing a harmonized international solution. The Representative encouraged and supported the SCP in continuing its good work on that issue and to develop a straightforward harmonized solution whereby countries recognized and sought to uphold the protection that existed in another jurisdiction from the forced disclosure of confidential client-patent advisor communications. The Representative took note of the discussion about a possible soft law approach within the Committee. The Representative stated that while that might not be AIPPI's preferred solution, AIPPI understood the wishes of the SCP members to pursue that type of approach and certainly would not discourage them from moving in that direction. However, the Representative considered useful if further explanation or details could be provided as to what might be envisioned by the said soft law approach. In order to address some concerns that had been raised by certain national groups and NGOs at the SCP in the past, the Representative stressed that any such protection from forced disclosure of confidential communication between clients and patent advisors should be limited to actual communications exchanged and advice provided, and should not extend to facts such as the existence of relevant prior art.

AGENDA ITEM 9: TRANSFER OF TECHNOLOGY

193. The Delegation of China expressed its appreciation to the Secretariat for its continuous focus and efforts given to the agenda item, and to other Member States for their participation. The Delegation stated that efficient and free circulation of technologies had important meaning and positive impact on technological innovation, economic development, and public interest in the world. It noted that the Chinese government attached great importance to the transfer of technological results and also the important role of IP system to it. The Delegation pointed out that the Chinese law on promoting the transformation of scientific and technology achievements had established important provisions. It informed the Committee that China was also amending its patent law so that it could further complete the relevant measures and, in particular, the open licensing system, so that it could promote the incentive and safeguard roles of IP system for transfer of technology. The Delegation noted that in view of the amendment of its patent law, the regulations under the patent law would also provide more details. The Delegation looked forward to gathering knowledge on successful experiences of other countries, enhancing communication and exchange with them. It hoped that the SCP would continue to pay attention to the difficulties encountered by developing countries in transfer of technology and look for solutions. The Delegation therefore proposed that under the initiative of the Secretariat, a combination and collection of the rules and regulations of different countries, including but not limited to open licensing, should be carried out by the Secretariat so that countries could have reference documents and learn from it, and after that, according to the status of the study, country experience in transfer of technology could be shared at a later stage with an end to formulate rules of transfer of technology that would be operational.

194. The Delegation of Switzerland, speaking on behalf of Group B, reaffirmed the utmost importance of transfer of technology and WIPO's work regarding that matter. In its opinion, intellectual property helped to promote technology transfer on voluntary and mutually agreed terms, and supported a wide dissemination of new technologies for society's benefit. The Delegation observed that, for a number of years, WIPO had been engaged in a multitude of technology transfer-related activities that benefited low and middle-income countries. The Delegation stated that such activities had been extensively considered at the CDIP, for example. The Delegation recalled that, pursuant to a joint proposal by Australia, Canada and the United States of America (document CDIP/18/6 Rev.), a list of WIPO activities and resources related to technology transfer had been compiled by the Secretariat in document CDIP/20/11, and a mapping exercise concerning international fora and conferences within that area had been conducted (document CDIP/20/12). Likewise, the Delegation continued, a compilation of technology exchange and licensing platforms had been submitted at the CDIP. Consequently, the Delegation expressed its belief that concrete issues and activities related to the role of WIPO in technology transfer should be discussed at the CDIP rather than during SCP sessions. The Delegation considered that the CDIP was more competent to handle concrete projects, and that duplication of work among the Committees should be avoided. Moreover, the Delegation noted that Group B did not want to prejudice the CDIP's outcome.

195. The Delegation of Lithuania, speaking on behalf of the CEBS Group, reiterated the importance it attached to the topic on transfer of technology. The Delegation welcomed the sharing session on patent law provisions that contributed to effective transfer of technology and looked forward to having interesting discussions. The Delegation acknowledged the work of the WIPO Secretariat in that area, including running and constantly updating the WIPO webpage on Technology Transfer. The Delegation stated that while IP commercialization and transfer of technology were important issues for the CEBS members, the CEBS Group considered that the CDIP did the pertinent work in that area. The Delegation had greatly appreciated very topical

discussion on available technology transfer platforms and instruments listed in document CDIP/20/10, which had taken place during the previous CDIP session. Thus, the Delegation was of the view that any duplication of work needed to be avoided, bearing in mind the coverage of the issues relating to technology transfer in the CDIP.

196. The Delegation of Austria, speaking on behalf of the European Union and its Member States, noted that transfer of technology was an important factor in fostering development. The Delegation, therefore, was pleased to have a second sharing session on patent law provisions that contributed to effective transfer of technology during the twenty-eighth session of the SCP. Reiterating its position outlined during the twenty-seventh session, the Delegation stated that the Committee should avoid duplicating the excellent work that had been delivered by WIPO in the framework of the CDIP. The Delegation considered that transfer of technology was an issue taken very seriously by the European Union and its Member States, because it had the potential to create win-win situations in international economic relations. The Delegation observed that, according to the stocktaking action undertaken by the WIPO Secretariat and described in document CDIP/20/10 Rev., two out of five listed regional platforms for technology exchange were situated in the European Union and hosted by the European Commission to be of service for all Member States and stakeholders. For instance, the Delegation continued, the Enterprise Europe Network (EEN), was not only available to European Union's Member States but was active in more than 60 countries worldwide, including developing countries. The Delegation also took note of the various challenges related to technology exchanges and licensing platforms faced by developing and least developing countries. It noted that the European Union and its Member States were aware that those problems had to be considered by taking into account the general macro-economic situations in the Member States. As previously stated, the Delegation expressed its continued support for updating the WIPO web page on technology transfer regarding information on national, regional, and international technology exchange and technology licensing platforms.

197. The Delegation of India was of the view that there should be a balance between rights and obligations, and such balanced protection should contribute to the promotion of innovation and transfer of technology to the mutual advantage of producers and users in a manner conducive to social and economic welfare. The Delegation observed that a balance between rights and obligations were also emphasized in Article 7 of the TRIPS Agreement. Further, the Delegation stated that domestic transfer of technology was the very purpose of the patent system in India, and per its national IP policy, the technology transfer was one of the objectives of the patent system. The Delegation therefore noted that the Committee should also consider a further study on sufficiency of disclosure in continuation of the earlier study contained in document SCP/22/4. The Delegation observed that subsequent to the preparation of document SCP/22/3, a further study on inventive step (document SCP/28/4) had been presented at the twenty-eighth session under the agenda item, Quality of Patents, including Opposition Systems. Therefore, in its opinion, subsequent to the preparation of document SCP/22/4, a further study on sufficiency of disclosure should be prepared and presented at the upcoming session. The Delegation noted that such a further study was also relevant to the agenda item, Transfer of Technology, for which the sufficiency of disclosure was a core issue. In its opinion, that further study was also important, because the Committee had in its twenty-eighth session a sharing session on patent law provisions that contributed to effective transfer of technology. The Delegation observed that provisions of patent laws as well as various case laws with respect to written description requirements could help the Committee to understand the issues relating to transfer of technology disclosed in patent specifications and without any know-how or trade secrets.

198. The Delegation of the Czech Republic stated that technology transfer was for the transposition of research results into innovations in practice with the aim of increasing the competitiveness of industry, while applying the principles of sustainable development. The

Delegation noted that, besides non-commercial transfer of technology, such as publication of research results, there were other ways of transferring technology through commercialization of IP-protected research results, such as licensing or creating spin-offs. The Delegation stated that the Czech Patent Law regulated the exploitation of an invention protected by a patent based on a license agreement between a patent holder and a licensee. The license agreement must be in a written form and became effective against third parties by entering it in the patent register. According to the Czech Patent Law, an applicant or a patent holder could offer a license, i.e., the rights to exploit the invention, to any person. He or she must declare that fact to the Office, which would enter such offer of license in the patent register. While such declaration was irrevocable, the patent holder could profit from reducing renewal fees by half in case he or she maintained the patent. The Delegation further noted that another provision important for the transfer of technology was disclosure of invention. According to the Czech Patent Law, the invention must be disclosed in the patent application in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Where the invention concerned a microorganism, it must be deposited with a public collection prior to the date on which the applicant's priority right began. The Delegation stated that the Czech universities and research centers recognized the importance of transfer of technologies. The Delegation observed that, in order to support researchers and help them to commercialize their research results, majority of universities and research centers established its own teams for transfer of technologies. 18 technology transfer offices were associated in a unified functional platform called *Transfera*, protecting the interest of the Czech technology transfer community. The Delegation explained that the objective of *Transfera*, which had been established in November 2014, was to advance and strengthen the technology and knowledge transfer. Recently, *Transfera* had published the overview of technology transfer offices in the Czech Republic, describing their performance in the patents, utility models, and licenses concluded: in total, 74 licenses were concluded in 2016. Finally, the Delegation stated that it aligned itself to the statements made by the Delegation of Lithuania on behalf of the CEBS Group and by the Delegation of Austria on behalf of the European Union and its Member States.

199. The Delegation of Canada informed the Committee that on April 26, 2018, Canada had launched a new intellectual property strategy to help entrepreneurs better understand, commercialize, utilize, and protect intellectual property. The Delegation stated that Canada viewed commercialization as an essential component of technology transfer, since it was an important factor in disseminating new technology to ensure that society could effectively benefit from technological innovations. The Delegation noted that Canada's intellectual property strategy was comprehensive, and included both legislative changes and program initiatives. The Delegation highlighted some aspects that related to technology transfer. On the legislative side, the IP strategy would amend key IP laws to clarify expectations and reduce barriers to innovation, and would be creating a new governance regime for IP agents under a new College of Patent and Trademark Agents, which would ensure maintaining professional and ethical standards and supporting the provision of quality advice from IP professionals. On the program side, the Delegation continued, a number of initiatives had been proposed to better position Canada's use of the IP system to support innovation and to help businesses drive growth. The initiatives fell into two categories: (i) increasing education, awareness, and outreach; and (ii) strategic tools for growth. The Delegation highlighted four programs under those categories. First, the Canadian Intellectual Property Office would promote learning tools and resources to develop new educational resources to increase businesses' understanding of IP. That program would include several materials relevant to technology transfer, such as guides and toolkits for collaborating with academic researchers. The IP strategy would also include the creation of an IP marketplace, which would be a one-stop shop for firms to locate, access, and acquire public-sector IP and know-how with toolkits and templates to help collaborate, license, and share knowledge. Such a marketplace would help improve access to patents owned by Canadian governments and universities that could be bought or licensed. In that regard, the Delegation thanked Australia and Denmark for the information they had provided to Canada about their

own experiences with similar IP marketplaces. Along with that, the IP strategy included support for IP legal clinics at university law schools that enabled law students to learn more about IP, helped businesses, and facilitated access to the profession. Those clinics provided individuals and small businesses with free basic IP advice and were able to assist with prior art searches. Finally, the IP strategy would create a dedicated team of IP advisors to ensure that the government program officers had the knowledge and capacity to address IP issues. That team of IP experts would provide advice to the Federal Government program officers working with businesses, creators, and other government officials to boost engagement with IP.

200. The Delegation of Switzerland, speaking on behalf of Group B, stated that, in relation to the topic of sufficiency of disclosure, implementation of the existing patent system took into account the balance between the incentive for inventors and the third parties' use of their inventions. It noted that the PCT International Search and Preliminary Examination Guidelines, established by the International Bureau of WIPO after consultation with International Search and Preliminary Examining Authorities, provided legal basis on sufficiency of disclosure and a person skilled in the arts in paragraphs 4.12, 4.13, and 13.11, respectively. Keeping that in mind, Group B was of the view that there was no need to change a longstanding and balanced approach. Therefore, the Delegation stated that Group B did not support any additional work on those issues.

201. The Delegation of Uganda stated that technology transfer was one of the main purposes of the patent system, and therefore, it should be maintained as one of the SCP agenda items for its future work. In its view, that would reinforce the WIPO Development Agenda relating to technology transfer, indicated in Recommendations 24 to 32. The Delegation noted that its law provided for publication of the granted patents so that the knowledge would be conveyed to the rest of society for its use. The Delegation observed that, for countries at another stage of technological development, like Uganda, the most practical way of improving and upgrading technological capacities was by extracting technical information from patent applications. The Delegation noted that the Industrial Property Act of 2014 required the disclosure of the invention in all practical modes, including specification of the best mode of carrying out the invention known to the inventor, to allow the people to reproduce the claimed invention without the need to refer to any other background materials. The Delegation however acknowledged that in certain cases, it was difficult to effectively understand the patent description and claims. The Delegation noted that, because of those provisions, Cipla, an Indian pharmaceutical company, had been able to have a joint venture with a local manufacturer, Quality Chemicals, Limited, which locally produced retroviral, anti-malaria and hepatitis drugs. In its view, pharmacists, engineers and technicians had acquired the skills used in the production of those drugs, and in addition, it had also increased access to the essential lifesaving drugs in Uganda. The Delegation stated that it ensured that the intellectual property system in its country was tailored to its level of technology, allowing access to the information required to build domestic skills. The Delegation highlighted that it was trying to create an efficient linkage between its intellectual property administration and scientific and technology institutions in Uganda.

202. The Delegation of Australia stated that it was supportive of projects involving technology transfer, and was involved in a number of different initiatives. The Delegation informed the Committee about its initiative that created a platform for connecting Australian and public research organizations with entrepreneurs and product developers via Source IP. The Delegation explained that Source IP was a web platform which served as a single portal for information-sharing, licensing preferences, and facilitating contact in relation to IP rights generated by the Australia's public research sector. The Delegation noted that Source IP could help businesses access technology and innovation available for licensing and identify potential collaboration opportunities. It also provided a single source of key information on contacts to businesses, seeking to work with public-sector research partners, and could enable collaboration across projects. In that way, the Delegation continued, it facilitated innovation and

commercialization for providing a means for public-sector IP right holders to signal their patent holdings and licensing intent. One of the key aims of Source IP was to increase the rate of collaboration between industry and research institutions in Australia. In the opinion of the Delegation, that was an environment where universities could promote their research expertise and technology specializations to increase understanding of potential collaboration opportunities. The Delegation highlighted that the knowledge created by its higher education and research institutions provided significant opportunities to enhance the products and services delivered by industry, which had enabled successful business engagements, such as the successful collaboration of small start-up companies with universities based on technology that had been discovered through Source IP.

203. The Delegation of the United States of America stated that the United States government spent billions of dollars every year for funding research and development conducted by universities, government research institutions, private businesses, and individuals. In 2016, the Federal Government had spent around 70 billion US dollars on non-defense research and development and about 77 billion US dollars for defense-related research and development. The Delegation noted that university research was very important for advancing science, for expanding the knowledge pool, and for its economy, as the higher education sector was the second largest performer of US research and development. Universities and colleges had performed around 64 billion US dollars, or about 13% of the US research and development in 2015. In the recent year, that had accounted for just under half of the nation's basic research. The Delegation explained that about half of academic research in the United States was funded by the Federal Government, which was the largest sponsor of basic research. The Delegation observed that technology transfer from universities and other research institutions to industry for further development and commercialization was vital for maximizing the benefits of publicly funded research. As university research was usually an early-stage research, the Delegation was of the opinion that without transferring that research from the universities and public research institutions to the private-sector companies for further development and commercialization, the public might not reap the benefits from that research. In its view, patenting was absolutely crucial for forming partnerships and for the commercialization of inventions. The Delegation noted that in the absence of a strong patent system, most of those inventions would never see the light of day because of the significant cost associated with the development of those inventions into marketable products. In the absence of patent protection, the Delegation continued, no one would invest in those early-stage inventions. The Delegation explained that, in the United States of America, technology transfer from universities to the private sector was made possible, in large part, by legislation commonly known as the Bayh-Dole Act, codified in U.S. Code, Title 35, which addresses United States patent law. That legislation had passed in 1980, and had become effective in July 1981. The Delegation noted that it had represented a fundamental change in the U.S. government innovation policy. The Bayh-Dole Act gave the option to universities and companies to own the inventions they develop with federal funding and to grant exclusive licenses to them on those inventions. Universities were encouraged to collaborate with industry to translate research results into products benefiting the public. The Delegation explained that because the funding for the research came from U.S. taxpayers, by policy, the preference was given to small businesses and to those making products in the United States of America. Any income that universities obtain from licensing had to be used for rewarding university scientists and for further supporting the cycle of innovation. The Delegation stated that prior to the Bayh-Dole Act, recipients of federal funding, including universities, generally could not own title to the publicly funded inventions, and instead, federal agencies retained all IP rights and could only grant non-exclusive licenses to private companies. The Delegation observed that under those conditions, companies had been reluctant to invest in developing new products and markets, since competitors could later acquire licenses from the government and then manufacture and sell the same products. As a result, the Delegation continued, taxpayers had not benefited from the new useful products or the economic activity that would create additional jobs resulting from

the manufacture and sale of these products. The Delegation reiterated that the objectives of the Bayh-Dole Act included encouraging maximum participation of small businesses and nonprofits in federally funded R&D efforts to promote collaboration between businesses and nonprofits, ensuring that the government retained sufficient rights from federally funded inventions to meet its needs, and to encouraging use of inventions for public benefit. The Delegation further noted that the Bayh-Dole Act also included a number of safeguards designed to protect the public interest. Those safeguards included: first, the obligation to disclose each invention to the federal funding agency and to make a decision whether or not to retain title in the invention and therefore to file an initial patent application within a specific amount of time; second, there was a government use license that was non-transferable paid-up rights to practice or have practiced the invention on behalf of the U.S. government throughout the world; third, under certain circumstances, the U.S. government could require the patent owner to grant a license to a third party or the government might take title in grant licenses itself, which were referred to as the march-in rights; finally, preference was given to small and medium enterprises as far as licensing purposes are concerned. The Delegation was of the view that robust university research, coupled with the enabling legal environment created by the Bayh-Dole Act helped create entire new industries in the United States of America, such as biotechnology industry, where it continued to have a leadership role. The Delegation noted that in the past 25 years, more than 11,000 start-ups had been formed, based on the results of university research. It was observed that a majority of those had been located in close physical proximity of the university, contributing to the local and state economy and development. In 2016 alone, 8,024 start-ups had been formed, and 800 new products originating from university research had been introduced into the marketplace by companies in the private sector. Furthermore, over 200 new drugs and vaccines had been developed through public-private partnerships, since the Bayh-Dole Act had been enacted. The Delegation stated that university technology transfer created billions of dollars of direct benefits to the U.S. economy and supported millions of jobs every year. In its opinion, such a successful example of the United States of America demonstrated the importance of having an efficient patent system and clear and transparent laws on IP ownership that were conducive to technology transfer and technology commercialization. In addition to the Bayh-Dole Act, the Delegation noted that the U.S. patent law and patent regulations provided for patent fee reductions for universities and small or micro entities, which further encouraged patenting and licensing by those entities. Furthermore, the Delegation informed the Committee about two other important pieces of legislation to achieve national transfer technology goals. One was the Stevenson-Wydler Technology Innovation Act of 1980 codified in 15 U.S.C. Section 3701. The Delegation explained that it was the first major technology transfer law in the United States of America. It had required federal laboratories to have a formal technology transfer program and to actively seek opportunities to transfer technology to industry, universities, and state and local governments. The second legislation was the Federal Technology Transfer Act of 1986, referred to as FTTA. That Act had amended the Stevenson-Wydler Act and had made knowledge transfer a responsibility of every federal laboratory, scientist, and engineer. It had also authorized the generation of cooperative research and development agreements.

AGENDA, ITEM 10: FUTURE WORK

204. The Delegation of Kazakhstan, speaking on behalf of the Caucasian, Central Asia and Eastern European Countries (CACEEC), expressed its appreciation to the Secretariat for the great work it had done to prepare for the twenty-eighth session of the SCP, and to all delegations of Member States for their constructive contribution and proposals with regard to the Committee's future work. As regards Agenda Item 5, under the topic of exceptions and limitations, the Delegation noted that the Secretariat had prepared the second draft of a reference document on exception regarding acts for obtaining regulatory approval from authorities (document SCP/28/3). That document took into account Member States'

submissions, and streamlined and explored useful information with regard to the implementation of that exception. The Delegation was confident that the final paper would reflect all the implementation-related aspects in the Member States and would be submitted to future sessions of the Committee. As to future work, the Delegation suggested that the Secretariat prepare a reference document on compulsory licensing implemented by Member States. The Delegation noted that the SCP had information on Member States' relevant laws, as well as several examples of the implementation of patent law flexibilities provided for in the TRIPS Agreement. In its opinion, streamlining and exploring the available information would help the Committee to better understand national approaches to the implementation of compulsory licensing. As regards Agenda Item 6, the Delegation stated that quality of patents was among the priority issues for its Group and a matter of keen interest. With that in mind, the Delegation stated that it stood for continued discussions on that issue in future meetings. The Delegation believed that the Committee was a good platform for discussing best practices related to the quality of patents and sharing of work products between patent offices. It therefore expressed its interest in further studying those issues. In its opinion, the assessment of the quality of a patent – and primarily quality criteria or benchmarks – was a very important quality-related aspect. The Delegation further stated that the compliance of the description with the sufficiency of disclosure requirement was of great interest as well. The Delegation therefore suggested that the Secretariat draft questionnaires on those two issues to conduct a survey among Member States at a later stage. Since evaluation of the inventive step was a broad and complicated topic, the Delegation expressed its belief that it was important for the Committee to continue its work towards further study of the inventive step. The Delegation expressed its interest in sharing experiences among Member States with regard to the inventive step of inventions related to medicines and business methods. In addition, the Delegation suggested the inclusion of the topic of quality of patents with respect to blockchain, big data and artificial intelligence in the work program of the information session on IP, Development and the Digital Environment, to be held at the twenty-third session of the CDIP. Concerning Agenda Item 7, the Delegation supported continued work on patents and health. The Delegation stood for further studies on the availability and affordability of medicines. However, it still firmly believed that such work should be carried out under the mandate of the Committee to avoid duplication with other WIPO bodies. The Delegation expressed its support for further studies to explore issues regarding access to medicines, and supported the proposals made by the Delegations of Argentina, Brazil, Canada and Switzerland, contained in documents SCP/28/9, SCP/28/9 Add., and SCP/28/10. Furthermore, the Delegation also supported further discussion on the feasibility of the requirement with regard to the disclosure of International Nonproprietary Names in patents. As regards Agenda Item 8, the Delegation noted the importance of discussion on the confidentiality of communications. In order to better understand the challenges patent advisors and their clients faced in their cross-border relations, the Delegation suggested that the Secretariat prepare a questionnaire to highlight those obstacles. In its opinion, sharper focus on the challenges faced by clients and their patent advisors would help to bring delegations closer to the consideration of the proposal of an advisory document on confidentiality of communications.

205. The Delegation of Lithuania, speaking on behalf of the CEBS Group, noted that under each agenda item, it had already mentioned a number of proposals that could be a basis of the Committee's further work. The Delegation however reminded the Committee that the CEBS Group attached great importance to the quality of patents, which in its view, was at the core of the patent system. The Delegation stated that one of the topics in which it would have interest in further discussion was the inventive step. The Delegation further stated that another issue on which the CEBS Group had longstanding interest was the confidentiality of communication between clients and their patent advisors. The Delegation expressed its willingness to continue work, and see advancement, on the recognition of foreign patent advisor's privilege through a soft law instrument, and welcomed further studies in relation to that topic. The Delegation also welcomed continuation of discussions on exceptions and limitations to patent rights, taking into

consideration that the balance between the interests of right holders and the general public would be maintained. The Delegation stated that it could go along with examination of exceptions regarding prior use, patented articles on vehicles and aircraft, and experimental use and scientific research. As regards the agenda item on patents and health, the Delegation recalled that it had cited in its intervention on that item a number of documents on the basis of which the Committee could continue its work. The Delegation stated that it would not see the proposal by the African Group (document SCP/24/4) as a basis for discussion at the SCP.

206. The Representative of FICPI thanked the Chair and the Secretariat for a well-prepared and well-run meeting, and expressed its satisfaction with the very constructive and comprehensive interventions by the delegations with regard to quality of patents, which FICPI found one of the most crucial elements in the patent system. The Representative informed the Committee that FICPI had a resolution on oppositions which recommended to introduce a post-grant opposition system, retain or introduce a third party observation system, and to retain a reexamination system.

207. 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/26, the Secretariat will continue to work on a draft reference document on exceptions and limitations to patent rights in conjunction with patent protection. The Secretariat will prepare a draft reference document on the research exception, which will be submitted to SCP/29. Following the preparation and presentation of the draft reference document on the research exception, the Secretariat will prepare a draft reference document on the exception regarding compulsory licensing for SCP/30. Both reference documents will follow the style and structure of the draft reference document on the exception regarding acts for obtaining regulatory approval from authorities (document SCP/28/3). Document SCP/28/3 will be kept open for future discussion by the Committee. The Secretariat will invite Member States to send any additional inputs for the preparation of the draft reference document on the research exception.

Quality of Patents, including Opposition Systems

- The Secretariat will prepare a further study on inventive step (part 2), giving particular attention to the topics suggested in paragraph 8 of the Annex to document SCP/24/3 (Proposal by the Delegation of Spain).
- A half-day conference on cooperation between patent offices in search and examination, including sharing of information concerning the corresponding foreign applications and grants, will be held at SCP/29.
- A sharing session will be held at SCP/29 on approaches used by delegations to ensure the quality of the patent grant process within IP offices, including opposition systems, and any challenges faced and how they have been overcome, taking into consideration paragraph 7.a. of the Annex to document SCP/28/8 (Proposal by the

Delegations of the Czech Republic, Kenya, Mexico, Singapore and the United Kingdom).

- The Committee will continue discussion on the proposal by the Delegation of Spain (document SCP/28/7).

Patents and Health

- A half-day conference on publicly accessible databases on patent information status and data, on medicines and vaccines, will be held at SCP/29, taking into consideration the issues addressed in paragraphs 18 and 19 of the Annex to document SCP/24/4 (Proposal by the African Group for a Work Program on Patents and Health).
- The Secretariat will invite practitioners to share their experience on negotiating licensing agreements at SCP/29, giving particular attention to paragraph 20(a) of the Annex to document SCP/24/4 (Proposal by the African Group for a Work Program on Patents and Health).
- The Committee will continue discussion on the proposal by the Delegations of Argentina, Brazil, Canada and Switzerland (documents SCP/28/9 and SCP/28/9 Add.) and the proposal by the Delegations of Argentina, Brazil and Switzerland (SCP/28/10) at SCP/29, without prejudice to other proposals with respect to this agenda item.

Confidentiality of Communications between Clients and Their Patent Advisors

- The Secretariat will update document SCP/20/9 (Confidentiality of Communications between Clients and their Patent Advisors: Compilation of Laws, Practices and other Information), and submit it to SCP/29. This update will also be reflected on the dedicated website “Confidentiality of Communications between Clients and Their Patent Advisors”. The Secretariat will invite Member States to send any additional inputs for the preparation of the updated document.

Transfer of Technology

- Based on the discussions within the SCP, including those during the sharing sessions, the Secretariat will compile information on patent law provisions that contribute to effective transfer of technology, including sufficiency of disclosure.

AGENDA ITEM 11: SUMMARY BY THE CHAIR

208. The Chair introduced the Summary by the Chair (document SCP/28/11 Prov.).

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

210. 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 during 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, during its following session.

AGENDA ITEM 12: CLOSING OF THE SESSION

211. 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 July 12, 2018.

212. The Committee unanimously adopted this report at its twenty-ninth session on December 3, 2018.

[Annex follows]

LISTE DES PARTICIPANTS/LIST OF PARTICIPANTS

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Anne VON ZUKOWSKI (Ms.), Policy Officer, Industrial Property and Fight Against Counterfeiting, Directorate General for Internal Market, Industry, Entrepreneurship and SMEs, European Commission, Brussels

Oliver HALL ALLEN (Mr.), Minister Counsellor, European External Action Service, Geneva

Florin TUDORIE (Mr.), European External Action Service, Geneva

III. ORGANISATIONS NON GOUVERNEMENTALES/NON-GOVERNMENTAL ORGANIZATIONS

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Catherine Eunkyeong LEE (Ms.), Co-Chair, Patents Committee, Seoul

Association européenne des étudiants en droit (ELSA International)/European Law Students' Association (ELSA International)

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Chiara ARENA (Ms.), Delegate, Brussels

Thomas BAETENS (Mr.), Delegate, Brussels

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Olena KIZIUN (Ms.), Delegate, Brussels

Association internationale pour la protection de la propriété intellectuelle (AIPPI)/International Association for the Protection of Intellectual Property (AIPPI)

Steven GARLAND (Mr.), Observer, Zurich

Jonathan OSHA (Mr.), Observer, Zurich

CropLife International/CropLife International (CROPLIFE)

Tatjana SACHSE (Ms.), Counsel, Geneva

Fédération internationale de l'industrie du médicament (FIIM)/International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

Greg PERRY (Mr.), Executive Director, Geneva

Grega KUMER (Mr.), Head, Director General's Office, Geneva

Nahom TEKLEWOLD (Mr.), Officer, Geneva

Fédération internationale des conseils en propriété intellectuelle (FICPI)/International Federation of Intellectual Property Attorneys (FICPI)

Kim FINNILÄ (Mr.), Senior IP Advisor, European Patent Attorney, Helsinki

Health and Environment Program (HEP)

Madeleine SCHERB (Mme), President, Geneva

Institut des mandataires agréés près l'Office européen des brevets (EPI)/Institute of Professional Representatives Before the European Patent Office (EPI)

Francis LEYDER (Mr.), President, Munich
Filippo SANTI (Mr.), Member of the Harmonisation Committee, Munich

Instituto Fridtjof Nansen (FNI)/Fridtjof Nansen Institute (FNI)

Morten Walloe TVEDT (Mr.), Senior Research Fellow, Lysaker

International Intellectual Property Commercialization Council (IIPCC)

Johnson KONG (Mr.), Board Member, Hong Kong
Ronald YU (Mr.), Board Member, Hong Kong

Japan Intellectual Property Association (JIPA)

Terukazu TERAUCHI (Mr.), Chairman, Medical and Biotechnology Committee, Tokyo

Japan Patent Attorneys Association (JPAA)

Masashi MORIWAKI (Mr.), Member, Tokyo
Naoki OKUMURA (Mr.), Member, Tokyo

Knowledge Ecology International, Inc. (KEI)

Ellen 'T HOEN (Ms.), President, KEI Europe, Geneva
Thiru BALASUBRAMANIAM (Mr.), Representative, Geneva
James LOVE (Mr.), Director, Washington D.C.

Médecins Sans Frontières (MSF)

Katy ATHERSUCH (Ms.), Medical Innovation and Access Policy Adviser, Geneva
Shailly GUPTA (Ms.), Press and Communications Officer, Geneva
Fiona NICHOLSON (Ms.), Legal and Policy Intern, Geneva

Medicines Patent Pool (MPP)

Pascale BOULET (Ms.), Consultant, Geneva
Esteban BURRONE (Mr.), Head of Policy, Geneva
Maria Carmen TRABANCO (Ms.), Associate Counsel, Geneva
Elena VILLANUEVA OLIVO (Ms.), Policy and Advocacy Manager, Geneva

National Inventors Hall of Fame

Maggie PETRUSH (Ms.), General Counsel, North Canton, Ohio

Third World Network Berhad (TWN)

Safiatou SIMPORE DIAZ (Ms.), Consultant, Geneva

IV. BUREAU/OFFICERS

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Vice-présidents/Vice-Chairs: Adrian NEGOIȚĂ (M./Mr.) (Roumanie/Romania)
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V. 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

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Anna PILICHEVA (Mlle/Ms.), stagiaire, Section du droit des brevets, Division du droit des brevets, Secteur des brevets et de la technologie/Intern, Patent Law Section, Patent Law Division, Patents and Technology Sector

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