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# Standing Committee on the Law of Patents

## Twenty-Seventh Session
## Geneva, December 11 to 15, 2017

REPORT

*adopted by the Standing Committee*

1. The Standing Committee on the Law of Patents (the "Committee" or the "SCP") held its twenty-seventh session in Geneva from December 11 to 15, 2017.

2. The following Member States of WIPO and/or the Paris Union for the Protection of Industrial Property were represented: Albania, Algeria, Angola, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahamas, Belarus, Brazil, Cameroon, Canada, Chile, China, Colombia, Costa Rica, Cote d'Ivoire, Croatia, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Djibouti, Dominican Republic, Egypt, El Salvador, Ecuador, Estonia, Ethiopia, Finland, France, Gabon, Georgia, Germany, Ghana, Greece, Guatemala, Holy See, Honduras, Hungary, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Israel, Italy, Jamaica, Japan, Kuwait, Kyrgyzstan, Lao People's Democratic Republic, Latvia, Lesotho, Lithuania, Malaysia, Mexico, Monaco, Morocco, Nigeria, Norway, Oman, Pakistan, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Saudi Arabia, Senegal, Singapore, Slovakia, South Africa, Spain, Sri Lanka, Sudan, Sweden, Switzerland, Thailand, the former Yugoslav Republic of Macedonia, Turkey, Uganda, Ukraine, United Arab Emirates, United Kingdom, United States of America, Uruguay, Uzbekistan, Venezuela (Bolivarian Republic of), Zambia, Zimbabwe (96).

3. Palestine was represented in an observer capacity. Representatives of the following intergovernmental organizations took part in the meeting in an observer capacity: African Regional Intellectual Property Organization (ARIPO), African Union (AU), Eurasian Patent Organization (EAPO), European Patent Organization (EPO), 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), and World Trade Organization (WTO) (10).

4. Representatives of the following non-governmental organizations took part in the meeting in an observer capacity: ASEAN Intellectual Property Association (ASEAN IPA), Asian Patent Attorneys Association (APAA), Centre for International Intellectual Property Studies (CEIPI), Fridtjof Nansen Institute (FNI), International Association for the Protection of Intellectual Property (AIPPI), International Chamber of Commerce (ICC), International Federation of Intellectual Property Attorneys (FICPI), International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Intellectual Property Owners Association (IPO), Japan Intellectual Property Association (JIPA), Japan Patent Attorneys Association (JPAA), Knowledge Ecology International, Inc. (KEI), Médecins Sans Frontières (MSF), Medicines Patent Pool Foundation (MPP), Polish Chamber of Patent Attorneys (PCPA), and Union of European Practitioners in Industrial Property (UNION) (16).

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/26/8 Prov.2.); "Draft Agenda" (SCP/27/1 Prov.2); "Report on the International Patent System: Certain Aspects of National/Regional Patent Laws" (SCP/27/2); "Draft Reference Document on Exception Regarding Acts for Obtaining Regulatory Approval from Authorities" (SCP/27/3); "Summary: Draft Reference Document on Exception Regarding Acts for Obtaining Regulatory Approval from Authorities" (SCP/27/3 Summary); "Updated Responses to the Questionnaire on the Term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination (Parts 1 and 2)" (SCP/27/4 Rev. and SCP/27/5 Rev., respectively); "Constraints Faced by Developing Countries and Least Developed Countries (LDCs) in Making Full Use of Patent Flexibilities and their Impacts on Access to Affordable Especially Essential Medicines for Public Health Purposes in those Countries: Supplement to Document SCP/26/5" (SCP/27/6); "Accreditation of observers" (SCP/27/7); "Revised Proposal by the Delegation of Canada" (SCP/27/8); "Addendum to Document SCP/27/8 (Revised Proposal by the Delegation of Canada)" (SCP/27/8 Add.).

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. Francis Gurry, Director General of the World Intellectual Property Organization (WIPO), opened the twenty-seventh session of the Standing Committee on the Law of Patents (SCP) and welcomed the participants.

10. Mr. Marco Aleman (WIPO) acted as Secretary to the SCP.

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

11. Mr. Dámaso Pardo (Argentina) was elected as Chair. Mr. Adrian Negoita (Romania) and Mr. Serkan Ozkan (Turkey) were elected as Vice-Chairs.

## AGENDA ITEM 3: ADOPTION OF THE AGENDA

12. The SCP adopted the draft agenda (document SCP/27/1 Prov.2).

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

13. The Committee adopted the draft report of its twenty-sixth session (document SCP/26/8 Prov.2), as proposed.

## AGENDA ITEM 5: ACCREDITATION OF OBSERVERS

14. The SCP considered document SCP/27/7.

15. The SCP approved the accreditation of the National Inventors Hall of Fame, Inc. (NIHF) as an *ad hoc* observer.

**GENERAL STATEMENTS**

16. 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 Vice-Chairs, and also expressed its appreciation for the hard work done by the Secretariat towards the preparation for the meeting. The Delegation expressed the interest of the Asia and the Pacific Group in nominating Mr. Alfred Yep (Singapore) for the next election of the officers of the SCP. 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 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 publicly accessible databases on patent information status and data on medicines and vaccines, the sharing session on patents and other related issues on access to medicine, the information exchange on cooperation between patent offices in search and examination and the sharing session concerning examples and cases relating to inventive step. 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/27/2, 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 informative session on legislative assistance in the field of patents and related capacity building as well as to the discussion on exceptions and limitations to patent rights. The Delegation thanked the Secretariat for preparing document SCP/27/3 on the exception regarding acts for obtaining regulatory approval from authorities and its summary. 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 appreciated the additional submissions by members and observers to supplement document SCP/26/5 on the study of constraints faced by developing countries and Least Developed Countries (LDCs) in making full use of patent flexibilities (document SCP/27/6). In that regard, the Delegation was of the view that the submissions in document SCP/27/6 clearly indicated the need to ensure that WIPO's technical assistance in designing national patent laws, or national IP strategies, would take those constraints into consideration and would provide assistance to developing countries on how to overcome them and make full use of the available flexibilities. 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 noted that the Committee should ensure that the study on the constraints faced by developing countries and LDCs in making full use of patent flexibilities and their impact on affordable and especially essential medicines in those countries should involve the United Nations Development Program (UNDP) which had facilitated the preparation of the UNHLP Report. The Delegation took note of the Canadian proposal for conducting a review of existing research on patents and access to medical products and health technologies (document SCP/27/8). In that regard, the Delegation looked forward to the discussion on that proposal. Further, the Delegation drew attention to the fact that a 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 that 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 which was an important issue in Agenda Item 9. 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 constrains could be removed. In relation to the topic of quality of patents, the Delegation welcomed updated documents SCP/27/4 Rev. and SCP/27/5 Rev. which contained responses to the Questionnaire on the Term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination. 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. Referring further to Article 29.2 of the TRIPS Agreement, which stated that "Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grant", the Delegation requested the Secretariat to conduct a study on the extent to which that provision had been implemented in different countries, and how its broader use might promote quality. In relation to the session on the experiences in implementing the confidentiality of communication between clients and their patent advisors, the Delegation hoped that that session 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. Finally, the Delegation expressed its hope that the Committee would achieve productive outcome.

17. The Delegation of Georgia, speaking on behalf of the Group of Central European and Baltic States (CEBS Group), congratulated the Chair and the Vice-Chairs on their election. The Delegation expressed its confidence in the Chair's guidance and thanked the Secretariat for preparing the session. Additionally, the Delegation highlighted the importance it attached to the work of the Committee. The Delegation was pleased to note

that Member States agreed on the balanced future work during the previous session. In its view, the agenda items accommodated the interests of all Member States in a delicate balance. Further, the Delegation noted that the interest of each individual Member State lied at least in one of those five topics of the agenda and that as it had been agreed during the previous SCP session, the non-exhaustive list of issues remained open for future elaboration and discussion. The Delegation emphasized that the fact-finding work was important during the twenty-seventh session of the Committee. Further, the Delegation expressed its readiness to continue discussions on quality of patents and confidentiality of communications between clients and their patent advisors, because such discussions could contribute to a more predictable patent framework. Finally, the Delegation stated that the Committee should focus and achieve an agreement on the future work of the SCP. Nevertheless, the Delegation reiterated that an excessive amount of time should not be dedicated to the discussions on the future work. In conclusion, the Delegation stated that its Group was ready to engage in those discussions in a constructive manner.

18. The Delegation of Costa Rica, speaking on behalf of the Group of States of Latin America and the Caribbean (GRULAC), congratulated the Chair and the Vice-Chairs on their election. The Delegation stated that extensive experience of the Chair would help to guide the discussion and exchange 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 effort in preparing the meeting and the published documentation. The Delegation stated that the activities of the Committee were of high importance as it allowed to share ideas and experiences in areas that were crucial to the development. The Delegation called upon GRULAC and all regional groups to hold an inclusive and constructive debate which, despite the existence of different visions and priorities, would enable the Member States to agree on future work that precisely reflected that reality, the balance of which would require flexibility on the part of all. Further, the Delegation pointed out that such substantive issues 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 expressed its hope that a consensus would be reached on those topics in order to move forward. With regard to Agenda Item 7 on exceptions and limitations to patent rights, the Delegation stated that GRULAC had always supported its discussion. In that context, the Delegation supported the content of document SCP/27/3 containing a reference document on an exception regarding acts for obtaining regulatory approval from authorities and hoped that it would be a reference for Member States. With regard to Agenda Item 8, the Delegation was of the view that many Member States had been involved in that subject. Further, the Delegation noted that the relation between patents and health was essential for promoting a delicate balance. In that regard, the Delegation thanked the Secretariat for the preparation of the study on the difficulties encountered by developing countries and LDCs to make full use of patent flexibilities and their impacts on access to affordable medicines for public health purposes in those countries. The Delegation hoped that the information exchange sessions would become an important reference for Member States and would allow to address the challenges associated with the issue. With regard to Agenda Item 11 on technology transfer, the Delegation was of the view that that agenda item should continue making progress on study of examples and cases in which it allowed to exchange the technology as well as how to make that information available to the public. In relation to the legislative assistance on patents and related capacity building, the Delegation had shown an interest in receiving clarification from the Secretariat in order to facilitate the provisions of technical assistance. The Delegation noted that it was essential to continue the work of the Committee, and that part of that commitment was reflected in the various proposals the Delegation had submitted. The Delegation stated that its Group was committed to make progress with the discussions during the session.

19. The Delegation of Estonia, speaking on behalf of the EU and its Member States, congratulated the Chair and the Vice-Chairs on their election and thanked the Secretariat for preparing the meeting. The Delegation highlighted 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. The Delegation stated that without prejudice to the mandate of the SCP, the Committee agreed that its work for that session should be confined to fact-finding and would not lead to harmonization at that stage. However, the Delegation emphasized that 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 such a work program should provide opportunities for all Member States to make steps forward on important issues. In particular, the Delegation stressed the importance to 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 discussions about other factors of access to medicines than patent protection should be left to other more appropriate fora. With regard to discussions on the future work of the Committee, the Delegation expressed its hope that, similarly to the twenty-sixth session of the SCP, 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. Finally, the Delegation highlighted that the EU under its enhanced cooperation procedure had made significant advances on the European patents with unitary effect. In that context, the Delegation noted that significant advances had also been made on the creation of the Unified Patent Court. The Delegation stated that the Unitary Patent would help to attract and retain innovation, talent and investment. The Delegation remained committed to the work of the Committee and looked forward to a constructive session.

20. The Delegation of Switzerland, speaking on behalf of Group B, congratulated the Chair and the Vice-Chairs on their election. The Delegation 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-seventh session of the SCP, including the documents for discussion, the four sharing sessions and the informative session. Group B expressed its appreciation to the efforts and willingness of all Member States during the previous session that led to a balanced work program. The Delegation hoped that such constructive spirit would prevail during the twenty-seventh 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 mandates. 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 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. Additionally, 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 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 its Group 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.

21. The Delegation of Senegal, speaking on behalf of the African Group, congratulated the Chair and the Vice-Chairs on their election and expressed its gratitude to the Chair for his professionalism and leadership. The Delegation also thanked the Secretariat for preparing the session and for its work. The Delegation pointed out the importance of the subjects that were discussed during the previous session of the SCP, especially with regard to the crucial role of socio-economic development of the Member States of the African Group. The Delegation expressed its satisfaction with the fact that the work program of the SCP was the result of a consensus that was achieved by Member States during the twenty-sixth session of the Committee. The Delegation added that the session would mean that Member States would have exchange of information and points of views in relation to exceptions and limitations, the quality of patents including opposition systems, health and patents, confidentiality of communications and transfer of technology. The Delegation expressed its hope that the program would help to have fruitful discussions which would clarify substantive points of view, and as a result, Member States could achieve the mutual understanding on many issues. The Delegation took note of documents SCP/27/4 Rev. and SCP/27/5 Rev. with respect to the responses to the Questionnaire on the Term “Quality of Patents” and Cooperation between Patent Offices in Search and Examination, and thanked the Secretariat for preparing the documents for the meeting. The Delegation stressed the importance of the avoidance of unnecessary duplication of work that would not

necessarily translate into quality of patents. In that regard, the Delegation added that it should be ensured that IP offices carried out their work appropriately because it guaranteed transparency. With regard to confidentiality of communication between clients and their patent advisers, the Delegation recalled its position and stated that that issue had more connection with ethics and code of conduct than with the patent system. The Delegation pointed out that there was an essential function which required that patent systems be balanced and must be able to play a role in the socio-economic development of the Member States. In relation to that topic, the Delegation mentioned that also general interests and the differences in the development of Member States should be taken into account. The Delegation stressed that exceptions and limitations, transfer of technology and patents and health remained the priority of the African Group. However, the Delegation highlighted the importance of taking into account a general need for the protection of the interests of right holders as well as the general interest of the society. In that context, document SCP/27/6, which dealt with the difficulties facing in particular developing countries and LDCs, showed the importance of flexibilities with regard to the quality of medicines and access to essential medicines with affordable prices. Further, the Delegation pointed out that world health associated many complex issues, such as universal coverage of health and global resistance, hepatitis, HIV AIDS, tropical diseases, and therefore, that issue required very close cooperation between different actors in the fields of trade, intellectual property and health. In that regard, the Delegation stated that the SCP and WIPO played a meaningful role in establishing universal access to resources and information for developing countries and LDCs. The Delegation expressed its interest in the exchange of information and access to databases available to the public with regard to the status of patents. The Delegation thanked the Delegation of Canada for its revised proposal in the field of patents and access to medicines and health technologies (document SCP/27/8). Further, the Delegation recalled its proposal laid down in document SCP/24/4, which dealt with all above-mentioned elements. The Delegation continued to attach considerable importance to the issue of the exchange of information between Member States and experts and the use of flexibilities. In that connection, the Delegation further stated the importance of providing technical assistance to Member States and, in particular, to developing countries and LDCs with regard to the work done on those important issues. Additionally, the Delegation requested to create a working group in order to look at the recommendations on access to medicines. Further, the Delegation stressed the importance of looking at the orientations of intellectual property rights and access to medicines in order to ensure that Member States could identify the obstacles linked to the intellectual property system. The Delegation was of the view that the program proposed by the African Group was ambitious and balanced, and took into account the legitimate concerns of developing countries and LDCs with regard to their specific needs and characteristics. In conclusion, the Delegation stated that its Group was committed to make progress with the discussions during the session.

22. The Delegation of China congratulated the Chair and the Vice Chairs on their election, and expressed its confidence that under the leadership of the Chair and with the facilitation of the Secretariat as well as the active participation of Member States, the SCP session would be a great success. With regard to the work of the SCP, the Delegation noted that it had always cooperated with the work of the Committee and expressed its hope that, with the joint efforts, the patent system would facilitate innovations as well as socio-economic and technological development. Further, the Delegation affirmed its readiness to take an active part in the SCP sessions as well as share its experiences. In relation to exceptions and limitations to patent rights, patents and health and technology transfer, the Delegation stated that those topics were of vital importance for striking appropriate balance between the interests of right holders and the general public. In relation to those topics, the Delegation observed that the Member States would have the sharing sessions that would assist them 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 between 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 efforts of the SCP.

23. The Delegation of India congratulated the Chair and the Vice-Chairs on their election as well as the Secretariat for preparing the meeting. The Delegation aligned itself with the statement made by the Delegation of Indonesia on behalf of the Asia and Pacific Group. The Delegation believed that the TRIPS flexibilities had made significant advance for individual Member States to design their domestic patent laws. The Delegation stressed that those flexibilities were imperative for the developing countries and LDCs to streamline their socio-economic development priorities in their overall intellectual property policy making process. The Delegation was of the view that all Member States should work towards the revision of the 1979 WIPO Model Law on Patents, based on the fact that at that time, many developing countries and the LDCs has not been the members of WIPO or had just joined WIPO. In that connection, the Delegation pointed out that the Model Law should reflect the realities of the contemporary world, and therefore, the Delegation requested the Secretariat to create a study group in order to examine that issue. The Delegation looked forward to the sharing sessions and information exchange sessions under agenda items on patents and health, quality of patents, including opposition systems, confidentiality of communications between clients and their patent advisors, transfer of technology and legislative assistance in the field of patents and related capacity building. The Delegation expressed its belief that the relationship between quality of patents and opposition systems should be studied objectively. In that regard, the Delegation was of the view that a well-defined opposition system added value to the process of the patent examinations and helped to ensure quality in patent claims. The Delegation also expressed its appreciation for the UNHLP Report and further reiterated the importance of the TRIPS flexibilities to bridge the incoherence between international human rights, trade, intellectual property rights and public health objectives. In that connection, the Delegation requested WIPO to form a study group with proportionate participation of all stakeholders in order to identify the constraints and possible solutions. 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. 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. The Delegation remained committed to a constructive and participative discussion on those issues in the twenty-seventh session of the SCP, and looked forward to contributing meaningfully to the discussions. Finally, the Delegation wished to stress a leadership role of WIPO in all IP related matters for better management of intellectual property with a view to minimizing duplication of its work at other fora.

24. The Delegation of Iran (Islamic Republic of) congratulated the Chair and Vice-Chairs on their election. The Delegation expressed its fullest cooperation and constructive engagement in the course of the Committees 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. 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 balancing the interests of patent holders with those of public interest, in making effective use of the flexibility in patent systems and in understanding the social value of the patent systems. The Delegation further noted that extensive and in-depth exchange of information on the issues of the agenda 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 8 on patents and health, the Delegation took

note of the information contained in document SCP/27/6 on constraints faced by developing countries and LDCs in making full use of patent flexibilities. The Delegation also looked forward to the sharing session on publicly accessible databases on patent information and data on medicines and vaccines as well as to the sharing session on patent and other related issues on access to medicines. The Delegation was of the view that the deliberation on those topics would help the Committee to better understand the challenges encountered by developing countries and LDCs, and explore the way to better adopt the patent system to meet the national needs and priorities in those areas. On the issue of exceptions and limitations, the Delegation welcomed the decision that was made at the previous session of the SCP asking the Secretariat to prepare a draft document on the exceptions and limitations to patent rights. The Delegation expressed its satisfaction with the fact that the first step of that project on exceptions regarding acts for obtaining regulatory approval from state authorities had been submitted at the twenty-seventh session of the SCP (document SCP/27/3). The Delegation continued that the activities of the SCP should facilitate the dissemination and transfer of technology and ensure that the patent system contributed to foster innovation for broader human and social development in all countries. Therefore, the Committee was expected to discuss the issue of how patents could be a barrier to the transfer of technology. In that regard, the Delegation was of the view that the sharing session on patent law provisions would add substantive value to the deliberations of the Committee in that regard. 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 willingness that the Committee would make significant progress in advancing discussions on issues of particular relevance to the common interests of the Member States.

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 Costa Rica on behalf of GRULAC. The Delegation stated that at the previous SCP session, the Member States had reached 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. Further, the Delegation stated that market-driven R&D and profit-driven innovation were effective mechanisms for progress. The Delegation continued that, however, it should be recognized that the remaining gaps in health, innovation and access could be addressed without jeopardizing what had been functioning. 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 IP 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 first draft reference document regarding exception on acts for obtaining regulatory approval from authorities. In its view, that draft would contribute to the creation of a non-exhaustive reference document on exceptions and limitations to patent rights for the benefit of all Member States. 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 Sustainable Development Agenda (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 ones. The Delegation considered that

although important progress had already been made, it should be recognized that significant gaps in health, innovation and access persisted. The Delegation noted that, for example, according to the World Health Organization (WHO) and the World Bank, 400 million people worldwide lacked healthcare, including access to medicines, vaccines and medical devices, and three quarters of them lived in the middle-income countries. Furthermore, the Delegation stated that about 1,7 billion people in 185 countries needed treatment and care for neglected tropical diseases. 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. 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. In that connection, the Delegation mentioned that the SCP had taken the right step by inviting the Medicines Patent Pool (MPP), a United Nations-backed public health organization, to make a presentation about the Medicines Patents and Licenses Database (MedsPal), i.e., a publicly accessible database that provided information on the patent and licensing status of selected HIV, hepatitis C and tuberculosis medicines in low and middle-income countries. The Delegation supported the proposal of the African Group on patents and health, contained in document SCP/24/4, and stated that that document was an excellent basis for the discussions on public policy priorities related to public health. The Delegation also thanked the Delegation of Canada for making a proposal and opening a channel of dialogue, and reaffirmed its willingness to work constructively in order to find a language that would be accepted by all Member States. Further, the Delegation noted that it had responded to the Questionnaire on the Term “Quality of Patents”, and expressed its belief that additional exchange of views on quality of patents would contribute to enhancing the mutual understanding of patent laws and procedures of different Member States for the benefit of all countries. As regards the technology transfer, the Delegation expressed its appreciation of the sharing session for the contribution of patent law provisions, which had been put in place based on GRULAC’s proposal. The Delegation was of the opinion that additional efforts should be made in the Committee to develop an effective work program on technology transfer. The Delegation expressed its willingness to find ways to ensure that the patent system addressed the challenges posed by the accelerated pace of innovation. 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 Nigeria congratulated the Chair and the Vice-Chairs on their election and expressed its confidence in their professionalism. Further, the Delegation thanked the Secretariat for preparing the session. The Delegation supported the African Group’s statement delivered by the Delegation of Senegal. Additionally, the Delegation welcomed the work program and noted that the program would assist Member States to adapt their patent laws and make full use of the patent flexibilities in accordance with public health needs and in compliance with international obligations. In that regard, the Delegation stated that the proposal of the African Group (document SCP/24/4) offered a solution to the challenges of affordable access to health care and medicines internationally. The Delegation was of the view that discussions on the study submitted by the Secretariat at the fourteenth session of the SCP on transfer of technology (document SCP/14/4 Rev. 2) had not progressed beyond the preliminary stage. The Delegation therefore looked forward to seeing progress in that area, and, particularly on the issue of sufficient disclosure and transfer of technology. The Delegation stated that it had always attached great importance

to the various agenda items under discussion in the SCP. The Delegation expressed its willingness that Member States would be open, sincere and constructive in their discussions and looked forward to engaging constructively in the discussions of the SCP with the purpose of achieving consensus that would advance the objectives of WIPO.

27. The Delegation of Côte d'Ivoire congratulated the Chair on his election and 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 of aligned itself with the statement made by the Delegation of Senegal on behalf of the African Group. The Delegation noted that patents were an engine of innovation, that supported improvement of human wellbeing and a condition of transfer of technology. In that connection, it was important to make those conditions available for developing countries. The Delegation further stated that the latest technologies and therefore the patent system were at the heart of socio-economic and cultural development. The Delegation was therefore of the view that it was necessary to ensure through the SCP that they had a balanced implementation of the system, particularly with regard to medicines. In that connection, the Delegation stressed the importance of those issues and expressed its willingness to come back to that issue at a timely moment. The Delegation also pointed out that in the framework of future work, it wanted to focus on technical assistance and capacity building for implementation of the flexibilities for the benefit of developing countries and LDCs. Finally, the Delegation noted that it had supported the program of future work of the previous session in the spirit of compromise, and expressed its hope that a consensus and successful results would be reached by the Committee at its twenty-seventh session.

28. The Delegation of South Africa aligned itself with the statement made by the Delegation of Senegal on behalf of the African Group. The Delegation further thanked the Secretariat for preparation of the session. The Delegation stated that the work of the Committee had the potential to play a meaningful role for the attainment of the socio-economic development of Member States, particularly developing countries. In connection with the opening speech of the Director General, the Delegation stated that the previous SCP session was successful in agreeing on a work plan which although did not cater for all priorities of the Member States. However, the Delegation observed that the previous SCP session had represented some progress in ensuring that the critical work of the Committee would move forward. The Delegation looked forward to the finalization of the reference document on exceptions and limitations to patent rights (document SCP/27/3) as well as to the sharing and information sessions on inventive step, access to medicines and effective technology transfer. As regards the issue of access to medicines, the Delegation expressed its willingness that the SCP would agree on a more ambitious work plan in line with the proposal of the African Group in that regard. The Delegation reiterated that it was grappling with those issues, and noted that it would take into account the outcomes of the SCP discussions in formulating its national policy. The Delegation looked forward to the future work of the SCP, and stated that it would continue participating in the activities of the SCP.

29. The Delegation of Egypt congratulated the Chair and the Vice-Chairs on their election, and thanked the Secretariat for preparation of the session as well as for the intensive work represented in the events and the information sessions. The Delegation stated that patents should not be used to obstruct access by some countries to modern technology as well as to the related knowledge which would improve economic and social progress. The Delegation continued to confer 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 faced by

developing countries and LDCs in making full use of patent flexibilities (document SCP/27/6). The Delegation looked forward to a more comprehensive study regarding the needs in public health and access to medicines in developing countries and LDCs. Specifically, the Delegation expressed its interest in a study on restrictions to access TRIPS flexibilities as well as on Article 27 of the TRIPS Agreement. The Delegation was of the view that WIPO's database required additional information regarding the essential medicines list as well as information about their prices. Further, the Delegation stressed the importance of quality and the opposition system for developing countries. In that regard, the Delegation looked forward to further improvements in the quality of drugs, in patent examination and specifications and in standards of drug registration. In particular, the Delegation stressed that a patented drug should always involve an inventive step. In that regard, the Delegation looked forward to a constructive debate regarding the patents in the interest of socio-economic progress in all countries on the basis of national legislation. In that regard, the Delegation welcomed the proposal of the African Group regarding patents and public health, and looked forward to the presentations on that subject as well as the study on how patents helped to improve public health including access to medicines. The Delegation was of the view that the proposal made by the African Group was in line with current international efforts to improve public health, and particularly with the TRIPS Agreement which allowed to use flexibilities until 2030. Finally, the Delegation aligned itself with the Director General's report on public health, and health improvement.

30. The Delegation of Ethiopia congratulated the Chair and the Vice-Chairs on their election and thanked the Secretariat for preparation of that session of the SCP. The Delegation aligned itself with the statement made by the Delegation of Senegal on behalf of the African Group. The Delegation looked forward to the discussions on the constraints of the patent system for developing countries and LDCs. The Delegation expressed its hope that the sharing sessions would contribute significantly to the discourse and would shed light on the role of the patent system in facilitating knowledge and fostering innovation and technology transfer in an independent manner. 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 at all ages. In particular, the Delegation was of the view that the SDG Goal 3 referred to universal health coverage, including access to safe, effective, quality and affordable essential medicines and vaccines for all. In that connection, the Delegation supported the updated proposal of the African Group for the SCP work program on patents and health (document SCP/24/4). In its view, it was vital that the work of the SCP was to balance needs and interests of the diverse stakeholders in the international patent landscape in accordance with the WIPO Development Agenda. The Delegation looked forward to a more ambitious, transparent, balanced and progressive future work program and aligned itself with the WIPO Development Agenda recommendations. The Delegation also hoped to foster a more accessible patent system. Finally, the Delegation wished a successful session of the Committee.

31. The Delegation of the Republic of Korea congratulated the Chair and the Vice-Chairs on their election. The Delegation 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 in the WIPO, as it provided a multilateral forum for discussing patent-related issues. While each Member State had a different viewpoint on the specific agenda of the SCP, the Delegation was of the view that all Member States had made a lot of efforts in order to narrow the gaps. The Delegation expressed its opinion that the SCP agenda should be highly valued. The Delegation noted that in the fourth industrial revolution era where new technologies were rapidly developing and technical complexity increasing, the Member States had to quickly respond to the technical transition through the patent system. The Delegation expressed its belief that the SCP would play a huge role in the transitional

post-industrial revolution era where new technologies were rapidly developed, in particular concerning the quality of patents. On the definition of quality of patents, the Delegation was of the view that documents SCP/27/4 Rev. and SCP/27/5 Rev. would be a good basis for Member States to narrow the gaps during that session. The Delegation also welcomed an information exchange and sharing sessions, particularly the session on inventive step. In its view, those sessions would help reduce the differences among Member States. Furthermore, the Delegation expressed its hope that in the exchange sessions, Member States would exchange their views in order to promote mutual understanding on those issues. In conclusion, the Delegation expressed its willingness to have productive and constructive discussions in order to achieve a fruitful result.

32. The Delegation of Uganda congratulated the Chair and the Vice-Chairs on their election. Further, the Delegation thanked the Secretariat for the excellent preparation of the session. The Delegation aligned itself with the statement made by the Delegation of Senegal on behalf of the African Group. The Delegation expressed its hope that the information exchange and sharing sessions would allow Member States to reach a common understanding despite the diverse interests of Member States and to agree on a balanced and development-oriented work program taking into account the interests of developing countries. The Delegation welcomed document SCP/27/3 since in its view, the document would provide valuable lessons from other Member States that had been able to positively apply the specific exception to patent rights. The Delegation looked forward to the information on other exceptions that might be included in that document. On quality of patents and opposition systems, the Delegation welcomed documents SCP/27/4 Rev. and SCP/27/5 Rev. It stated that patent quality could not be improved by sharing IP offices experiences and adopting their different practices. Additionally, the Delegation pointed out that the issue of opposition system should also be studied carefully in order to examine how that issue reinforced the quality of patents. On patents and health, the Delegation took note of document SCP/27/6. In that regard, the Delegation mentioned that because of the lack of empirical data, document SCP/27/6 did not contain definitive conclusions. However, the Delegation was of the view that that fact should not derail future work on that question. In particular, the Delegation stated that the proposal of the African Group could be a good basis for future work under that agenda item. As regards technology transfer, the Delegation stated that access to technology, as well as to other health-related needs, was of great importance for the Delegation. In particular, the Delegation specified that as its State imported about 85% of medicines, diagnostics, vaccines and other medical products from the global market, it aspired to build its domestic industry for production of medicines. In that connection, the Delegation looked forward to the information sharing session on patent law provisions that contributed to effective transfer of technology. In conclusion, the Delegation expressed its hope for successful discussions on the different agenda items.

33. The Delegation of Belarus congratulated the Chair on his election and welcomed all Member States. The Delegation also thanked the Secretariat for preparing document SCP/27/3. The Delegation stated that the document contained information with regard to the exception in relation to testing for marketing approval, and therefore, it could be used as guidance. The Delegation also expressed great gratitude to the Secretariat for updating the website of the SCP and stressed the importance of the SCP work. In addition, the Delegation highlighted the importance of the issues on limitations and exemptions on patent rights, patents and health and technology transfer. In its view, those issues were particularly important for optimal use of the patent system. With regard to confidentiality, the Delegation noted that a questionnaire on that issue was placed on the website of the National Institute of Intellectual Property of the Republic of Belarus and as a result some feedbacks for that questionnaire has been received. The Delegation noted that violation of confidentiality in its State was quite rare. Finally, the Delegation expressed its willingness that the agenda items would contribute to the improvement of the patent system.

34. The Representative of the South Center stated that next session of the SCP would mark the tenth anniversary since the SCP had reconvened in 2008 with a focus on developing a balanced work program on issues relating to the law of patents. In that connection, the Representative noted that the work of the SCP was integral in advancing the WIPO Development Agenda. The Representative further noted that the list of issues in the agenda of the SCP included such important issues such as exceptions and limitations to patent rights, quality of patents, including opposition systems, patents and health, and transfer of technology. He further stated that a number of studies, fact-finding surveys, sharing sessions had informed the discussions on those issues. The Representative added that the SCP had sufficient tools to develop impactful solutions to address identified challenges that arose in the context of the patent system and their interface with various public policy questions. He further noted that the development of document SCP/27/3 marked concrete progress towards developing a reference document on exceptions and limitations to patent rights that could be a useful reference tool for Member States in the process of designing their patent laws and policies. The Representative was of the view that the SCP should advance its work in order to develop reference documents on other exceptions and limitations to patent rights. On quality of patents, the Representative stated that the SCP should also address the importance of pre-grant and post-grant patent opposition systems for ensuring the grant of high quality patents through a robust search and examination process. On patents and health, the Representative pointed out that the SCP should substantially engage on the proposal by the African Group on patents and health that was submitted in 2011 and updated at the twenty-fourth session of the SCP (document SCP/24/4). The Representative further noted that many elements of that proposal were reflected in the recommendations of the UNHLP Report which had been adopted by consensus among all panel members of the UNHLP after extensive consultations with a diversity of stakeholders all over the world. Further, the Representative stressed that any review of existing literature on patents and health should be strictly limited to patent-related issues pertaining to access to medical products.

**AGENDA ITEM 6: REPORT ON THE INTERNATIONAL PATENT SYSTEM: CERTAIN ASPECTS OF NATIONAL/REGIONAL PATENT LAWS**

35. Discussions were based on document SCP/27/2.

36. The Secretariat made a presentation on document SCP/27/2.

37. The Delegation of Singapore wished to inform the Committee about some amendments to the Patent Law of Singapore which had entered into force on October 30, 2017 (document SCP/27/A/PATENT SYSTEM SINGAPORE). The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_a_patent_system_singapore.pdf. The Delegation stated that there were three roads for the search and examination in Singapore: (i) the local route (the full examination process conducted by a local examiner); (ii) the mixed route (a local examiner prepared a substantive examination report based on a search report prepared by a foreign IP office and submitted by an applicant) and (iii) the foreign route (a local examiner conducted a supplementary examination based on an examination report prepared by a foreign IP office and submitted by an applicant). The Delegation stated that the local and mixed routes were available for a fee, and that the foreign route was available free of charge. Further, the Delegation pointed out that the foreign route would be closed on January 1, 2020, with the aim of increasing the quality of patents granted in Singapore as well as to align with the practices of other jurisdictions. With respect to the second amendment of the Patent Law of Singapore, the Delegation noted that the previous law had allowed an applicant to switch from one route to another route only

before responding to a written opinion. The new patent law allowed the applicant to switch routes any time before the issuance of a final report by the IP office. The Delegation expressed its belief that that amendment would give more flexibility to the applicants. Finally, the Delegation stated that the previous law allowed a grace period of 12 months in limited circumstances, particularly, when the disclosure had been made in an international exhibition and also when the disclosure was made in breach of confidence. The Delegation stated that the third amendment to the patent law was to broad a grace period, including any disclosure by the inventor or the person who obtained information from the inventor. Additionally, the Delegation pointed out the two new initiatives of IP office. The first initiative was the Patents Open Dossier (the POD), which was a new online service that provided the public access to a collection of published patent documents with the aim of enhancing the transparency of the records within the IP office. In that connection, the Delegation stated that the POD allowed to download all of the documents. Finally, as regards the patent manual, the Delegation noted that in August 2017, a new patent manual had been published to provide applicants with a better understanding on current practices as well as the requirements of the patent law. In conclusion, the Delegation advised to access the website of the Patent Office of Singapore in order to get more information on the changes that had been enacted.

38. The Delegation of Switzerland, speaking on behalf of Group B, thanked the Secretariat for preparing document SCP/27/2, the SCP members that provided inputs on changes in their national patents law, and the Delegation of Singapore for its presentation. The Delegation believed that the regularly updated SCP electronic forum website was an important source of information. The Delegation noted that data contained in such website provided insights into the patent legislation of various countries and contributed to a better understanding of the international patent system.

39. The Delegation of Argentina congratulated the Chair and Vice-Chairs for their election. The Delegation expressed its gratitude also to the Secretariat for the organization of the SCP meeting and the preparation of the documents. The Delegation endorsed the statement made by the Delegation of Costa Rica on behalf of GRULAC. The Delegation understood that exchanging information regarding national and regional legislations on patents, as well as sharing experiences, helped the Member States to extend their knowledge, and improve their national practices and their legislation. The Delegation commended the Secretariat for the update of the website of the electronic forum of the SCP, according to the information received by the Delegations of Bhutan, Germany, Jordan and Montenegro, and the presentation made by the Delegation of Singapore on recent amendments to its patent legislation and other initiatives.

40. The Delegation of Georgia, speaking on behalf of the CEBS Group, congratulated the Chair and Vice-Chairs for their election. The Delegation thanked the Secretariat for having prepared the twenty-seventh session of the SCP and stressed the importance attached by the CEBS Group to the work of the Committee. The Delegation was pleased that the Member States agreed on the balanced future work during the previous SCP session. The Delegation believed that the agenda items accommodated the interests of all Member States in a delicate balance, as the interest of each individual Member State lied at least in one of the five topics to be discussed. The Delegation emphasized that the fact-finding work was important during the Committee. The Delegation looked forward to continue discussions on the quality of patents and confidentiality of communications between clients and their patent advisors, as the discussions could contribute to a more predictable patent framework. The Delegation believed that the Committee should focus its efforts and achieve an agreement on the future work of the SCP without an excessive amount of time dedicated to the discussions on the future work. The Delegation was ready to engage in those discussions in a constructive manner.

41. The Delegation of Estonia, speaking on behalf of the EU and its Member States, thanked the WIPO Secretariat for preparing document SCP/27/2. The Delegation expressed its gratitude also to the Delegations of Bhutan, Germany, Jordan, and Montenegro for their input, based on which the SCP electronic forum website had been updated. The Delegation believed that the SCP 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 it was important to keep such tool up-to-date. The Delegation also thanked the Delegation of Singapore for its presentation. The Delegation remained interested in any information on the recent developments of national/regional patent laws.

42. The Delegation of Ireland, in relation to the presentation made by the Delegation of Singapore, observed that the three models illustrated in the presentation, i.e., the local, mixed, and foreign routed, echoed the way the system operated in Ireland, where they had adopted the same approach. The Delegation specified that in May 2016, they reintroduced substantive examination. The Delegation further explained that, until recently, the patent office had required a search report or a granted patent as evidence of novelty, but had not actually examined novelty, inventive step or industrial applicability of the claimed inventions until such recent reform. The Delegation informed the Committee that further information would be submitted to the Secretariat so that the WIPO website could be updated.

## AGENDA ITEM 7: EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

43. Discussions were based on document SCP/27/3.

44. The Delegation of Iran (Islamic Republic of) believed that exceptions and limitations to patent rights played an important role in supporting the appropriate functioning of the patent system, as they provided a balance between the interests of the public and those of the rights holders. In that regard, the Delegation was of the view that a flexible policy space was necessary to allow Member States to develop and adopt the set of exceptions and limitations more adequate for their realities, independent of whether they were developed or developing countries. The Delegation welcomed the decision made at the previous session of the Committee to develop a document entitled “Reference Document on Exceptions and Limitations” and the implementation of the first step of that project. The Delegation took note of document SCP/27/3, and expressed its appreciation to the Secretariat for providing information contained therein, for the appropriate format and structure of the document, as well as for its presentation made by the Secretariat. The Delegation recognized that the information contained in document SCP/27/3 had been collected through the material that SCP produced in the past years as well as from submission from Member States and regional patent offices. 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. Furthermore, the Delegation was of the opinion that the document would contribute significantly to overcome challenges associated to that exception in addressing developmental issues. The Delegation requested the Secretariat to use such material in its technical and legislative assistance provided to WIPO Member States. The Delegation looked forward to the development of the document in the future work plan of the Committee though the inclusion of new subjects. The Delegation also encouraged the Secretariat to update regularly the document based on the new submission by Member States or regional offices.

45. The Delegation of Chile congratulated the Chair and the Vice-Chairs for their election. With regard to Agenda Item 7, the Delegation believed that exceptions and limitations to patent rights were a fundamental mechanism to ensure a balanced patent and intellectual property system, able to achieve the objective of promoting innovation while respecting the rights and interests of all the involved stakeholders. The Delegation thus considered that, with regard to the act carried out to obtain regulatory approval by the regulatory national authorities, an adequate balance was given by the incorporation of flexibilities. The Delegation stressed that such flexibility would avoid that the time of exclusivity granted by a patents extended beyond the validity of the patent during the time necessary to carry out the mandatory procedures to obtain the sanitary registration of a medicine. With that regard, the Delegation was of the opinion that the exception regarding acts for obtaining the approval of the regulatory authorities, or "Bolar" exception, was an effective mechanism for the generic pharmaceutical industry. In fact, the Delegation specified that such exception would enable the generic drug producer to prepare and present the dossier with the documentation required by the regulatory authority, without implying an infringement of the exclusive rights of the patent holder, as long as the commercialization of the generic pharmaceuticals did not take place until after the expiration of the patent. The Delegation explained that in Chile, such exception was contained in Article 49 of Law 19,039 of industrial property, which established that the patent did not confer the right to impede that third parties import, export, manufacture, or produce the material protected by a patent with the aim of obtaining the registration or sanitary authorization of a pharmaceutical product. The Delegation specified that such provision of law in any case did not allow for the marketing of patented pharmaceutical products without the authorization of the patent holder. The Delegation believed that such exception complied with the public policy objectives provided for at the time of its incorporation into Chilean legislation, since it facilitated access to medicines, promoted competition and incentivized the development of the national generic medicines industry. Finally, the Delegation mentioned that Chile was considering the incorporation of additional exceptions and limitations to patent rights in the draft law which would substitute the law 19,039 of industrial property. The Delegation specified such draft law was discussed in the National Congress. The Delegation stressed that, at the same time, the national public strategy on industrial property launched in December 2016 by the National institute of Industrial Property (INAPI) together with His Excellency, the President of the Republic of Chile, aimed to propose a system that allowed greater transparency to the system by making the date of the effective term of a pharmaceutical patent public with a certain advance, so that the interested parties had knowledge of that fact with a reasonable opportunity and could make use of the mechanism of the Bolar exception, if they wished.

46. The Delegation of Georgia, speaking on behalf of the CEBS Group, thanked the Secretariat for the preparation of the 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. Furthermore, the Delegation believed that, based on the limited information provided in the summary, there was no specific need for normative work at the international level concerning the regulatory review exception at that stage. While the Delegation valued efforts contributing to understanding of the topic of exceptions and limitations, it looked forward to seeing the full report on specific exceptions and limitations to patent rights. The Delegation favored an approach where appropriate balance was achieved between the interests of rights 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.

47. The Delegation of Switzerland, speaking on behalf of Group B, thanked the Secretariat for the preparation of document SCP/27/3 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 the WIPO 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 7 had produced sufficient information for reflections on the implementation of exceptions and limitations.

48. The Delegation of the Republic of Korea considered that exceptions and limitations to patent rights of each State should be approached from the viewpoint that patent rights promoted the public interest. Furthermore, the Delegation was of the view that there should be a balance between patent rights and public interests. The Delegation thanked the Secretariat for document SCP/27/3, and the Member States for their inputs on that issue. Considering the balance between the patent rights and the public interests, the Delegation explained that its government had introduced the regulatory exception in 2013, and informed the Committee that should new amendments be adopted, it would inform the WIPO Secretariat.

49. The Delegation of Senegal, speaking on behalf of the African Group, thanked the Secretariat for having compiled document SCP/27/3 and for its presentation. The Delegation welcomed such first draft reference document and waited with interest further documents on other exceptions. The Delegation reiterated the importance that they attached to the issue of exceptions and limitations to the patent rights, for their contribution to effectively striking the correct balance between private interests and general interests in different countries. The Delegation believed that those exceptions and limitations provided for the necessary policy space to policy-makers to take the right provisions and measures in order to meet their concerns and development priorities. The Delegation noted that the exceptions and limitations had a crucial place amongst the strategic development objectives, particularly the recommendations of WIPO's Development Agenda and the TRIPS Agreement, and that they had a direct and indirect link to the Sustainable Development Goals. The Delegation also stressed that the exceptions and limitations played an important role in the social and economic development through research and innovation, they promoted scientific and technological development, and encouraged access to knowledge and information. However, the Delegation highlighted that their mere inclusion into a formal legal framework, was not enough to measure their effectivity and efficacy, and they should not disguise the challenges related to their implementation. The Delegation was of the view that objectives and targets indicated in document SCP/27/3 were crucial in relation to the TRIPS Agreement and its implementation at the national and regional levels. Noting the difficulties surrounding the implementation of the TRIPS Agreement, the Delegation observed the relatively low number of countries using the regulatory review exception. The Delegation believed that such data highlighted the awareness-raising and

outreach work, technical assistance and capacity building that WIPO should have undertaken with a view to ensuring that such difficulties could be overcome by Member States in the implementation of those exceptions, in particular with regard to their concrete utilization. The Delegation requested WIPO, when assisting developing countries and LDCs, to draw to their attention to the Bolar exception, to provide them with options on how to integrate it into their legislation, and to give advice about its optimal use. In relation to document SCP/27/3, the Delegation requested the Secretariat to further develop it in order to provide solutions to the difficulties and challenges illustrated in it.

50. The Delegation of Estonia, speaking on behalf of the EU and its Member States, thanked the WIPO Secretariat for preparing document SCP/27/3. 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. The Delegation believed that it was a good example of making use of such information and the work previously conducted by the SCP. The Delegation noted that the reference document covered the list of issues which the Committee decided to address at its previous session. In particular, the Delegation specified that it provided for a description of the regulatory review exception, an overview of its objectives and goals, national/regional implementation, challenges faced by Member States in implementing the exception, and results of such national/regional implementation. The Delegation also noted that, compared to the agreed list of issues, the element of the multilateral legal framework of the regulatory review exception had been added by the Secretariat. Considering its relevance to the topic at hand, the Delegation considered the overview provided on the WTO Dispute Settlement Panel report regarding the Canada Patent Protection of Pharmaceuticals Products case, justified. The Delegation found interesting to learn that such exception was regulated in the applicable laws of more than 65 countries and that different approaches were taken in implementing that exception at the national level, as regards to various important elements of its implementation, such as the source of law, beneficiaries, products, and acts covered by the exception, as well as the conditions of taking advantage of the exception. The Delegation was particularly interested in the part dealing with results of implementation of exception in national/regional laws. On the one hand, the Delegation observed that it appeared that some Member States had reported positive effects on the timeliness of regulatory registration and entry of generic versions of medicines into the market, but on the other hand, the impact of the exception on competition between originator and generic products and reduction of price of the originator products remained unclear. 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 concluded that, based on the draft reference document, 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 reminded that at the twenty-sixth session of the SCP, it was decided to prepare a draft reference document covering the exception regarding acts for obtaining regulatory approval from authorities, which would be a first step of the SCP work in analyzing the specific exceptions and limitations to patent rights in conjunction with patent protection. The Delegation declared its readiness to further discuss the value of that exercise and whether it should be repeated for other exceptions and limitations. The Delegation expressed the support of the EU and its Member States for initiatives which truly contributed to the Committee's knowledge and understanding of the topic of exceptions and limitations, including those which had the potential of addressing development issues. 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 was patentable, such as novelty, inventive step, and industrial applicability. The Delegation believed those two topics were closely interlinked. Therefore the Delegation suggested adopting a holistic approach in order to find an appropriate balance between the interests of the right holders and the general public. The Delegation looked forward to hearing the views of other participants on the Draft Reference Document and the constructive discussion on Agenda Item 7.

51. The Delegation of China noted that at the previous session of the Committee, members of the SCP and observers had shared their experiences, case studies and the challenges faced in relation to Agenda Item 7. The Delegation thanked the Secretariat for having prepared document SCP/27/3 based on the aforementioned information. The Delegation found such information valuable and useful for the drafting of patent law and its implementations. 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. The Delegation considered it important to continue discussing that topic and to get more information from other countries on their experiences and practices. The Delegation noted that in document SCP/27/3, the Secretariat had identified and summarized the information provided by different countries. The Delegation was of the opinion that such document had paved the way and laid a very solid foundation for discussions. The Delegation explained that China had amended its patent law and had added one specific provision on the exception related to regulatory review approval, which established that if any person produced, used or imported patented drug or patented medical apparatus and instruments, for the purpose of providing information required for administrative examination and approval, or any third party imported patented drugs or patented medical apparatus and instruments for that person, that was not considered as a patent infringement. The Delegation stated that the implementation of that provision had produced very positive impact: however, it also realized that efforts should be made to increase public awareness on that subject.

52. The Delegation of Gabon congratulated the Chair and the Vice-Chairs for their election. The Delegation also thanked the Secretariat for the preparation of the working documents. The Delegation endorsed the statement made by the Delegation of Senegal on behalf of the African Group. The Delegation appreciated the information and explanations contained in the document prepared by the Secretariat, which enabled the Committee to better understand the importance of the topic under examination. The Delegation stated that in Gabon, the piece of legislation dealing with industrial property was the Bangui Agreement, which found application also in the other Member States of the African Organization of Intellectual Property (OAPI). The Delegation explained that the Bangui Agreement only regulated, in Annex 1, Article 8, limitations to patent rights, and it did not take into account the exceptions to the patent rights. The Delegation declared that the Gabonese Industrial Property Office acted as the national liaison structure with OAPI. The Delegation stressed that the question on exceptions and limitations arose in Gabon and the need to look at it properly into its legislation was pressing. The Delegation specified that such question was raised internally by the Ministry of Trade, in order to take advantage of the available flexibilities. The Delegation believed that limitations and exceptions to patent rights were legal mechanisms which enabled them to have a broader access to vital products such as pharmaceuticals. The Delegation stated that the implementation of that provision was not effective, although needs in that regard were evergrowing. The Delegation observed that the reasons which explained the difficulty related to the implementation of exceptions and limitations should not just be limited to those illustrated in document SCP/27/3, page 3, paragraphs 11 and 12. In fact, the Delegation believed that such difficulty was also linked to the conceptual and factual complexity of exceptions and limitations, their cross-cutting nature, as well as the fact that their implementation required a synergy amongst the different administrations. In that respect, the Delegation stressed the interest of Gabon in the results

of the Committee's discussions in order to find solutions to those challenges. For all those reasons, the Delegation endorsed the statement made by the Delegation of Senegal on behalf of the African Group concerning technical assistance for the implementation of exceptions and limitations to patent rights.

53. The Delegation of Indonesia thanked the Secretariat for preparing document SCP/27/3. The Delegation attached great importance to the issue of exceptions and limitations to patent rights. The Delegation commended the Secretariat for all the efforts of collecting and compiling information on that subject matter. The Delegation noted that the discussion on such topic had been going on since the fourteenth session of the Committee and resulted in rich, available information. Nevertheless, the Delegation believed that there had been limited qualitative analysis done regarding exceptions and limitations. Consequently, the Delegation was of the view that studies on exceptions and limitations should not be limited to only inputs and information shared by Member States, but needed to be extended to cover evaluation of the effectiveness and challenges faced in the implementation of exceptions and limitations. The Delegation hoped that the work on the draft reference document would be continued until the completion of the reference document, also including further analysis on how various exceptions and limitations were utilized by different countries in addressing the various public policy objectives to provide balanced solutions for various challenges.

54. The Delegation of Brazil commended the Secretariat for the elaboration of the first part of the draft reference document on exceptions and limitations to patent rights contained in document SCP/27/3. Furthermore, the Delegation thanked the Secretariat for the presentation of such document. 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 mentioned that according to the Doha Declaration on TRIPS and Public Health, the TRIPS Agreement did not and should not prevent members from taking measures in protecting public health. The Delegation further specified that the TRIPS Agreement, according to the Doha Declaration, could and should be interpreted and implemented in a manner supportive of WTO members right to protect public health, and in particular to promote access to medicines to all. The Delegation stated that WIPO and WTO 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. 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. The Delegation noted that document SCP/27/3 contained three important aspects that provided concrete contributions: it highlighted the differences in the legislations of Member States, it described some of the challenges faced by Member States in the implementation of the exception, and it presented the results of the implementation of the exception. In the Delegation's view, the structure of the document was balanced and in line with the objective of the proposal. As for the

substance, the Delegation stated it would have preferred to see more space dedicated to the challenges in the subsequent documents, since out of 54 paragraphs of document SCP/27/3, only three had been dedicated to that part. The Delegation considered that the topic was especially important for developing and LDCs, as they had less experience in implementing exceptions and limitations. The Delegation observed that it was the first draft of the reference document, and was not an easy task. The Delegation expressed the hope that those suggestions would be taken into account, and thanked the Secretariat for preparing that document. Furthermore, the Delegation expressed its willingness to provide additional inputs for the future topics. The Delegation was convinced that such material 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. The Delegation was equally convinced that it could be done without harming in any way the legitimate interests of IP right holders.

55. The Delegation of Argentina 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 was of the opinion that they helped the proper function of the patent system, since they balanced public interests with those of the right holders. The Delegation thanked the Secretariat for the preparation of document SCP/27/3 and its presentation. The Delegation noted that such document compiled valuable information on a relevant issue for all the countries, i.e., the Bolar exception. The Delegation considered that such exception, when it facilitated the entry into the market of competitive products, immediately following the expiry of the patent, was of crucial importance in the area of pharmaceutical products, since it could promote the access to medicines and reduce the treatment costs. The Delegation highlighted that according to document SCP/27/3, more than 65 countries adopted that exception in their legislation, amongst them, Argentina. The Delegation also took note of what was expressed in the said document that the Member States had indicated that, generally speaking, the application of such exception in national legislation had a positive effect on the registration of generic medicines and their entry into the market.

56. The Representative of KEI congratulated the Chair for his election. The Representative further commended the work of the WIPO Secretariat in preparing document SCP/27/3 entitled “Draft Reference Document on Exception Regarding Acts for Obtaining Regulatory Approval from Authorities”. 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 65 countries. The Representative considered that, importantly, such document also described the challenges faced by countries in its implementation. The Representative noted that, with respect to the impact of the exception, the report provided the results of an impact assessment conducted by the United Kingdom in conjunction with Section 60(5)(b) of its Patents Act. The Representative stressed that the impact assessment estimated that the regulatory review exception would reduce the cost of undertaking trials, for example, by eliminating cost of freedom to operate investigations, which would save companies between 3,000 to 135,000 pounds per trial and would make the United Kingdom a more attractive place for companies to undertake R&D. As a follow-up to the Secretariat’s work on the draft reference document, the Representative requested the WIPO Chief Economist to conduct an impact assessment of the regulatory review exception in at least seven countries. The Representative proposed that terms of reference of this impact assessment could include an examination of the effects of the regulatory review exception, if any, on the costs of undertaking clinical trials, and secondly, a study on how the regulatory review exception affected the entry of generic medicines into the market.

57. The Delegation of India expressed its support for the work proposed in document SCP/19/6 on exceptions and limitations to patent rights. The Delegation noted that it was important to ensure the use of TRIPS flexibilities. 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 and also in other relevant areas in the knowledge-based economy, namely environment and technology transfer to developing countries. The Delegation considered that patent rights could not be absolute, since public policies also implied the companies' obligations to benefit public at large. In that regards the Delegation believed that those rights and obligations should balance each other. The Delegation reiterated that since scientific and research institutes were crucial places to use research exceptions and civil society involved in public policy could be a good source of information regarding the use of such exceptions, the Secretariat should take into account data from those institutions in compiling such information.

## AGENDA ITEM 8: PATENTS AND HEALTH

58. Discussions were based on documents SCP/27/6 and 8.

59. The Delegation of Indonesia, speaking on behalf of the Asia and Pacific Group, took note of all the topics under the agenda item of patents and health to be discussed at the twenty-seventh session of the Committee, as well as all the proposals and related documents with regard to that agenda item. The Delegation appreciated the additional submissions by SCP members and observers to supplement document SCP/26/5 entitled "Constraints Faced by Developing Countries and LDCs in Making Full Use of Patent Flexibilities", which were incorporated in document SCP/27/6. The Delegation observed that the submissions reflected in that document clearly indicated the need to ensure WIPOs technical assistance in designing national patent laws or national IP strategies, taking those constraints into consideration, and the need to provide assistance on how developing countries could overcome such constraints and make full use of the available flexibilities. The Delegation was of the opinion that the Committee should ensure that the study on the constraints faced by developing countries and LDCs in making full use of patent flexibilities, and their impact on access to affordable and essential medicines in developing countries and LDCs, would involve the UNDP, which had facilitated the UNHLP Report. As the Asia and Pacific Group had already stated in previous sessions of the Committee and in its opening statement, the Delegation drew the attention of the Committee to the fact that the UNHLP Report had specifically explored the policy incoherence between IP, trade, and human rights and had made a number of recommendations in that regard. The Delegation observed that some recommendations were specifically addressed to WIPO, hence, the Delegation requested the SCP to initiate the exploratory discussion based on that report. Furthermore the Delegation took note of the revised proposal by the Delegation of Canada to conduct a review of existing research on patents and access to medical products and health technologies. The Delegation was looking forward to the discussion on that proposal.

60. The Delegation of Georgia, speaking on behalf of the CEBS Group, recalled the importance attached to that issue by the members of its Group. The Delegation believed that the issue was very complex and the need for a holistic approach was obvious in order to address it. The Delegation understood that the access to medicines was a major challenge and showed its commitment to participate in the initiatives that facilitated it. The Delegation recalled the WIPO-WTO-WHO Trilateral Study entitled "Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, IP, and Trade". Nevertheless, the Delegation believed that the Committee had to avoid duplication with the work of other international organizations on such topic. The Delegation stated that the

CEBS Group was open to studies only in a balanced work program that would advance the common understanding of policies and initiatives enhancing access to affordable medicines and health care technologies through the similar proposals that were put forward by the Delegation of the United States of America in document SCP/17/10 and the Delegation of Canada in document SCP/27/8. The Delegation thanked the Secretariat for the preparation of document SCP/27/6, and took note of it. Furthermore, the Delegation took note of the revised proposal of the Delegation of Canada to conduct a review of existing research on patents and access to medical products and health technologies, and thanked the Delegation of Canada for improving the text. The Delegation looked forward to hear discussions on the document.

61. The Delegation of Costa Rica, speaking on behalf of GRULAC, reiterated what had previously been said in its opening statement as regards Agenda Item 8. The Delegation noted the renewed interests of many Member States on such an important topic, taking into account the difficulties of the countries to ensure the availability of medicines in a sustainable manner. The Delegation considered the debate on the relationship between patents and health, in the SCP forum, crucial to promote the very delicate balance required for the patent system. Furthermore, the Delegation thanked the Secretariat for the compilation of studies on difficulties faced by developing countries and LDCs in fully using patent-related flexibilities, and their impact on access to affordable medicines. The Delegation hoped that the sharing sessions would be an important reference point for the Member States, which would enable them to deal with the challenges related to that topic.

62. The Delegation of Senegal, speaking on behalf of the African Group, thanked the Secretariat for document SCP/27/6, and the Member States and the observers of the SCP which provided their contribution to the discussions on the elements of flexibility in the patent system. Furthermore the Delegation took note of the revised version of the proposal on that agenda item of the Delegation of Canada, contained in document SCP/27/8. The Delegation declared that the issue of patents and health was a priority for the African Group in the SCP agenda. The Delegation believed that the problem of access to affordable medications affected all the countries of the world, independently of their level of development. The Delegation observed that the debate on the cost of medicines continued to occupy the sociopolitical space in many States, and that situation should motivate the SCP to deal with challenges and concerns of patents linked to access to medicine. The Delegation considered that even if other obstacles existed in that regard, the SCP should limit its work strictly to the issue of patents, in accordance with its mandate. In the globalized world, seen as a global village, where people and goods could freely circulate, the Delegation noted an aggravation of sanitary crisis with repercussions, very often difficult to control, due to factors such as the migration of pathogens, viruses, and bacteria, which, unfortunately, did not know any borders. Furthermore, the Delegation observed that health was a fundamental human right, a precious collective good, and an enshrinement of the SDG Goal 3, to which it was tributary the realization of other SDGs in the achievement of related objectives. In that regard, the Delegation believed that the challenge of public health should be in the collective responsibility of the international community stakeholders. The Delegation considered that universal health insurance coverage, viral hepatitis, chronical diseases, HIV, transmissible diseases, neglected tropical diseases and anti-microbial resistance requested adequate support in order to provide accessibility to adequate health technologies and medical products of quality at affordable prices. In that context, the Delegation was of the opinion that intellectual property in general, and the patent system in particular, had a fundamental role to play in promoting the availability of pharmaceuticals. In its opinion, the UNHLP Report proved that well. The Delegation noted that based on Article 27 of the TRIPS Agreement, the experts who contributed to that report, recommended, amongst other relevant advice, limiting the perpetuation of patents through the phenomenon of evergreening, facilitating compulsory licenses, and prohibiting the threat of sanctions or

retaliation. Furthermore, the Delegation noted that the report established that a perfect balance between the patent holders, on one side, and general interests, on the other side, was essential, since patents had a direct link with the treatment of severe pathologies. The Delegation found regrettable that, despite an international legal framework which established adequate elements of flexibility able to reduce the cost of access to pharmaceutical and health treatments, developing countries and LDCs did not yet manage to make full use of those flexibilities, according to the information contained in document SCP/27/6. The Delegation stated that it was the Committee's responsibility to treat such question in order to allow developing countries and LDCs to take advantage of those flexibilities in order to protect and promote public health. The Delegation recalled that it was in that spirit that during the twenty-fourth session of the Committee, held in June 2016, the African Group submitted a proposal for the work program on the agenda item dedicated to patents and public health, contained in document SCP/24/4. The Delegation stated that such proposal was still current, and invited the SCP to set up a working group or an expert team to deal with the UNHLP recommendations, and to invite the UN Special Rapporteur on the Right to Health to present the Report on Intellectual Property and Access to Medicines, which constituted a precious resource to feed the Committee's discussions. Furthermore, the Delegation suggested that WIPO, together with its Member States and with the WHO's support, set up an international register on patents regarding essential medicines, and another international register dedicated to licenses on medicines in order to facilitate access to information and to improve transparency on that issue. The Delegation looked forward to the sharing session on information regarding data bases on the status of patents, and data on vaccines and patents.

63. The Delegation of Estonia, speaking on behalf of the EU and its Member States, reiterated their understanding of the challenges and constraints certain countries might face in handling public health problems. The Delegation believed 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 everybody should support. The Delegation remained committed to increasing access to affordable medicines and to find solutions to the worlds pressing public health challenges and inequities. The Delegation recalled that, as set out in the 2010 Communication and Council Conclusions on the EU Role in Global Health, the EU pursued a human-rights-based approach to health, strengthening all areas of health systems including the availability of qualified health workers and the provisions of affordable medicines. In that regard, the Delegation stressed that the adequate financing of the sector was central to moving towards universal health coverage with quality health services, accessible and affordable for all. Furthermore, the Delegation specified that the quality and integrity of the pharmaceutical distribution chain was also essential to improving public health. The Delegation observed that the current innovation model, including the role of trade related to IP, had delivered consistent progress in global public health, leading to key, new, and improved treatments, as well as much extended life expectancy, from developed countries to LDCs. The Delegation noted that such model already integrated a variety of tools, such as incentives for innovation based on intellectual property, public and private financing, and awards for public research. The Delegation considered that such variety was necessary to address situations where there was a functioning market and where there could be market failures. The Delegation believed 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, such as those proposed by the Delegation of the United States of America in document SCP/17/10. The Delegation thanked the Secretariat for the preparation of document SCP/27/6. The Delegation took note of that further work, which complemented the study with additional input from members and observers of the SCP. The Delegation welcomed the revised proposal by the Delegation of Canada, contained in document SCP/27/8. The Delegation, as previously stated during the twenty-sixth session of the SCP, saw some merit in conducting analysis on existing research on the

topic of patent protection and access to medical products and health technologies. The Delegation was glad to note that several comments made by the EU and its Member States about the earlier version of the proposal had been taken on-board in the revised version. In particular, the Delegation pointed out that the terms “medical products” and “health technologies” had been clarified, and the scope of the proposed paper had been better confined to the mandate of the SCP. Considering the changes made to the initial proposal, the Delegation was prepared to further discuss it. The Delegation reiterated its previous position according to which, 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. Furthermore, the Delegation emphasized that it saw the role of the potential report as a collection of information and as a document supporting future discussions of the SCP, and not as an outline of different policy options for WIPO Member States.

64. The Delegation of Switzerland, speaking on behalf of Group B, thanked the Secretariat for preparing document SCP/27/6 and for organizing the Information Exchange Session on Publicly Accessible Databases on Patent Information Status and Data on Medicines and Vaccines. The Delegation reiterated that both innovation and access to it were equally important in the field of patents and health. The Delegation stressed that innovation was fostered by the patent system. The Delegation believed that the patent system was a key incentive for research and development of medical products, including life-saving medicines. The Delegation noted that investments in research and development for innovative medical products had contributed to crucial improvements in public health outcomes, and intellectual property rights had played a key role in facilitating such innovation. The Delegation was of the opinion that continuous innovation was needed to face current and future health challenges. The Delegation pointed out that the protection of intellectual property rights, including patents, served as an incentive for medical innovation and thereby support the availability of new medicinal products for all. In the Delegation’s view, it was of public interest to have further research and development of safe and effective medical products. The Delegation believed that patents, as incentive for research and development, were part of the solution to the problem of availability of future medical products. Therefore, the Delegation stated that it was important to keep in mind the whole context of patents and health and not to focus only on one specific element of it. The Delegation recalled that, as pointed out in the WIPO-WTO-WHO Trilateral Study promoting access to medical technologies and innovation, the lack of access to medical technologies was rarely due to a single isolated factor, but it rather had different dimensions and causes. The Delegation explained that lack of access to medicines might be influenced by inadequate financing of health care, shortage or lack of access to trained health care personnel, inadequate medical facilities, fragmented and unreliable programs and systems and processes, lack of infrastructure, conflicting policies that discouraged market entry and competition of innovative drugs, supply chain management, full visibility of demand, retail markups, taxes, tariffs, etc. The Delegation mentioned that different projects or collaborations showed how the patent system incentivized innovation and served to provide available and accessible key information about patented inventions. The Delegation specified that those projects included MPP’s MedsPal and recently launched Pat-INFORMED. The Delegation looked forward to the information exchange session on public databases on patent information status and data on medicines and vaccines. The Delegation stated that innovation in medical products, and access to those technologies, was a major concern for all Member States. The Delegation supported work under the agenda item on patents and health that took into consideration the whole context of that field, fell under the mandate of the SCP, and avoided duplication of work already being done by other committees or by other multilateral organizations. The Delegation observed that the issues 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. The Delegation noted that extensive work had already been done in that area by those organizations and other multilateral fora. Consequently, before undertaking new studies of the SCP, the Delegation recommended making an inventory of studies and analysis produced by those bodies in order to avoid unnecessary duplication with existing work. The Delegation took note of the proposal put forward by the Delegation of Canada and Switzerland and thanked the Delegations for their constructive efforts to foster meaningful discussions under that agenda item. The Delegation looked forward to further discussions. The Delegation 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-WTO-WHO Trilateral Study promoting access to medical technologies and innovation. The Delegation believed that such document could serve as the basis for productive discussions. The Delegation supported a holistic view in the area of patents and health as proposed in document SCP/17/11. The Delegation took note of the updated document SCP/27/6 and paragraph 56 of the related document, SCP/26/5. The Delegation was of the opinion that the said paragraph 56 provided a complete look of the flexibilities that WIPO Member States had introduced in establishing their patent systems. The Delegation pointed out that those flexibilities were only one part of the socioeconomic policies that might be adopted by a country. In conducting any examination of flexibilities, the Delegation considered that the broader purpose of an effective regime for patent protection should also be kept in mind. The Delegation did not support the initiative to request from Member States their views on the flexibilities while creating their IP system. The Delegation reiterated the support of Group B for the work under that agenda item which took into consideration the areas of patents and health that fell under the mandate of the SCP, in order to avoid duplications. In that regard, the Delegation believed that the proposal of the African Group, contained in document SCP/24/4, presented some elements which fell outside the mandate of the Committee. With respect to paragraph 14 of such proposal, the Delegation reiterated its position that the UNHLP Report had not been a Member State driven process. The Delegation noted that the report had not reflected the opinions of the Member States, neither had it been endorsed by the Member States. The Delegation was eager to discuss the issue of access to medical products in a holistic manner and in accordance with the mandate of the SCP, but was of the opinion that the UNHLP Report should not constitute the basis for such discussion. The Delegation emphasized that any discussion and future work should take into account of the wide range of views and factors affecting access to medicines. With respect to paragraph 15 of the African Group proposal, concerning the invitation of the UN Special Rapporteur on the Right to Health, the Delegation highlighted that the UN Special Rapporteur had a different mandate and parameters of work that should be considered inappropriate for discussion within a technical body such as the SCP. Therefore, the Delegation did not agree on that part of the African proposal.

65. The Delegation of China thanked the Secretariat for preparing document SCP/27/6. The Delegation believed that the patent system should not only protect and stimulate innovation, but also take care of public health. Therefore, the Delegation was of the opinion that WIPOs work on patents and health was of great significance. The Delegation considered that such work would enhance not only the understanding of the use of flexibilities in different countries, especially developing countries and LDCs, but also the understating of how to overcome obstacles and make better use of those flexibilities. In that regard, the Delegation looked forward to the information sharing session. The Delegation recommended that the Committee continue its research and information exchange activities and develop a work plan to facilitate the discussion on that issue. The Delegation noted that the purpose of the study was to enable all parties to better understand the patent-related flexibilities contained in international treaties, and able to promote the improvement of public health-related legislation and practice as well as to ensure the balance of the public interest of health and access to medicines. For that reason, the Delegation supported the proposal

of the African Group contained in document SCP/24/4. Furthermore, the Delegation welcomed the revised proposal of the Delegations of Canada and Switzerland, and hoped that Member States, especially developing countries and LDCs, would make new proposals so that the future studies would be more comprehensive, reflecting all the requests from all parties.

66. The Delegation of Iran (Islamic Republic of) thanked the Secretariat for preparing document SCP/27/6 and the Delegation of Canada for its revised proposal, cosponsored by the Delegation of Switzerland. The Delegation stated that having access to essential medicines at an affordable price was a specific and important component for fulfilling the right to access to health as a fundamental and basic human right. The Delegation observed that, as there was no other international forum where countries could share experiences on the use of health-related patent flexibilities, the work of the SCP in that direction was quite vital. The Delegation was convinced that the SCP should identify a specific constraint 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 that regard, the Delegation highlighted the importance and relevance of the recommendation of the UNHLP Report, which was published in 2016. In the Delegation's view, SCP should discuss substantively the issue of patents and public health and draw up a working program that assisted WIPO Member States to adopt their patent laws and to make full use of the patent-related flexibilities in accordance with public health needs and in compliance with their international obligations. The Delegation was of the opinion that such a work program should provide the possibility of analyzing the potential impediments and obstacles created by the patent system in accessing medicines, such as the legal and structural impediments and capacity constraints in making full use of flexibilities and how those constraints could be overcome. Accordingly, the Delegation continued to support the proposal made by the African Group and looked forward to the recommendations contained in the proposal being operationalized within the future work program of the Committee.

67. The Delegation of Nigeria aligned itself with the statement delivered by the Delegation of Senegal on behalf of the African Group. Furthermore the Delegation thanked the Secretariat for the preparation of the documents under that agenda item. The Delegation expressed its interest in the agenda item on patents and health and reiterated that the SCP needed to seek a concrete solution to the continued lack of access to affordable health care and medicines globally. The Delegation believed that it was important for WIPO, which had the competence on that issue, to identify the specific constraints in making full use of the patent-related flexibilities in order to address public health needs in Member States. Furthermore, the Delegation emphasized the importance of health care needs and the persistent lack of access to affordable medicines, particularly in developing countries and LDCs. The Delegation observed that, despite the current international focus on the rule of patents in public health, there were still obvious challenges to public health concerns, including access to health technologies. The Delegation believed that a patent system should work towards the establishment of a perfect balance between the rights of patents holders and the public health interests in relation to the SDGs. The Delegation looked forward to achieving positive results in relation to that agenda item.

68. The Delegation of Indonesia echoed that patents and health was a topic of great importance to all Member States. The Delegation noted that providing access to essential and life-saving medicines at affordable prices was in the interest of all countries. The Delegation mentioned that the SDGs recognized and affirmed the importance of public health. The Delegation looked forward to the information exchange session on publicly accessible databases on patent information status and data on medicines and vaccines, as well as the sharing session on patents and other issues related to access to medicines. The Delegation hoped that the presentation of MedsPaL would lead to a greater collaboration

between WIPO and MPP. The Delegation believed that the objective of the exercise on patents and health within the Committee was to develop a work plan able to improve WIPO's assistance to its Member States in the understanding and the full use of patent-related flexibilities in the field of public health, including the TRIPS flexibilities. With regard to the implementation of the TRIPS flexibilities, the Delegation recalled the cooperation agreement for technical assistance between WIPO and the WTO, which clearly gave WIPO the mandate to offer assistance on IP related matters which were also covered by the WTO agreements. Furthermore, the Delegation drew the Committee's attention to the UNHLP Report published in September 2016. The Delegation noted that the UNHLP Report had the same focus of the exercise on patents and health of the SCP. Therefore, the Delegation considered crucial that the recommendations contained in such report would constitute the basis for further discussion on patents and health within the Committee, including the recommendation that governments should draft national laws in a way that facilitated prompt and expedient use of a compulsory license or government use of a patent for non-commercial purposes. The Delegation urged further discussion on the African Group proposal contained in document SCP/24/4 and the adoption of a work program on patents and health. The Delegation noted that some issues identified in that proposal had not been discussed in any other fora, and therefore, considered that WIPO had the competence on that issue. The Delegation looked forward to a meaningful discussion with the delegations that suggested adopting a holistic view with regard to patents and health and avoiding any duplication of work. In the Delegation's view, topics such as health care financing, medical facilities, lack of infrastructure, supply chain management, taxes, and pricing were certainly outside of the mandate of WIPO and the SCP. Furthermore, the Delegation supported the proposal of the African Group, since some elements identified in that proposal, which were within WIPO's and the SCP's mandate and competence had not been discussed in any other fora. The Delegation expressed its appreciation to the Delegation of Canada for its revised proposal, and looked forward to contributing to its discussion. The Delegation hoped to have a meaningful discussion and to make progress on that agenda item. The Delegation was ready to make further comment or intervention under that agenda item and looked forward to a balanced work program on patents and health.

69. The Delegation of Côte d'Ivoire thanked the Secretariat for document SCP/27/6. The Delegation supported the proposal of the African Group contained in document SCP/24/4. The Delegation noted that, as other groups had already mentioned, people of developing countries had very limited, and sometimes difficult, access to medicines. Providing some figures, the Delegation highlighted that the TRIPS Agreement had instituted global governance for IP by introducing minimum standards of IP protection, and had particularly established the obligation to grant patents on pharmaceuticals also in countries of the South, as well as some flexibilities. The Delegation believed that the increased power of patents in countries of the South had happened within a critical health context, due also to a growing gap in the area of health between developed and developing countries. The Delegation was of the opinion that the challenge for developing countries was to promote public health while granting patents. Furthermore, the Delegation stated that those countries had to significantly reduce the health gap in a scenario including multiplication of patents leading to increase in prices and consequent inaccessibility of essential medicines for the people. The Delegation regretted to observe a concentration of infections such as HIV, in countries in the South. The Delegation highlighted that 90% of people affected by such disease were in the South. The Delegation mentioned also tuberculosis and malaria, which itself alone killed three people out of every ten affected. The Delegation stressed that global burden of morbidity was mainly borne by countries in the South, particularly in Africa and South Asia. The Delegation specified that those areas assembled 37% of the world population but only 2% of global health care spending. The Delegation noted that, by contrast, countries in the North accounted for 20% of the global population, but supported less than 10% of the world's burden of morbidity while absorbing 90% of health care spending in the world. The

Delegation concluded that while health care spending was concentrated in the North, infections were mainly in the South, and that represented a considerable health gap. The Delegation mentioned that in 2000, such situation had led the UN Member States to adopt the Millennium Development Goals (MDGs) and to dedicate three of those objectives to promote public health, to reduce such health gap, to decrease child morbidity, to improve maternal health, and to fight against HIV, malaria and other significant infections which particularly affected countries in the South. The Delegation pointed out that in practice, the achievement of those goals presupposed the mobilization of significant financial resources to provide the most essential health care to people of countries of the South and to significantly reduce the health burden. The Delegation believed that, if nothing was done, there would be an increase in the health gap between countries in the North and those in the South in the years to come. The Delegation was of the opinion that, as health was an essential vector of development for a country, if such health gap continued to grow, the development processes might be jeopardized. The Delegation considered that in the context where health needs were growing due to multiple epidemics affecting countries of the South, the increased number of patents would increase the prices of medicines and hindered the capacity of countries of the South to promote public health. In the Delegation's view, in such a framework, it was difficult for countries in the South to achieve the MDGs related to public health. The Delegation stressed that a large number of people in the South resorted to using counterfeit medicines. The Delegation noted that in those countries, the demand for those counterfeit medicines was so high that the markets proliferated. The Delegation highlighted that if nothing was done, people would continue to die, not merely of diseases, but also of poisoning caused by counterfeited medicines. The Delegation believed that there were no advantages for developing countries nor for developed countries and even less for the pharmaceutical industry. The Delegation therefore suggested that WIPO Member States increase their awareness of that situation, and authorize WIPO to provide its technical assistance to those countries that wished to implement the flexibilities contained in the TRIPS Agreement. Furthermore, the Delegation considered that WIPO should assist countries in the promotion of measures to fight anti-competitive practices related to Intellectual Property. The Delegation thanked the Director General of WIPO for his willingness to work for the wellbeing of nations in WIPO Member States. In that regard, the Delegation was particularly grateful for the project aimed at establishing Technology and Innovation Support Centers (TISCs) in developing countries. The Delegation explained that such a project allowed developing countries to have access to technical information services of high-quality as well as other connected services at the local level. Furthermore, the Delegation believed that the TISCs allowed those countries to fully exploit their potential and to create, protect, and manage their intellectual property rights. The Delegation expressed its appreciation for the technical assistance and support of WIPO to developing countries and LDCs. The Delegation hoped that a spirit of compromise would prevail during the SCP discussions in order to ensure that the Committee's work could conclude with an outcome favorable to the most marginalized people.

70. The Delegation of the Republic of Korea extended its appreciation to the WIPO Secretariat for document SCP/27/6 and thanked the Delegation of Canada for the revised version of its proposal cosponsored by the Delegation of Switzerland and contained in document SCP/27/8. The Delegation considered that the topic under Agenda Item 8 was very important. The Delegation observed that patents and public health were closely related, in particular with regard to access to medicines. The Delegation was of the opinion that it was important to take a comprehensive and balanced view on that issue. The Delegation considered that the organization of sharing sessions during the twenty-seventh session of the SCP would promote the mutual understanding and sharing of the various viewpoints of WIPO Member States. The Delegation noted that it was important to analyze and understand the situation in different countries in order to produce a positive outcome related to patents and public health. The Delegation supported the proposal of the

Delegation of Canada contained in document SCP/27/8. In the Delegation's view, the proposed study should be conducted in order to achieve desirable outcomes. The Delegation hoped that Member States would discuss that agenda item with an open mind.

*A half-day information exchange session on publicly accessible databases on patent information status and data on medicines and vaccines*

71. The Representative of the WHO made a presentation on publicly accessible databases on patent information status and data on medicines and vaccines. The presentation is available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=393559.

72. The Representative of the MPP made a presentation on the work of the MPP and MedsPaL. The presentation is available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=393558.

73. The Delegation of Iran (Islamic Republic of) thanked the Representatives of the WHO and the MPP for their presentations and asked the Representative of the WHO two questions. Firstly, the Delegation referred to the UNHLP Report which had been published in 2016, and asked the Representative of the WHO how the WHO had reacted on the recommendations contained in the report that were addressed to the WHO. Secondly, the Delegation wanted to know about any initiatives of the WHO to assist LDCs to overcome the constraints concerning IP in accessing essential medicine.

74. The Representative of the WHO responded that the WHO had recently completed a further analysis of the UNHLP Report which would be addressed during the meeting of the Executive Board of the WHO. Since the WHO had been part of the Expert Advisory Group to the UNHLP, the WHO had made recommendations to the panel while it had been writing the report. The Representative stressed that the WHO needed a mandate from all its Member States to carry out certain projects. The Representative stated that the mandate of the WHO was quite broad and therefore, he was of the opinion that the WHO could work on all of the areas mentioned in the report. The Representative continued that, for example, the WHO in the area of TRIPS flexibilities established the so-called Global Price Reporting Mechanism for pharmaceuticals against HIV, tuberculosis and malaria, which was a database containing procurement data for various countries. The Representative further stated that the report contained another recommendation to the WHO, WIPO, the WTO and other organizations to work with patent offices to train patent examiners on public health-related aspects. The Representative affirmed that the WHO was already working with the relevant agencies on this aspect and would continue to do so in the future. In regard to the second question, the Representative stated that the WHO had country offices in all LDCs which worked on access to medicines and health systems in those countries. With respect to LDCs using TRIPS flexibilities, the Representative assumed that LDCs had less issues with patent barriers, as for example, Bangladesh had already been producing the new hepatitis C treatment in generic versions.

75. The Delegation of the Côte d'Ivoire asked the Representative of the WHO to explain the term "data exclusivity" in regard to patent protection and if data exclusivity was not contrary to the TRIPS Agreement.

76. The Representative of the WHO stated that data exclusivity protected certain data which were submitted to authorities to receive an authorization to distribute a certain medicine within a country. The Representative continued that the TRIPS Agreement only required some kind of protection for such kind of data and that data exclusivity was only one form of protection that certain countries had chosen. The Representative pointed out that the existing data exclusivity rights in a certain country hindered that country of purchasing a generic version of pharmaceuticals for the period of the data exclusivity, which might be three, five, eight or ten years.

77. The Delegation of Brazil thanked all Member States and the Secretariat for preparing the sharing session and the Representatives of the WHO and the MPP for their presentations. The Delegation asked the Representative of the MPP what the main challenges for MPP currently were in improving the MedsPal database, and if the Member States could do anything to support the MPP.

78. The Representative of the MPP responded that the main challenge was to collect accurate data for the MedsPal database on a national level, especially regarding licenses and data exclusivity. As that involved a lot of work and all data needed to be verified, the MedsPal database did not contain all kinds of pharmaceuticals and information for all countries. The Representative stated that more information would be added on a continuous basis. With regard to the second question, the Representative stated that he was wondering if cooperation agreements could be established with national patent offices in countries where data was not available online so that the national patent offices would provide the required information to the MPP. He noted that such commitment could make a huge difference for the MPP and the MedsPal database. The Representative highlighted that each user should confirm any information found in the MedsPal database with the relevant national patent office or a legal advisor and that the MedsPal database should not be regarded as replacing such confirmation or advise.

79. The Delegation of Djibouti thanked the Representatives of the WHO and the MPP for their presentations and stated that during the General Assembly in September, WIPO in collaboration with IFPMA had launched a new database providing data on certain pharmaceuticals, which was called Pat-INFORMED. The Delegation asked the Representative of the MPP if there was any cooperation in regard to the Pat-INFORMED and the MedsPal databases.

80. The Representative of the MPP replied that according to his understanding, the Pat-INFORMED database from WIPO and IFPMA was currently being developed and not ready for use. The Representative continued that according to his understanding, the Pat-INFORMED database would contain information directly obtained from pharmaceutical companies, and that the MPP would use the data contained in the Pat-INFORMED database once it was available. The Representative stated that the largest source of data for the MedsPal database came from national patent offices and that the MPP would benefit from other databases like the Pat-INFORMED database from WIPO and IFPMA, which contained data from other sources.

81. The Representative of IFPMA congratulated the Chair on his election. The Representative explained that IFPMA represented more than 30 research based pharmaceutical companies and more than 50 national pharmaceutical associations across the globe on all continents. The Representative aligned itself with the statement made by the Delegation of Brazil on the importance of patents and respect for IP rights. The Representative congratulated the MPP for creating the MedsPal and stated that many members of IFPMA worked closely together with the MPP in creating the MedsPal database, which was a concrete example of multi-stakeholder collaboration. The Representative

asked if the Representative of the MPP could provide more details on the collaboration. Furthermore, the Representative thanked the Director General of WIPO for his opening remarks and highlighted that during the last WIPO General Assembly, 21 leading research based pharmaceutical companies supported by WIPO and the IFPMA had announced the creation of a patent information initiative for medicines, which made it easier for national and international drug procurement agencies to access patent information. The Representative continued that that initiative was built upon the industry's firm belief that the properly implemented patent system should not only work sustainably with innovation, but should strive to make information about inventions available and accessible to the public, to inform and educate others to add to the body of scientific and technological knowledge and to promote the further enhancement and improvement of technology. The initiative included a searchable database that held basic information about patents that covered approved medicines of participating companies, in particular for small molecule products within oncology, hepatitis C, cardiovascular diseases, HIV, diabetes, respiratory therapy as well as any other product on the essential medicine list of the WHO. The Representative continued that its facility for follow up inquiries would provide a channel for procurement agencies to seek additional clarification regarding the patent status of the products they wished to procure directly from patent owners. According to the Representative, the database was planned to be ready by the middle of 2018. The Representative believed that a short presentation of the initiative could be part of the agenda of the next SCP as a follow-up on discussions on publicly accessible databases on patent information status and data on medicines and vaccines.

82. The Representative of the MPP stated that the MPP interacted with patent holders of whom many were members of IFPMA and explained that MPP had good collaboration and partnerships with a wide range of pharmaceutical companies. The Representative further explained that the MPP had license agreements with 15 pharmaceutical companies and 20 manufactures of generic medicines, and stated that those cooperations had been very fruitful. The Representative continued that the licensing agreements contained annexes listing all patents that were covered by the license agreements, which the MPP used to update the MedsPal database. The patent numbers contained in the annexes made it easier for the MPP to verify the current status of each patent in the relevant databases of the patent offices.

83. The Delegation of China thanked the Secretariat for organizing the sharing session and the Representatives of the WHO and the MPP for their presentations. The Delegation asked the Representative of the MPP about its future plans for obtaining further license agreements and the fees for such licenses.

84. The Representative of the MPP clarified that no fees were charged for the use of the MedsPal database. Furthermore, the Representative explained that regarding the license agreements, no royalties were paid to the MPP, but only from the generic manufactures to the originating companies. The Representative continued that the MPP was not funded through any of the royalty payments, but by Unitaid and more recently also by the Swiss Agency for Development and Cooperation for undertaking a study to see if the MPP also could work on licensing in relation to patented essential medicines in other areas, e.g., diabetes, cardiovascular disease, etc. The Representative stated that so far the licensing work of the MPP was exclusively focused on HIV, hepatitis C and tuberculosis. The Representative continued that for the study, the MPP collected patent data on many of the relevant medicines, and soon thereafter received requests from various people to access the collected information. The Representative explained that the MPP decided to include all collected data into the MedsPal database because of those requests. Furthermore, the

Representative clarified that the MPP was currently only expanding the MedsPal database but not the licensing work of the MPP. Once the results of the study were available and the MPP consulted with the stakeholders, it would decide if the licensing work should be expanded.

85. The Representative of the MSF congratulated the MPP for the excellent work on the MedsPal database. The Representative stated that it was important and encouraging to discuss the transparency issues in the meeting room, and that one issue causing a lack of transparency was not only the difficulty to find patent information, but also the patent strategy that had been adopted by the industry in regard to patents on medicines and evergreening of patents. The Representative highlighted that there was a huge number of patents in the field of medicines, of which many might not be valid. The Representative stated that the MedsPal database contained some information on license agreements, but that it was difficult to have the full license agreement disclosed, as many licensors did not want their license agreements to be disclosed. The Representative asked the Representative of the MPP what the difficulties were in obtaining full information on the concluded license agreements and what could help to improve the situation in the future.

86. The Representative of the MPP stated that all license agreements which were negotiated by the MPP were publicly available on the website of the MPP. In the MedsPal database, it was shown if a license agreement had been negotiated and if so, the MedsPal database showed a chart listing the countries covered by the license and the names of the licensee and the licensor and a link to a summary or the full text of the license agreement. The Representative continued that for a bilateral license agreement, a first challenge was to find out if there was public data available. In many cases, companies indicated publicly which countries and products were covered by the license agreements and who the licensees were. The Representative noted that in such cases, all publicly available data would be included in the MedsPal database and a link would lead the users to the original source on the pharmaceutical companies' website, if such source was publicly accessible. The Representative continued that there were some instances in which the information was not publicly available, but the MPP nevertheless knew, for example, the number of countries that were covered by a bilateral license agreement, but not the names of the countries. In such instances, it was difficult to include such information in the MedsPal database. The Representative explained that the MPP had had discussions with pharmaceutical companies, and some were willing to provide information on their license agreements or commitments not to enforce a patent in a certain country on a specific product, so that the MPP could update the MedsPal database. However, the Representative noted that the MPP would not receive the original license agreement and therefore could not include a link to those license agreements. Nevertheless, the Representative observed that it was possible for the users of the MedsPal database to contact directly the licensor or the licensee, if they would like to receive further information.

87. The Representative of the EPO congratulated the Chair on his election and thanked the Secretariat for organizing the sharing session. The Representative stated that the EPO attached great importance to the topic of transparency of patent information and that since its inception, the EPO had invested resources to collect, digitize and store patent information for the benefit of users and the general public. The Representative continued that the EPO provided public access to the largest single source of technical information in the world, and that the EPO's database contained over 100 million patent documents from over 90 different countries. Recognizing the need to promote, improve and strengthen the access to high quality patent information, the EPO had signed in October 2016 a Memorandum of Understanding with the MPP. The Representative continued that through that collaboration, a two-fold objective was achieved. On one hand, the accuracy of information contained in the MedsPal database was enhanced as data was extracted automatically through the

EPO's open patent services: a web service which provided access to the EPOs raw data via a standardized XML interface. The Representative of the EPO continued that on the other hand, the reach of the EPO patent information services was expanded for the benefit of a much wider range of stakeholders, beyond the traditional profile of patent information experts. The Representative of the EPO highlighted the recent initiative of the WIPO and the IFPMA Pat-INFORMED which aimed to link public patent information to registered medicines in a new online gateway. The Representative concluded that she was confident that such an initiative would provide yet another means to enhance accessibility to patent information.

88. The Delegation of Georgia, speaking on behalf of the CEBS Group, thanked the Secretariat for organizing the sharing session, and the Representatives of the WHO and the MPP for their presentations. The Delegation believed that the interface providing access to patent information and medicines was an important tool to provide access to the technical information needed for further advancement of access to patent information. The Delegation thanked all other delegations for their interesting questions and referred to the intervention made by the Representative of the IFPMA on its joint initiative on the Pat-INFORMED database. The Delegation expressed its excitement to learn more about the database and the relevant issues in the next session of the SCP.

89. The Delegation of Senegal, speaking on behalf of the African Group, thanked the Representative of the MPP for his presentation and the Secretariat for preparing the sharing session. With regard to the content of the MedsPal database and on how the WHO worked with the MPP, the Delegation highlighted the difficulties that those bodies had with access to information on patents and license agreements. The Delegation stated that WIPO should become a lead organization in helping accessing information on patents and license agreements enabling developing countries and LDCs to overcome their public health challenges with regard to patents. Referring to document SCP/24/4, the Delegation continued that with regard to a better access to patent information, a central information source, to which all relevant information would be sent from the patent offices, would help the WHO, the MPP, WIPO and the Member States to work together in updating the various databases.

90. The Delegation of Brazil noted that the topic of patents and health was important to every country represented in the SCP. The Delegation believed that the market driven R&D had produced a number of important health technologies which had improved the health conditions substantially worldwide. The Delegation referred to the mass contribution of science and technology in the advancement of healthcare and stated that the patent system was an essential tool, but it was not a complete one. The Delegation continued that in some areas, the market alone might not provide adequate incentives. The Delegation reiterated that an estimated 1,7 billion people in 185 countries still needed treatment and care of neglected tropical diseases, according to the WHO and the World Bank. The Delegation concluded that gaps and failures in addressing disease burdens and access to treatment remained a worldwide challenge. The Delegation stated that approximately 60% of the spending on health, technology, research and development in developed countries derived from the private sector and 40% from public and non-profit sources. In low and middle income countries, those percentages were reversed as the public sector was responsible for 60% of the total R&D funding, which effected the treatment of diseases like HIV, tuberculosis and malaria. The Delegation noted that such diseases and many other neglected ones were far from being absent in even the richest countries, and that the challenges faced in that area were not small, but not unsurmountable. The Delegation reminded that focus and determination were important to ensure that the patent system provided meaningful contribution to public health priorities. The Delegation was convinced that the SCP had made the right decision in inviting the MPP to present on the MedsPal database which

contained valuable information on the patent and licensing status of selected HIV, hepatitis C and tuberculosis medicines in low- and middle-income countries. The MedsPal database covered 6,800 national patent applications on 70 priority treatments in more than 100 countries, and enabled users to search for patent and license information by country in a user-friendly manner, which was understandable not only for examiners or experts, but also for government representatives, procurement agencies, patent groups, public health organizations and pharmaceutical companies. The Delegation further stated that by providing precise and comprehensive information on the status of patents, the MedsPal database enabled policymakers and other stakeholders to make informed decisions in full compliance with the legislation and multilateral obligations. The Delegation believed that the sharing session would usher in a new era of closer collaboration between WIPO, the WHO and the MPP, which would contribute to building a more inclusive, balanced and more effective patent system, a desire shared by all Member States. The Delegation announced that the National Institute of Industrial Property of Brazil had signed a collaborative agreement with the MPP to provide crucial data on the intellectual property status of medicines for the MedsPal database.

91. The Delegation of Argentina thanked the Secretariat for organizing the sharing session and the Representatives of the WHO and the MPP for their presentations. The Delegation stated that the MedsPal database was a tool which gave greater transparency to the patent system, and facilitated decision making for health authorities by enabling them to get data on licenses and the legal status of patents for hepatitis C, tuberculosis and HIV/AIDS. The Delegation was pleased to announce that the Industrial Property Organization of Argentina had concluded a collaboration agreement with the MPP, under which the Industrial Property Organization of Argentina would share non-confidential patent information with the MPP on a regular basis. The Delegation hoped to promote a system of patents which would be transparent and balanced, giving better access to medicines, particularly in low and middle income countries.

92. The Delegation of Ecuador congratulated the Chair and the Vice-Chairs on their elections, and thanked the Secretariat for preparing the sharing session and the Representatives of the WHO and the MPP for their presentations. The Delegation stated that access to information through MedsPal was a useful tool for improving the lives of millions of people with catastrophic diseases. The Delegation informed that Ecuador had signed an agreement with the MPP to provide information. In its view, that reconfirmed the commitment of Ecuador to provide information on medicines and patent holders in Ecuador, thereby contributing to a balanced patent system in which transparency of information on patents was the best way to provide access to medicines in low- and middle-income countries. The Delegation highlighted that it was important to strengthen the initiatives like the ones of the MPP, and that the Member States needed to contribute to that work.

93. The Delegation of Japan congratulated the Chair on his election and thanked the Representatives of the WHO and the MPP for their presentations. The Delegation stated that it appreciated the continuous efforts made by WIPO and the IFPMA in enhancing access to patent information, including in the area of pharmaceutical products. The Delegation aligned itself with the statement made by the Delegation of Switzerland on behalf of Group B under Agenda Item 8. The Delegation supported the idea of having a presentation by the IFPMA on the Pat-INFORMED database.

94. The Delegation of Mexico congratulated the Chair on his election and the Secretariat for preparing the sharing session. The Delegation further expressed its appreciation to the Representatives of the WHO and the MPP for their presentations and informing about the various different tools for accessing the status of the patents related to medicines. The Delegation was convinced of the importance of that topic and shared its experience with the

database that the Mexican Industrial Property Institute had had since 2004. The Delegation explained that in view of Article 47 of the Mexican Industrial Property Law, the Mexican Industrial Property Institute published a Medicines Gazette which contained a list of pharmaceutical products that were patent protected and listed the relevant patent numbers. The Delegation continued that the list linked the generic name with the name of the substance or active ingredient of the pharmaceutical and the relevant patent. Further, the list contained information on the legal status of patents for medicines and vaccines in Mexico. The Delegation explained that the Medicines Gazette was published every six months, and was made available to the public through the "Information System of the Industrial Property Gazette" (SIGA), located on the official website of the Mexican Industrial Property Institute. That system allowed for free electronic consultation of patents for medicines by: name, free text searches, patent number, product, name of the applicant or any combination of the above. Further, it was possible to download a copy, either in the PDF or XML format. The Delegation stated that the Medicines Gazette had supported cooperation activities between the industrial property authority and the health sector by providing information on the status of patents and licenses. The Delegation noted that led to more transparency for patent holders and those who would like to produce generic medicines when a patent had expired. In its opinion, such publication enabled Mexico to establish a balance between the industrial property system and access to medicines, because the regulatory framework of Mexico allowed for a fair competition for all parties, mainly benefitting access to medicines at an affordable price.

95. The Delegation of the United Kingdom congratulated the Chair and the Vice-Chairs on their election and thanked the Representatives of the WHO and the MPP for their presentations. The Delegation stated that the United Kingdom supported the MPP and the MedsPal database, and provided funding of around 60 million Euros per year to Unitaid, which was the founder of the MPP. The Delegation was pleased to hear that the MPP had taken steps to include all essential medicines into the MedsPal database. The Delegation looked forward to hear about the outcome of the feasibility study as to whether it could be expanded to other areas. The Delegation affirmed its commitment to ensure an access to quality, low cost effective medicines in the developing world and supported the important role of the MPP to negotiate prices. The Delegation believed that voluntary licensing was especially advantageous, as knowledge exchange was important for the mutually beneficial relationships. The Delegation recognized the role of the MPP and the MedsPal database in promoting innovation in the public disclosure and the freedom to develop new treatments. The Delegation welcomed the new patent forum initiative, launched during the General Assemblies and supported by WIPO and the IFPMA. The Delegation stated that such publicly accessible database would make it easier for national and international drug procurement agencies to access patent information, and expressed its support to hear more about that tool.

96. The Delegation of Chile expressed its thanks for the sharing session with regard to the publicly available databases, and considered such tools as very useful in working on access to medicines and vaccines for developing countries and LDCs. The Delegation stated that the MPP, in particular the MedsPal database, provided valuable information on the status of patents and licenses for selected medicines for the treatment of HIV/AIDS, hepatitis C and tuberculosis in low- and middle-income countries. The Delegation explained that as Chile was committed to the MPP, the Chilean National Institute of Industrial Property had signed a memorandum of understanding with the MPP, committing itself to regularly providing and verifying information on the status of patents on specific pharmaceutical products to the

MPP. The Delegation encouraged other industrial property offices to join that initiative and to take more responsibility with regard to the information that they could provide to society. The Delegation was pleased to announce that the next annual meeting of the Group of Experts of the MPP would be held in Chile in 2018.

97. The Delegation of Switzerland, speaking in its national capacity, congratulated the Chair and the Vice-Chairs on their elections. The Delegation thanked the Secretariat for preparing the sharing session and the Representatives of the WHO and the MPP for their presentations. The Delegation expressed its appreciation for the dedication and the work of the MPP, and congratulated the MPP on the expansion of the MedsPal database in regard to the cancer medicines. The Delegation stated that the government of Switzerland placed high importance in the work of the MPP and the MedsPal database and in the transparency of patent information. The Delegation believed that building on voluntary and inclusive efforts, of which the MPP was one example, was the way forward in the area of patents and health, which corresponded better to the collaborative spirit of the 2030 Agenda for Sustainable Development. The Delegation continued that the MPP constructively and creatively used the patent system to engage all stakeholders, particularly patent holders and generic producers in the process to increase access to medicines in the important areas of HIV, hepatitis C and tuberculosis in low- and middle-income countries. In its view, such creative use of the patent system enabled generic manufacturers in low- and middle-income countries to produce and sell needed medical products, which would also result in technology transfer, the enhancement of manufacturing capacities and even in economic development in the wider sense in those countries. The Delegation continued that it also aimed to ensure that licensees produced medical products according to quality standards and that the MPP contributed to transparency of information by publishing the licenses concluded with pharmaceutical companies. The Delegation highlighted that the information of the patent status on essential medicines had been a longstanding demand and that the health authorities, procurement agencies and other stakeholders required easily accessible information in order to make effective decisions on procurement of important medicines. The Delegation continued that the information on patent status was further necessary for other companies to determine the freedom to operate or for research purposed, as stated by the Representative of the WHO. The Delegation stated that the MPP was created to serve that long felt need of accurate, reliable information and that the MedsPal database provided particular benefits and advantages, including transparency on the patent status, license agreements and data exclusivity. In the opinion of the Delegation, the MedsPal database with its design and structure allowed non-patent experts to access essential information and to understand that information. The Delegation stated that with the expansion to all medicines on the essential medicine list, the MedsPal database was and would become a crucial source of information for all interested parties. The Delegation observed that according to the MPP, the continuation of such an important tool depended, in particular, on the collaboration with national patent offices. The Delegation encouraged all Member States of WIPO to consider options for collaborating with the MPP and thanked the Delegations of Brazil and Argentina for the information regarding their engagement. The Delegation took note of the new joint initiative between WIPO and the research-based pharmaceutical industry, and was interested to learn more about that initiative. It therefore supported the proposal to have a presentation on that initiative.

98. The Representative of ARIPO congratulated the Chair on his election and thanked all presenters for their excellent presentations. The Representative noted that ARIPO had not yet signed an agreement with the MPP, and looked forward to signing one at the appropriate time and place. The Representative stated that ARIPO, upon request, continued to provide crucial data on intellectual property covering medicines. The Representative confirmed that ARIPO would continue to provide the same kind of information despite the lack of an agreement.

99. The Representative of CEIPI stated that CEIPI did teaching and research with regard to intellectual property. The representative noted that while CEIPI did neither represent the interests of patent holder, nor public health institutions, it did take into account the interest of all. The Representative continued that he was happy to learn about the initiatives presented. He observed that it was very comforting to see that through concrete measures, it was possible to bring together the different sides and overcome ideological quarrels. The Representative hoped that those initiatives would continue in the future.

*A sharing session on patents and other related issues on access to medicines*

100. The Representative of the WHO made a presentation on patents and health and the role of the WHO. The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_e_health_access_who.pdf.

101. The Representative of the WTO made a presentation on the availability of generic medicines in developing countries and LDSs. The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_f_generic_medicines_wto.pdf.

102. The Delegation of Brazil thanked the Representatives of the WHO and the WTO for their presentations. The Delegation referred to the WHO list of essential medicines, and stated that it was often heard that only a small number of medicines contained on that list were actually patented. The Delegation wondered whether it was due to the fact that the list had been prepared already some years ago, and asked the Representative of the WHO to comment on that point.

103. The Representative of the WHO confirmed that only a relatively low number of the medicines on the WHO list of essential medicines were patented. However, the Representative stated that for a number of years, the question of price had not been a barrier to add new drugs on the list, and that, for example, all new drugs for treating hepatitis C had been added to the list despite their high price. The Representative explained that the WHO had been taking a more systematic approach for a number of years: for example, the whole chapter of antibiotics had been revised to identify the medicines that should be included. The Representative stated that the same had been done for cancer drugs and that the WHO in 2015 had added a number of patented medicines for cancer. The Representative continued that until today, the patents for some of those medicines had expired in many countries. Furthermore, referring to his presentation, the Representative explained that according to a study, 57% of the new drugs (which mostly were under patent protection) were not bringing any added value compared to the already available generic drugs, and that such products would not be added on the WHO list of essential medicines.

104. The Delegation of the Russian Federation congratulated the Chair on his election and thanked the Secretariat for organizing the sharing session and all Member States for their contributions and initiatives. The Delegation noted that the topic of patents and health was an important one to the Delegation. The Delegation further stated that on December 12, 2017, the Russian Federation had celebrated the Day of the Constitution, because the Constitution of the Russian Federation had been adopted on December 12, 1993. The Delegation pointed out that the Constitution of the Russian Federation was the fundamental and basic law of the Russian Federation which covered almost all the rights of every citizen of the Russian Federation, including the right to health and life. In that regard, the Delegation noted that the creation of the conditions for achieving such right should be the main task not only for the Russian Federation, but for every state. The Delegation further stated that it supported many of the arguments which had been presented by the Representative of the WHO, especially in regard to patent rights and

procurement of medicines. In that regard, the Delegation stressed that in the Russian Federation, there was no uniform view between the Ministry of Health of the Russian Federation and the Russian Patent Office (ROSPATENT) with regard to that issue, and therefore, there were difficulties in interactions between those two governmental bodies. With regard to the issue of considering objections to patent rights, the Delegation pointed out that in relation to a patent for the sofosbuvir compound, the ROSPATENT looked at the objections on that patent and decided to limit the legal protection of the sofosbuvir patent in the territory of the Russian Federation. In relation to the presentation of the Representative of the WTO, the Delegation noted that on July 26, 2017, the Federal Law of the Russian Federation No. 84 had been adopted in relation to the amendments to the TRIPS Agreement. The Delegation was also of the view that Member States should take into account the information provided by the MPP. The Delegation stressed the necessity to discuss and systemize the information that was received, especially with regard to access to medicines. Further, the Delegation noted that at the twenty-sixth session of the SCP, the Delegation supported the proposal of the African Group about carrying out a study on those issues. The Delegation observed that the interest in the proposal of the African Group was growing. The Delegation noted that the issue of access to medicines was linked to the TRIPS flexibilities. The Delegation was of the view that it was very important to inform the public as well as the representatives of businesses and pharmaceutical manufacturers about the possible implementation of the TRIPS flexibilities as well as their possible impact on future developments. The Delegation further noted the importance of building confidence in the use of the revised TRIPS provisions. In particular, the Delegation pointed out the possibility to use compulsory licenses as well as the right of the government to use inventions based on national security considerations. The Delegation noted that extensive exchange of information and experience on the advantages and implementation of the TRIPS flexibilities would facilitate further understanding on those issues. Finally, the Delegation expressed its belief that document SCP/27/6 could be a good basis for further work in that area and probably for draft recommendations on the topic of limitations and exceptions to patent rights.

105. The Delegation of the United States of America thanked the Representatives of the WHO and the WTO for their presentations. The Delegation wanted to share some thoughts on the role of patents and the IP system in the availability of medicines. The Delegation believed that the example of the United States of America clearly showed how patents, together with the effective protection for marketing authorization data, worked with other government policies to help stimulate an environment that promoted investment, R&D, job creation, technology transfer and the creation of new products. The Delegation continued that in turn, that environment also maintained and promoted a strong generic pharmaceutical industry in the United States of America and that strong IP policies were essential for the development of new life saving medicines and improving quality of life. The Delegation was of the opinion that a robust IP system, including in the areas of patent, regulatory data protection, trademarks and trade secrets, was critical to provide the incentives for investment in the development of future treatments and cures that would benefit patients in all countries. The Delegation believed that the model in the United States of America was a good example of how those principles intersected to create new treatments and cures and to facilitate a thriving generic marketplace as the United States of America was the largest pharmaceutical market in the world, amounting to over 45% of the global pharmaceutical market in 2016. The Delegation informed that nowadays, in the United States of Americageneric drugs accounted for 90% of all prescriptions filled in and according to the report by the IQVIA Institute entitled “Medicine Use and Spending in the United States – a Review of 2016 and Outlook for 2021”, generics might account for 91 to 92% of prescriptions volumes by 2020. The Delegation continued that the United States of America not only enjoyed a very robust generic pharmaceutical industry, but at the same time, the United States pharmaceutical industry was a leading global innovator. The Delegation noted that, for example, as of 2010,

the pharmaceutical industry in the United States of America had been responsible for the development of about 43% of new molecular entities produced worldwide. The Delegation noted that protecting innovation was important for creating new medicines and for maintaining a generic industry, and that without new innovative products, the pipeline for new generic products would dry up. In its opinion, patents and regulatory data protection requirements encouraged investments in the risky, lengthy and expensive business of drug development. The Delegation indicated that those incentives also helped to incentivize R&D investments needed to bring a drug to the marketplace, and that a number of recent studies looked at the value of patent and other IP assets to start-ups. In the United States of America, start-ups and small companies were driving pharmaceutical innovation and accounted for a significant number of new jobs. The Delegation continued that 64% of drugs approved in 2015, had originated in smaller companies and that a study had found that the patent grant had increased a start-ups chance of securing funding from a venture capital by 47% and of securing a loan by pledging the patent as a collateral by 76% within three years of the patent decision. It further noted that, in addition, a patent grant had more than doubled the odds of the start-up being able to raise funding from public investors to an IPO. The Delegation continued that the study had concluded that a patent grant had set a start-up on a growth path through funding that had enabled it to transform its ideas into products and services that generated jobs, revenue and follow on inventions. Another study commissioned by WIPO titled “Patents at the Core: the Biotech Business” had specifically looked at the issue of why patents were crucial for biotechnology companies in the pharmaceutical sector, and had concluded that protection of intellectual property had been at the core of the business for biotechnology firms. The Delegation continued that the study stated that the business model of biotech firms often relied heavily on intellectual property rights, in particular patents, as they offered the most crucial assets they owned in a sector that was extremely research incentive and with low imitation of costs. The Delegation highlighted that as investors in biotech companies were well aware of the centrality of patents the survival of such companies might very well depend on their ability to convince investors that they had a solid IP strategy and that risks were reduced to a minimum. Thus, the Delegation considered that patents facilitated access to financing, which was crucial in drug development because of the associated cost and risk, including those arising in the regulatory approval process. The Delegation noted that patents also led to follow-on invention and that the information disclosed in the patent specification, which was generally published 18 months after the patent application was filed, provided a great source of information and inspiration for other researchers and contributed to the pool of knowledge. The Delegation noted that in fact, the studies on patents in the public domain, which were part of the WIPO CDIP project on patents and public domain, demonstrated that for over 100 years, the patent system had been a rich source of publicly available information and had contributed tremendously to the creation of a rich and accessible public domain. The Delegation further stated that as to other issues related to access to medicines, the development of new medicines was also incentivized by the market exclusivity given to the innovative company that obtained the first marketing approval of a new pharmaceutical product. In order to receive approval to market a new pharmaceutical product, most governments required companies to submit clinical study data that proved that the product was both safe and effective for its intended use, before it could be legally sold in the country. The Delegation noted that the time, effort and money invested in collecting such data was often very significant, and that only a small fraction of drug molecules, about 5 in 5,000 identified for testing in the lab, made it to the clinical research phase. Further, only 20 to 30% of drugs that had managed to reach the clinical testing stage actually received marketing approval eventually. The Delegation noted that the process of bringing a new pharmaceutical product to market might require significant amounts of funding for the basic science involved in the initial drug research and discovery stage. However, the Delegation continued that it also required the innovators to conduct extensive tests to obtain the data necessary for the government regulatory authority to determine whether the drug identified

for investigation was safe and effective for administration to humans. The Delegation reported that in 1984, the United States Congress passed a law designed to providing incentives to brand name drug companies to produce innovative drugs, while offering an expeditious route for approval of low-cost generic drugs. That law was the Hatch-Waxman Act. The Delegation stated that that Act stimulated drug innovation and research by providing limited patent term restoration to compensate for the duration of the patent term lost while carrying out FDA marketing approval procedures and by providing for a marketing exclusivity period for new innovator drugs. Further, the Act also stimulated production of safe and effective low-cost generic medicines by establishing the abbreviated new drug application, ANDA process. The Delegation explained that that mechanism was designed to avoid the high cost of full clinical trials by providing that bioequivalence data were sufficient for receiving marketing approval for a generic drug. The Delegation highlighted that the Act also provided for what was generally known as the Bolar exemption, which allowed the manufacture and use of patented drugs to conduct the testing needed for generic marketing approval prior to the expiration of the patent of a pioneer drug. In its opinion, the Hatch-Waxman Act was a great example of how the law of the United States of America could successfully balance the incentives for research and development of new drugs and the promotion of speedy access to low cost generics. The Delegation stated that in the end, the result was that patients in the United States of America and around the world won, as new life saving drugs in their low cost generic versions became available. For example, in November 2011, the United States patent protection expired for Lipitor, an anticholesterol drug owned by Pfizer with annual sales of more than 10 billion. The generic version of the drug quickly entered the market, and by 2014, more than 90% of sales were of the generic version of the drug. The Delegation further stressed that once generic drugs were introduced to the market in the United States of America, they were typically sold at a steep discount, about 50 to 70% compared to the brand name reference drugs. The Delegation reiterated that the United States of America encouraged the development of new products by providing incentives, such as the patent and marketing exclusivity laws. The Delegation further noted that a healthy market for medical products also offered initiatives for the development of those products and provided financial resources that were available for research and development. In the view of the Delegation, another advantage available in the United States of America was a strong regulatory system which allowed the marketing of products that were safe and effective, while restraining those that were not. The Delegation concluded that by working to remove products that were not manufactured according to good manufacturing practices or that were of inacceptable quality, the United States of America helped to ensure the innovative and the generic products reaching the patients were the products that were intended to be purchased and helped to avoid wasted resources.

106. The Delegation of Gabon thanked the Representatives of the WHO and the WTO for their presentations and asked the Representative of the WTO to note to what extent he thought the Facilitation Agreement for Trade would enable countries to act on a reduction or drop in prices for certain drugs. Further, the Delegation wanted to know from the Representative how he assessed all the factors that he mentioned during his presentation to increase the prices of pharmaceutical products.

107. The Representative of the WTO emphasized that he did not have a breakdown of how the different factors affected the prices, but that the estimate of the WTO's trade economists suggested that costs of imports of medicines for lower income countries could reduce on average by 14,5%. For more detailed figures, the Representative referred the Delegation to the experts on this topic at the WTO. The Representative noted that the objective of the Trade Facilitation Agreement was to reduce costs and there were significant technical assistance packages available to assist countries in implementing that Agreement.

108. The Delegation of Australia congratulated the Chair and Vice-Chairs on their elections. It thanked the Secretariat for preparing the sharing session and the Representatives of the WHO and the WTO for their presentations. The Delegation wished to update the Member States on recent revisions of the patent regulations in Australia to ensure that they correctly referred to the TRIPS Protocol. The Delegation stated that Australia had previously amended its Patent Acts in 2015 to implement the TRIPS Protocol and that the amendment had come into effect at the same time as the amendment of the TRIPS Agreement came into force on January 23, 2017. The Delegation continued that eligible countries were able to source generic versions of patented pharmaceuticals in accordance with the TRIPS Agreement.

109. The Delegation of Uganda aligned itself with the statement made by the Delegation of Senegal on behalf of the African Group. The Delegation stated that although scientific and technological innovation had contributed to significant improvements in health conditions, unequal development in different countries in the promotion of health and control of disease, especially communicable disease, was a common danger to all countries, whether developed, developing or least developed. The Delegation believed that the threat caused by new pathogens that had the capacity to transcend continental borders, without showing any visible signs or symptoms in initial stages, demanded a shared, coordinated and cooperative international response. Referring to the example of the Zika virus, the Delegation stated that the Zika virus infected tens, if not hundreds, of thousands of people in the Americas in recent months and might be linked to a spate of children born with underdeveloped brains. However, scientists in the Uganda Virus Research Institute first discovered Zika in the blood of a rhesus monkey back in 1947. The Delegation continued that Uganda never had had an outbreak of the virus, and that was thanks to the country's unique approach to monitoring the spread of the disease and other similar diseases which could hold the key to stopping future epidemics in their tracks, even if there was still no specific medicine or vaccine to prevent Zika. The Delegation noted that it was time for the SCP to keep connecting its discussions on patents and health with real life realities and to make concrete progress on the proposals that directly referred to issues of access to affordable and essential medicines and other medical products. Further, the Delegation noted that access to affordable and essential medicines and other medical products depended on numerous factors, and that high prices of patented drugs constituted one of the major obstacles that should be addressed in a comprehensive and sustainable manner. The Delegation took note of the Secretariat's studies on the constraints faced by developing countries and LDCs in making full use of patent flexibilities and their impacts on access to affordable medicines, contained in documents SCP/26/5 and SCP/27/6. The Delegation stated that the study did not draw definitive conclusions, citing lack of empirical data. The Delegation highlighted that rather than a questionnaire methodology, the Secretariat should study in-depth the flexibilities in the TRIPS agreement, such as use of transition periods for LDCs and strict implementation of patentability criteria. According to the Delegation, it was interesting to know the extent to which filing of numerous patent applications for the same medicine, as well, as extending the life of a patent delayed or blocked the market entry of generic medicines. In regard to the future work on that issue, the Delegation took note of the proposal by the Delegation of Canada contained in document SCP/27/8, and stated that it contained some elements which the Delegation could work with and that the proposal called for a review of existing studies conducted by the WHO, the WTO and WIPO. The Delegation continued that it did not support the inclusion of topics which were widely beyond the mandate of the SCP, and for the choice of existing studies to be reviewed, the Secretariat should be allowed its discretion to select relevant studies/reports that spoke directly to the issue of patents and health. The Delegation concluded that the proposal made by the African Group, contained in document SCP/24/4, provided the SCP with a solid basis for its future work on patents and health, in particular, on technical assistance and technology transfer to developing countries and LDCs. The Delegation noted that WIPO, by

virtue of its agreements with the UN and the WTO, had the mandate as the main provider of technical assistance to WIPO Member States and WTO members on IP related issues. The Delegation therefore encouraged the SCP to develop a work plan for WIPO to improve how it assisted Member States in the understanding of, and enhancing their capacity to use, TRIPS flexibilities for health.

110. The Delegation of South Africa aligned itself with the statement made by the Delegation of Senegal on behalf of the African Group. The Delegation stated that access to 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 continued that the global community had recognized the importance of health and access to public health, as addressed in SDG Goal 3. In its opinion, that Goal was particularly important, because it recognized that there were large unmet health needs present in both developed and developing countries, and that there were significant health inequalities within countries themselves. The Delegation welcomed the pertinent conclusions and recommendations of the UNHLP Report, and stated that in spite of the numerous agreements in place, the misalignment between the access to medicines on the one hand and intellectual property protection on the other continued. The Delegation noted that in that regard, the right of Member States to use the TRIPS flexibilities to ensure access to medicines for all remained imperative. The Delegation continued that since access to safe and affordable medicine remained a fundamental challenge for developing countries and LDCs, the SCP could play an instrumental role in alleviating that situation, as pricing issues still remained a problem. The Delegation believed that the proposal by the African Group on patents and health could assist the SCP to promote access to more affordable medicines. The Delegation stated that the proposal suggested that, among others, WIPO 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. Further, the Delegation noted that the proposal by the African Group also included the request for the Co-Chairs of the UNHLP to share their views on the UNHLP's objectives, findings and recommendations, as the UN General Assembly through its resolution RES/71/159 of 2016 acknowledged the need for further discussions on access to medicines among Member States. The Delegation noted that the report had been welcomed by several countries, including from the developed world, through among others, statements at the various UN meetings a statement of support by the European parliamentary working group on innovation, access to medicines and poverty related diseases in October 2016. The Delegation continued that many developing countries had also been supportive of the UNHLP, and concluded that the report had wider support, with only a few countries opposing it. The Delegation urged those who had opposed to come on board and at least accept to discuss the UNHLP Report in the SCP.

111. The Delegation of India stated that the patent system should strike a balance between public health and ensure accessibility of medicines to the public at affordable prices. The Delegation reiterated its request that a study on patent protection and the cost of medicines, which could be broadly divided into issue of patent law on inventive step and the relationship of Markush formula with the sufficiency of the disclosure, be conducted. The Delegation found that there might be many factors affecting the availability and affordability of medicines, whereby patent protection directly affected the developing countries. The Delegation reiterated its stand on the inclusion of INN in the patent specification, which, in its view, would facilitate granting of quality patents, and noted that INN was assigned by the WHO for single well defined substance but not for a mixture of substances, herbal substances and homeopathic products. The Delegation stated that during substantive examination, an examiner could easily access the details, such as IUPAC chemical names, structural formula, molecular formula, therapeutical use and pharmacological action of the molecule, if the INN was known to him/her. Consequently, in its opinion, patent grant for

obvious modification of the existing molecule could be minimized to some extent. The Delegation emphasized that the Secretariat should conduct a feasibility study for inclusion of INN in the patent specification if the INN had been known. Furthermore, the Delegation supported the updated proposal made by the African Group, which was composed of three items, namely studies, access to information and technical assistance taken under WIPO's work program on patents and health.

112. The Representative of KEI reiterated its strong support for the proposal by the African Group on a work program for patents and health, contained in document SCP/24/4. The Representative urged the SCP to schedule a presentation by experts on the legal basis and experience of States in permitting the non-voluntary use of patents on medical inventions as a limitation on the remedies available in Part III of the TRIPS Agreement, including cases of running royalties for infringement of medical devices and diagnostic tests, and the export of those products outside of the WTO 31*bis* framework. Furthermore, the Representative referred to the recommendations of the WHO's overall program review of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, published on November 30, 2017. The Representative stated that the expert panel had specifically recommended the WHO and its Member States to work on the transparency of R&D costs and the prices of medicines, in addition to encouraging the "implementation of schemes which partially or wholly delinked product prices from research and development costs." The Representative stated that in 2014, WIPO published a study on alternatives to the patent system – including delinkage – to support R&D efforts, contained in document CDIP/14/INF/12, and suggested that the study be presented at SCP/28 under the agenda item on patents and health. The Representative further suggested that the proposal by Canada and Switzerland be expanded to address issues relating to transparency, as it related to the litigation over patent validity and scope, the economic aspects of drug development and commercialization, including the costs of R&D and the prices and revenues of products, as well as the utilization and gaps in accessing new drugs.

113. The Representative of JIPA stated that JIPA comprised about 900 major Japanese companies as members, and was pleased to make the statement in collaboration with the Japan Pharmaceutical Manufacturers Association (JPMA) and with the support of the IFPMA. The Representative believed that it was important for the SCP to agree that providing excellent medicines to a lot of patients all over the world was a mission of governments and companies in both developed and developing countries. The pharmaceutical industry had developed a number of medicines over the past century, especially over 550 medicines in the last 15 years which had contributed to human health and saving lives. The Representative continued that developing a new medicine involved high costs and a long R&D period. In order to successfully distribute medicines to patients in a new country, pharmaceutical companies had first to bear the costs for conducting additional clinical trials to meet local requirements, obtaining local regulatory approval, setting up local distribution and marketing networks, educating healthcare providers about the benefits of the new product, and undertaking post-marketing research and surveillance. The Representative stated that IP rights could provide a company, which invested in launching a new medicine to a market, with an opportunity to recover the investment costs before generic competitors could enter the market. He referred to the National Bureau of Economic Research in the United States of America, which reported 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 activities for excellent medicines, which would contribute to human health and saving lives in developing and developed countries. The Representative stated that as mentioned in document SCP/26/5, 95% of the 2013 WHO list of essential medicines were not under patent protection in most lower-income countries, meaning that patents with respect to those medicines had expired, or had not been filed. The Representative believed that access to

medicines was triggered by a combination of other factors than patent protection, such as costs of some tests, production capacity, regulation for safety, quality and efficacy. In his view, a compulsory license did not resolve the problem associated to access to medicines. The Representative stated that Japanese pharmaceutical companies recognized the struggles in solving the issue of access to medicines in developing countries. He noted that in June 2017, 12 Japanese pharmaceutical companies, including Astellas, Eisai, Takeda, Chugai, Daiichi-Sankyo, Shionogi, had announced that they would fund the Global Health Innovative Technology Fund (GHIT Fund) over the next five years. The Representative stated that Chugai had been working on a project for developing a new medicine for dengue fever in collaboration with the Singapore Immunology Network, and the GHIT Fund selected the project as a grant recipient of 5,3 million US dollars based on its recognition for contributing to the "fight against NTDs in developing countries." The Representative continued that Chugai had promised to keep contributing to the enhancement of health and medical access for people in developing countries and to the economic development of those countries. Furthermore, the Representative stated that Takeda had been working on a project for developing a commercial formulation for a medicine for the treatment of malaria in collaboration with Medicines for Malaria Venture (MMV) with a total of 4,4 million US dollars awarded from the GHIT Fund. The Representative noted that Takeda and Eisai had addressed the improvement of the affordability of its product through collaborative cost-sharing models and a tiered pricing approach, while Astellas Pharma and Daiichi Sankyo flexibly filed and enforced patents on a per-country basis, with consideration given to improving access to medicines. The Representative stated that on October 3, 2017, the research based pharmaceutical industry and WIPO had launched a new partnership to promote accessibility to drug patent information for drug procurement agencies, and that currently five Japanese research-based pharmaceutical companies, Astellas, Daiichi-Sankyo, Eisai, Takeda and Shionogi, were committed to join that drug patent information initiative project called "Pat-INFORMED", and to provide patent information to the Pat-INFORMED database. The Representative believed that the Pat-INFORMED database would promote access to medicines by providing procurement agencies with a clear link between public patent information and the corresponding sold product. The Representative informed that further activities of JPMA on access to medicines in developing countries could be found on the JPMAs website and that Japanese pharmaceutical companies had been joining about 30 partnerships for developing medicines for neglected tropical diseases. The Representative further believed that for access to medicines in developing countries, it was necessary to set patent systems at the center of promoting R&D of medicines, and was convinced that the patent system promoted public health in both developed and developing countries.

114. The Representative of MSF stated that discussions on the topic of patent protection on pharmaceuticals had been repeated many times and should move away from the fundamental ideological discussion as to whether there should be patent protection for pharmaceuticals or not. The Representative considered that the SCP discussion was about balance and appropriate protection, which, from the Representative's perspective, took into account the social benefit at both national and international levels. The Representative aligned itself with the statement made by the Representative of KEI on the importance of discussion of alternative R&D models. Referring to the long lasting argument used by the industry on the essential role of the patent system in recouping R&D costs, the Representative noted that, from its experiences, that might not be the only way to finance R&D. The Representative continued that there were already a number of examples and experiences from the past on other alternative ways to deal with the costs of R&D. The Representative hoped that the SCP would take that into consideration in the future discussion. Moreover, the Representative stated that discussions on the issue of patent information database was a welcoming move forward. She stressed that patent information was never confidential, and therefore, it should be public in the first place. The

Representative observed that while it was good that the industry could consolidate all patent information and made them available at a single source, the industry should never be given the credit for making the patent information public, as it was a governments obligation to make it public.

115. The Secretariat made a presentation on document SCP/27/6.

116. The Delegation of Canada congratulated the Chair and the Vice-Chairs on their elections and was pleased to note that the Delegation of Switzerland had agreed to cosponsor the proposal of Canada. The Delegation thanked the Delegation of Switzerland and the Member States and Observers for their positive engagement, and stated that Canada and Switzerland were advancing their proposal in the constructive spirit and contributing to discourse on the essential topic of the relationship between patents and access to medical products and health technologies. The Delegation noted that since the last session Canada and Switzerland had made revisions on the proposal to reflect the feedback received and that the Delegation had an interest in ensuring that all Member States saw value in its proposal. The Delegation highlighted that the key differences in the revised proposal were under paragraph 5.a, namely the addition of a definition of medical products and health technologies, to help clarifying the scope of the proposal. Further, the Delegation noted that under paragraph 5.c, of the category on non-patent barriers to access to medicines had been removed, and the category on availability of essential medicines in countries where those medicines were not under patent protection had been added. That was intended to address the view that non-patent barriers fell outside the scope of the SCP, and should not be addressed in the proposal. The Delegation continued that it was not intended to compete or replace other work under the agenda item on patents and health. The Delegation believed that its proposal could move forward in parallel with other work, and that at the same time, Member States could take account of the results of its proposal when making decisions about the topic of the research the Delegation wished to commission. The Delegation acknowledged the vigorous debate with many points of view on the relationship between patents and access to medical products and health technologies. The Delegation explained that the proposed exercise was not intended to settle that debate but rather to ensure that it was grounded on a foundation of high quality research. It was of the view that Member States might then review the results, and draw their own conclusions. The Delegation further noted that given the breadth of the studies that would be captured by the exercise, it expected that all sides of the debate would be well represented in the final report.

117. The Delegation of Switzerland, speaking in its national capacity, aligned itself with the statement made by the Delegation of Canada, and referred to three points of the proposal that it considered as important. Firstly, the review would focus on fact finding and on research-based technical expertise. Secondly, the Delegation noted that it did not prejudge the other proposals on that agenda item, namely the proposals by the African Group contained in document SCP/24/4 and by the United States of America, contained in document SCP/17/11. Thirdly, the Delegation continued that the resulting document of the review would not include original recommendations. Based on the document, the Delegation noted, Member States were free to develop their own conclusions on defining the way forward. The Delegation stated that during SCP/26, it supported the proposal of Canada and was now a cosponsor of the proposal. The Delegation believed that the review of existing studies would benefit all Member States and the work of the SCP. The proposed study would shed light on the research and quality evidence related to the relation between patents and access to health technologies. Further, it would provide the Member States with a state of knowledge and might even improve the knowledge base in that field. The Delegation noted that it was not aware that such exercise had been undertaken so far in other fora, and believed that it would be beneficial beyond the SCP. The Delegation stated that there was a rich documentation on a variety of aspects and issues relating to patents

and health. The Delegation referred to the WIPO-WTO-WHO Trilateral Study, Promoting Access to Medical Technologies and Innovation, which contained five pages of references with far more than 150 cited documents. The Delegation believed that a review of that documentation was a constructive step forward before entering on further work on the topic of patents and health. The Delegation noted that it could help advancing the future work of the Committee, providing a genuine and original contribution to the state of knowledge on the relation between the patent system and access to health technologies. The Delegation stated that other delegations had expressed concerns related to the scope of the study, the definition of medical products and the purpose of the proposal or its relation or impact on the proposal put forward by the African Group. The Delegation highlighted that all those concerns had been addressed by the Delegation of Canada during the SCP/26 or by the changes made in its proposal. The Delegation stated that Canada and itself were prepared to respond to any further concerns or open questions from other Member States.

118. The Delegation of Senegal speaking on behalf of the African Group, thanked the Delegation of Canada for its revised proposal and for including some aspects which the Delegation of Senegal brought up during the last session of the SCP. However, the Delegation remained concerned in regard to paragraph 2 of the introduction of the revised proposal, which contained, from its point of view, a large number of elements that exceeded the mandate of the SCP and might spill over into other fora and bodies. The Delegation stated that it had taken due note of the explanations that had been given by the Delegation of Switzerland with regard to the results of such a review or study. However, the Delegation was concerned about the idea of what was indicated in paragraph 2 of the introduction, as it seemed to give some guidance on the outcome of the study, namely, patents were, in fact, only a small part of the problem of accessibility to medicines and health technology. The Delegation noted that while it remained very interested in continuing to have bilateral consultations to discuss the revised version of the proposal in greater depth, it presently was not able to support the proposal.

119. The Delegation of Iran (Islamic Republic of) commented that according to its understanding, the scope of any study to be reviewed should be restricted to the patent-related aspects of technologies and access to medical products and health technologies. Therefore, in its opinion the scope of such studies should be restricted to issues which fell within the mandate of WIPO and the SCP. The Delegation further commented that as the end of 2017 was approaching, the studies published in 2017 should also be covered by the review. The Delegation stressed that its preference for future work on that item was the proposal made by the African Group.

120. The Delegation of Indonesia, speaking in its national capacity, thanked the Delegation of Canada for the revised proposal and the Delegation of Switzerland for cosponsoring it. The Delegation stated that it appreciated the presentation of the revised proposal and noted that it had a very solid background on the reasons for carrying out such study. However, the Delegation stressed that while it did not have concerns, it still had some input on the proposal so that the Committee could move forward and conduct the study as proposed by Canada and cosponsored by Switzerland. The Delegation was delighted to know that both proponents of the proposal agreed that the activity would not prejudge the discussion of the Committee on patents and health. However, the Delegation noted that one of the proponents of the proposal had stated that that study would guide the future work of the SCP. The Delegation stated that it was important to agree that the study would not prevent or prejudge any future discussion in the SCP while the study was being conducted. The Delegation stressed, along with the Delegation of Iran (Islamic Republic of) and other delegations, that there should not be any duplication of work and that the work of the SCP should stay within its mandate. Further, the Delegation was of the opinion that it would be wise to limit the study only to the patentability criteria and to access to medicines and

technologies, instead of covering other issues that were out of the mandate of the SCP and WIPO. In addition, the Delegation pointed out that the review period of the study should also cover 2017 and not end with 2016. The Delegation stated that it had informally consulted the Delegation of Canada on that point and the Delegation of Canada was open and flexible to extend the review period to 2017. Furthermore, the Delegation thanked the Delegation of Canada for including paragraph 5, and noted that beside WIPO, the WHO and the WTO as well as other UN organizations should be included.

121. The Representative of KEI welcomed the opportunity to provide inputs on the constraints faced by developing countries and LDCs in making full use of patent flexibilities in promoting access to medicines and safeguarding public health. The Representative noted that KEI's 21-page submission to the Committee documented some notable examples of political and trade pressures brought against countries which exercised, or contemplated exercising, the flexibilities available to them under the TRIPS Agreement. The Representative referred to examples from Brazil, Colombia, Ecuador, India, Indonesia, South Africa and Thailand, and noted that its full submission was available at: http://www.wipo.int/export/sites/www/scp/en/meetings/session_27/3rdparty_comments/kei.pdf. The Representative stated that he would provide a few examples of pressures countries had faced. The Representative explained that in early January 2001, a few days before leaving office, President Clinton requested the establishment of a panel at the WTO, designed to challenge Article 68 of Brazil's 1996 industrial property law, which contained provisions regarding the local manufacturing of products. After Clinton had left office, the Bush Administration had withdrawn the WTO case against Brazil on June 25, 2001. The Representative referred to an article in the New York Times which read as follows: "The United States unexpectedly withdrew a patent complaint against Brazil in the World Trade Organization today and agreed to settle out of court a dispute widely seen as symbolic of the debate over who may manufacture and sell drugs to treat AIDS in poor countries. Brazil, which had been moving to the forefront of an international challenge to large Western pharmaceutical companies and their high-priced anti-retroviral medicines, has sharply cut its mortality rate from AIDS in recent years with an aggressive campaign to make drugs available cheaply and effectively, experts say. American officials, who had threatened Brazil with trade sanctions, said two months ago that this case was important to uphold the general principle of protecting intellectual property rights and that Brazil was using a provision in its law to pressure patent owners to make products there. Brazil's AIDS chief, Dr. Paulo Roberto Teixeira, responded on May 2, by saying that "his country was being punished for challenging American companies in ways that other nations did not." The Representative stated that as noted in document SCP/27/6, prepared by the Secretariat, the Ministry of Health of Colombia described the difficulties and pressures experienced in taking administrative steps to issue a declaration of public interest in order to issue a compulsory license. The Representative continued that in particular, paragraph 9 of document SCP/27/6 described the communication, dated April 27, 2016, from the Colombian Embassy in Washington, D.C. to the Colombian authorities in Bogota recounting the concerns expressed by the United States Trade Representative (USTR) and the Finance Committee of the US Senate on the granting of a compulsory license for Imatinib, a cancer medicine. The Representative noted that such pressure specifically linked U.S. funding for "Paz Colombia," an Obama Administration initiative in the Colombian peace process, to the granting of the compulsory license. Furthermore, the Embassy conveyed concerns from the US Senate Finance Committee that a compulsory license on Imatinib would violate the intellectual property rights of Novartis, a Swiss pharmaceutical company.

122. The Delegation of Georgia, speaking on behalf of the CEBS Group, stated that balanced policies and initiatives enhanced access to affordable medicines and health care technologies, and took note of the revised proposal of Canada, cosponsored by Switzerland, to conduct a review of existing research on patents. The Delegation thanked those

Delegations for improving the text and stressed that the policy workers should rely on quality evidence. It agreed with the Delegation of Canada that the review was a good opportunity to build upon existing research. The Delegation concluded that it could consider the revised proposal as a good basis for the future work discussions.

123. The Delegation of Colombia congratulated the Chair and the Vice-Chairs on their elections and thanked the Secretariat for its work and preparing all documents. The Delegation aligned itself with the statement made by the Delegation of Costa Rica on behalf of GRULAC. The Delegation noted that the discussions within the Committee were of great importance for Member States and that the benefits of its discussion lied specifically in the diversity of opinions and approaches of the Member States on the different topics dealt within the Committee. The Delegation stated that the SCP was a place for discussing the progressive development of patent law, and noted that Colombia was a country that promoted free expression and always had recognized the contributions which the intellectual property system provided for a productive promotion of innovation, creativity and competitiveness. The Delegation thanked the Secretariat for preparing document SCP/27/6 which summarized the difficulties faced by developing countries and LDCs in making full use of the patent flexibilities. It stated that the document summarized the different contributions made by the Member States, thereby specifically referring to the contributions made by the Ministry of Health of Colombia. The Delegation underscored the importance of the discussion on patents and health, where it was one of the areas with great challenges to find a proper balance, thereby taking into account the 2030 Sustainable Development Goals and the Development Agenda. Noting that the initial study contained in document SCP/25/5 provided very important background information, the Delegation considered that a supplementary study in document SCP/27/6 had to take into account what had been mentioned in the paragraphs on national governance and extrinsic influences. The Delegation noted that all contributions, that were made in the SCP, were part of a whole dynamic process within countries, which involved the necessary participation of different governmental departments and ministries. In that regard, the Delegation stressed the importance of adopting a cooperative approach at the national level with the participation of all stakeholders. The Delegation explained that that was occurring in Colombia, and noted that its statement reflected the viewpoints, opinions and visions of the governmental actors, the private sector and the civil society.

124. The Delegation of Canada thanked the Member States for the constructive and useful feedback they had expressed regarding its proposal. Further, the Delegation responded to some of the questions made by some Member States. Specifically, the Delegation clarified that the proposed literature review was described in paragraphs 4 and 5 of its proposal and that it did not include non-patent factors. The Delegation explained that since paragraph 2 of the proposal simply set the stage, it did not define the scope of the proposal. Nevertheless, the Delegation stated that it would agree to remove that paragraph, if it was found problematic. With respect to comments on the time period of the review, the Delegation agreed to broaden the scope of the literature review to cover 2017. As regards the comments made on the relationship between the proposal and future work, the Delegation stated that based on the outcome of the literature review, there might be future work. The Delegation explained that, for example, if, as a result of the literature review, the Committee would conclude that there were areas where there were gaps in the research, then the Committee could consider commissioning new research in those areas. Responding to the question regarding the organizations whose studies would be covered in the review, the Delegation stated that there was no intention to limit the scope of the literature review to the work produced by the three organizations listed in its proposal and that the list was open-ended.

**AGENDA ITEM 9: QUALITY OF PATENTS, INCLUDING OPPOSITION SYSTEMS**

125. The Secretariat introduced documents SCP/27/4 Rev. and 5 Rev.

126. The Delegation of Georgia, speaking on behalf of the CEBS Group, reiterated its strong support to advance the work on the topic of quality of patents. The Delegation stated that the topic was at the core of the patent system and that high quality patents enabled the system to fulfill its functions. The Delegation stressed that a work sharing was one of the instruments for the patent offices to avoid duplication of work and that it could contribute to a high quality examination process. The Delegation believed that work sharing would benefit all Member States and all patent offices. The Delegation thanked the Secretariat for updating the responses to the Questionnaire on the Term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination and for sharing with the Committee the tendencies and approaches of how each Member State understood the term "quality of patents" (document SCP/27/4 Rev). The Delegation observed that while the document showed that different opinions existed regarding the factors defining the quality of patents, there was a similar understanding on the main issues. Further, based on the updates made to document SCP/27/5 Rev., the Delegation was pleased to see the extensive cooperation between IP offices and a growing use of different collaboration methods at the bilateral, regional and international levels. The Delegation noted that such cooperation facilitated the work of IP offices. The Delegation looked forward to the information exchange session on cooperation between the patent offices in search and examination during that session and to hear successful examples. The Delegation welcomed the decision of the Committee to hold a sharing session on examples and cases relating to assessment of inventive step, as suggested in the proposal by the Delegation of Spain (document SCP/24/3). 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. In conclusion, the Delegation expressed 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).

127. The Delegation of Senegal, speaking on behalf of the African Group, thanked the Secretariat for preparing documents SCP/27/4 Rev. and SCP/27/5 Rev. Noting the importance of the issue of quality of patents and of cooperation between patent offices in search and examination, the Delegation underlined that there were conceptual differences with regard to understanding of the term "quality of patents". 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. The Delegation stressed that the Member States needed a political space for establishing a mechanism that would take into account their own priorities, objectives and concerns. The Delegation noted that, as to that date, there was no common understanding of the term "quality of patents", since it was inevitably subjective. The Delegation further stated 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. Further, the Delegation noted that the issue of quality of patents was not only related to search and examination and the application of the inventive step criteria, but that it was also related to the opposition systems, which were absolutely vital for an effective patent system. The Delegation suggested that the Secretariat would undertake a study on national and regional practices with regard to the opposition systems. While recognizing the importance of any activity that could overcome

duplication and would help offices to work more efficiently, the Delegation, however, noted that given the different socio-economic levels of development of countries, prudence was needed before coming up with a specific work program on the issue of quality of patents. In conclusion, the Delegation stated that it was pleased that there would be a sharing session on further examples and cases relating to assessment of inventive step held during that session, and that it looked forward to the presentation by the Secretariat of the web page on opposition systems and other administrative revocation mechanisms.

128. The Delegation of Estonia, 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. The Delegation expressed its content over the agreement reached on the topic at the previous session of the SCP. The Delegation further thanked the Secretariat for updating the responses to the Questionnaire on the Term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination, taking into account the additional responses submitted by the Member States after the twenty-sixth session of the SCP. Noting the number of new contributions made, the Delegation stated that the additional possibility for Member States and Regional Patent Offices to submit responses to the questionnaire had increased its weight and value. The Delegation stated that the questionnaire and the compilation of answers by the Secretariat would be helpful to pursue work in the area of quality of patents. In particular, the Delegation stated that the results of that exercise would help the Committee to gain a better understanding of how each Member State understood the term "quality of patents". 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 the questionnaire would prove useful in carrying out the Committee's work in the area of quality of patents, and in engaging in harmonization of substantive patent law in the future. The Delegation further stated that the additional questions set out in the proposal by the Delegations of Canada and the United Kingdom (document SCP/18/9) would provide a useful next step in that area and would allow the Committee to learn more about how Member States evaluate and improve quality of patents. Turning to document SCP/27/5 Rev., the Delegation stated that the compilation of responses in that document reinforced their earlier conclusion that a wide range of cooperation between IP offices and the growing use of different collaboration methods existed at bilateral, regional and international levels, facilitating the work of IP offices. The Delegation continued that the work sharing had also proven to have a positive impact on efficiency of patent examination and the validity of granted patents. Given the benefits of work sharing, the Delegation welcomed the decision of the previous session of the SCP to hold a half-day information exchange session on cooperation between patent offices in search and examination during the ongoing session. The Delegation looked forward to hearing about the experiences and successful examples of Member States on such cooperation, including its effect on patent granting procedures and capacity building. 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. In addition, the Delegation stated that it saw merit in a study by the Secretariat on how different laws and practices might limit the potential for work sharing and what voluntary measures could be put in place to address any problems at the international level. The Delegation further thanked the Secretariat for maintaining and updating a dedicated page on the WIPO website for various work sharing activities which would further improve access to existing initiatives and enable patent offices to collaborate more efficiently. The Delegation stated that the WIPO CASE platform could be seen as a good example of cooperation between IP offices and dissemination of information about a particular method of work sharing. Further, the Delegation welcomed the decision of the Committee to have a sharing session at the SCP

on further examples and cases relating to assessment of inventive step. The Delegation stated that paying particular attention to the topics suggested in the proposal by the Delegation of Spain, contained in document SCP/24/3, inventive step was a central concept in substantive patent law and its proper evaluation was a key to guaranteeing a high quality patent system. Thus, the Delegation welcomed the fact that the discussion of that complex topic had been continued in the SCP. The Delegation expressed its belief that the discussions on the concept, as well as methods of assessing the inventive step used in the WIPO Member States, greatly benefited the Member States in conducting work in that area. The Delegation stated that that was evidenced by the success and usefulness of a similar sharing session held during the twenty-fifth session of the SCP. The Delegation expressed its confidence that the sharing session at the twenty-seventh session would be useful for preparing a further study on inventive step to be submitted to the following session of the SCP. In conclusion, 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, and looked forward to constructive discussion on that agenda item.

129. The Delegation of Switzerland, speaking on behalf of Group B, 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. From the presentations of cases during that sharing session, the Delegation noted that similar evaluation approaches could often lead to different results in different jurisdictions. The Delegation continued that, the sharing session on further examples and cases relating to assessment of inventive step had shed more light on the practical implications of those concepts in various countries. The Delegation stated that the responses to the questionnaire contained in document SCP/23/3 highlighted the importance that countries had attributed to appropriate evaluation of the patentability requirements. 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) and on the earlier proposals of the United States of America. Turning to the information exchange session on cooperation between patent offices in search and examination, the Delegation thanked the Secretariat for the excellent work on the questionnaire and the summary of the responses contained in documents SCP/26/3 and 4, as well as documents SCP/27/4 Rev. and SCP/27/5 Rev.. In addition, the Delegation thanked those Member States that had contributed to the updated documents. With respect to the term “quality of patents”, the Delegation highlighted that many responses had indicated that both quality of patents itself and quality of the patent

granting process formed that term. The Delegation agreed that quality of patents was closely related to quality of a patent granting process. The Delegation continued that, most commonly, quality of patents was considered as those that complied with substantive patentability criteria. The Delegation observed that factors contributing to such high quality patent granting process included a thorough and comprehensive search and examination process that complied with the applicable law and established standards. The Delegation continued that, to perform those tasks, examiners needed proper search tools and databases. Furthermore, the Delegation observed that many countries had mentioned the timeliness of office actions and decisions, and that some other countries had highlighted the importance of well-trained staff having sufficient skills to carry out their duties as a prerequisite for quality granting process. The Delegation continued that, other responses had referred to the aspect of transparent communication between the office and the stakeholders. Furthermore, the Delegation noted that some countries had provided inputs on the quality management system introduced within their offices. Noting that many countries had a common understanding on the term “quality of patents”, the Delegation considered that document SCP/27/4 Rev. was a good basis for further discussions on the definition of the concept, should a formal definition proved to be needed. The Delegation noticed that some delegations which had expressed the strong interest in defining what quality meant had not contributed to the questionnaire and invited them to do so. With respect to cooperation between patent offices in search and examination, the Delegation stated that the responses contained in document SCP/27/5 Rev. indicated the existence of extensive cooperation activities at the bilateral, regional and international levels and the wide range of cooperation. The Delegation further stated that the information exchange session on cooperation between patent offices in search and examination would further enhance their understanding on the topic. Additionally, the Delegation stated that document SCP/27/5 Rev. also highlighted the positive impact of cooperation in improving search and examination, and consequently, the validity of granted patents. The Delegation continued that prior art found by other offices complimented the search work of examiners, particularly where prior art documents were in foreign languages, and that examiners might consult opinions on patentability of other offices, since they would provide the rationale behind the decision taken by the examiners of those other offices. Particularly, the Delegation noted that the document reported that small offices with limited resources benefited from other offices’ search and examination reports, as well as from cooperation on substantive examination. Further, the Delegation observed that 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 continued that the PPH program was an example of a successful model for work sharing, as it allowed fewer office actions which had led to reduced costs for applicants and the offices and that it also provided an examiner with a better starting point from which to start their prior art search. The Delegation stated that, in addition, many responses referred to improvment of professional knowledge and competencies of examiners and optimization of internal processes through cooperation with others. The Delegation further stated 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. In that regard, the Delegation wished to see that work on that topic proceeded based on the proposal made by the Delegation of the United States of America, contained in document SCP/23/4. Further, the Delegation reiterated that the Committee should continue to build its work on technical topics that would contribute to a higher quality of patent prosecution, the national examination processes and of the granted patents. Therefore, the Delegation was of the view that works on the topics of work sharing and collaboration, as well as on inventive step, should be proceed. The Delegation stated that document SCP/18/9 included further questions on information access and process improvement and technical infrastructure development that could serve as a basis for further work on quality of patents.

Further, recalling the proposal for an annual work sharing event, the Delegation stated that such event would be a productive forum for sharing experiences and best practices allowing delegates to identify ways to increase the usefulness of work sharing and collaboration programs, and updating the Member States of new work sharing arrangements. The Delegation stated further that many Member States had expressed their strong interest in conducting further work on inventive step and that a larger number of responses to the questionnaire had highlighted the importance of a proper assessment of the patentability requirements in order to obtain high quality patents. Therefore, 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. Specifically, the Delegation wished to see a further study by the Secretariat covering the topics as described in paragraph 8 of that proposal.

130. The Delegation of China thanked the Secretariat for updating the responses to the Questionnaire on the Term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination. The Delegation stated that a comprehensive analysis of the results of the questionnaire would help the Committee to further consider the definition of the term "quality of patents", to collect information on the work carried out by Member States on work sharing, and to help countries to learn from each other's experiences. With regard to the quality of patents, the Delegation was of the opinion that the issue was related to innovation, examination, use and patent protection. The Delegation noted that the definition of the term was complex and that it could be measured by referring to several aspects, such as technological innovation, patent drafting, patent stability, patent utilization, etc. The Delegation stated that each country might have its own different understanding of the term. Further, the Delegation stated that the State Intellectual Property Office of China (SIPO) was implementing the "Patent Quality Improvement Project", aiming at improving the overall quality of patent examination and patents. 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. The Delegation considered that trainings of patent examiners in developing countries were very important for the quality of patents. Noting that many countries made explicit reference to such trainings in their responses to the questionnaire, the Delegation reported that SIPO had been devoting itself to the training of examiners in developing countries within its own capabilities. Specifically, the Delegation informed the Committee that, in 2017, more than 100 training courses had been provided to over 100 officials or examiners from more than 40 developing countries. Furthermore, in May 2017, SIPO had organized a patent examination training course for national IP institutions under the "One Belt and One Road" initiative, providing training to examiners from 16 developing countries. In addition, a training course on intellectual property in Latin America was held in China, in which representatives of IP agencies from eight countries had participated.

131. The Delegation of Iran (Islamic Republic of) took note of the information contained in documents SCP/27/4 Rev. and SCP/27/5 Rev. and extended its appreciation to the Secretariat for the preparation of documents. 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 underscored a different perception of those issues by countries. 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. In the Delegation's view, work sharing was a matter of procedure which fell outside the mandate of the SCP, which was a Committee dealing with substantive issues. With regards to that agenda item, 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. The Delegation believed that harmonizing patent laws across countries could widen the differences in economic and scientific development among countries, and could create a concentration of intellectual property assets within certain regions which would not help developing countries and LDCs. 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 in order to avoid the high social cost of granting patents to insignificant improvements. 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. The Delegation noted that despite the fact that opposition systems continued to be maintained in the agenda along with the quality of patents, the focus of discussion under that agenda item had been exclusively on patent quality. The Delegation thus suggested giving equal prominence to the topic of opposition systems in the future SCP work program.

132. The Delegation of Brazil welcomed 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 noted that its country had been supporting many of the proposals regarding the topic such as the one contained in document SCP/24/3, and that it had recently sent its contributions to the questionnaire. The Delegation stressed that, for Brazil, patents of high quality were key to the promotion of a 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 and to the balance of rights and obligations. 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. The Delegation further stated that, in light of the 47 years of existence of the Brazilian patent office, it wished to highlight some of the initiatives that its office had implemented for improving the efficiency of their patent system to enhance the quality of patents. In particular, the Delegation mentioned about the electronic platform of collaborative examination, e-PAC which was an examination system that allowed the collaboration and exchange of information during the patent examination by different entities registered through a friendly graphical interface and with tools that permit the interaction in real time, contributing to speeding up the patent examination. The Delegation further stated that another important measure had been adopted in April 2017, when the Brazilian patent office

had signed a joint order with the Health Regulatory Agency of Brazil, ANVISA, with a view to speeding up the patent grants in the pharmaceutical sector. According to the joint order, ANVISA assessed the applications of prior consent focusing on impact on public health, whereas the Brazilian patent office had the exclusive attribution of evaluating the patentability criteria. The Delegation stated that the agreement would streamline patent processes in those areas in addition to avoiding patent term extensions due to processing time, and facilitate the arrival of generic drugs to the market. The Delegation also informed the Committee that the Brazilian Patent Office had also hired 210 new patent examiners in 2017, and had signed Patent Prosecution Highway (PPH) agreements with the USPTO, JPO and more recently with the SIPO. In conclusion, the Delegation wished to stress that all of the aforementioned measures had been adopted under the leadership of the head of the IP office, Mr. Otávio Pimentel, and that their objective was to streamline the patent granting process and enhance the legal certainty to investors and IP holders.

133. The Delegation of the Republic of Korea thanked the Secretariat for preparing documents SCP/27/4 Rev. and SCP/27/5 Rev., Updated Responses to the Questionnaire on the Term “Quality of Patents” and Cooperation between Patent Offices in Search and Examination. The Delegation stated that quality of patents was a key factor in effectively creating innovated technologies, protecting the right of an inventor and improving efficiency of patent administration by the government. Considering that there were divergent views on the term “quality of patents”, the Delegation was of the opinion that the above-mentioned Questionnaire was a good and useful basis for the further discussion. 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 conclusion, the Delegation stated that in order to improve the quality of patents, the Republic of Korea conducted various kinds of work sharing with other countries and that it focused on cost effective administration based on work sharing.

134. The Delegation of the Dominican Republic thanked the Secretariat for preparation of the documents on the issue of quality of patents, and expressed its support for the continued discussion on the topic within the Committee. Noting the value of information exchanged and progress made through the previous discussions, the Delegation stated that that would substantively improve the efficiency of the patent system.

135. The Delegation of Colombia thanked the Secretariat for the preparation of documents SCP/27/4 Rev. and SCP/27/ 5 Rev. The Delegation stated that the quality of patents was linked to the fulfillment of the patentability requirements in a specific jurisdiction. The Delegation stated that the fulfillment of those requirements was conducted in the examination stage, and that thereafter third parties might have the possibility of filing oppositions/appeals in the administrative stage and/or the judicial stage, which guaranteed the due process in the interest of both, the users and developers of technological creations. The Delegation stated that Colombia was a Contracting State of the Patent Cooperation Treaty since 2001, which was the most long-standing and efficient legal instrument as regards cooperation, filing of patent applications, search and examination. The Delegation stated that all the examiners in the world might use the work results of the International Authorities. The Delegation noted that Colombia had been carrying out an extensive cooperation with other offices through accelerated examination procedures since 2011, and that it became the first Latin American country participating in the PCT-PPH. With respect to the system for technical cooperation among industrial property offices of Latin American countries called “PROSUR”, the Delegation stated that that regional agreement allowed participating offices to have information on the patent examination processes of the offices

involved. The Delegation expressed its hope that that collaboration would be successful and could deliver more results. Noting that offices faced some challenges as regards the sharing information on patent examination, the Delegation stated that it had been proposed by PROSUR that the results of the patentability examination of the Latin American offices should be included in the WIPO Centralized Access to Search and Examination Case (WIPO CASE) database. Finally, the Delegation stressed the importance of having the technological standards and tools to be able to share the information among different databases.

136. The Delegation of Chile stated that it had responded to the Questionnaire on the Term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination, which was made available on the WIPO website. Noting that the web page on national/regional laws on opposition and other administrative invalidation procedures did not contain updated information regarding its legislation, the Delegation stated that it would send the Secretariat such information. The Delegation continued that, in its view, a quality patent was the one that: (i) was granted in accordance with the requirements of the law; and (ii) provided certainty about the protected matter, its scope and the distinction between the patented invention and what had been already known. In addition, according to the Delegation, a quality patent was the one in which, among other reasons: (i) the state of the art had been established in a pertinent manner *vis-à-vis* the scope of the invention; (ii) office actions had been carried out in a timely manner through an expedited process; (iii) protection had been granted to inventions that had indeed complied with the requirements established under the national legislation; and (iv) all the above had been done efficiently in terms of resource management. In relation to the cooperation between patent offices in search and examination, the Delegation informed the Committee that its National Institute of Industrial Property (INAPI) participated in the WIPO CASE as a "Providing" and "Accessing" office, i.e., by sharing search reports and patentability examination results and, at the same time, consulting the information available in the system. Further, the Delegation wished to point out that 100 experts in charge of patent examination could access the valuable information in WIPO CASE. The Delegation continued that in the framework of cooperation with the EPO, INAPI shared the bibliographic data of its database under the ST36 Standard, so that applications submitted in Chile could be identified through the PATENTSCOPE platform, and the Latipat platform. In addition, the Delegation stated that, during 2017, 100 patent search and examination reports had been shared with the patent office of the Dominican Republic in the area of biotechnology. Furthermore, in 2017, the implementation of the PPH program had also been completed under the PROSUR and the Pacific Alliance, which became operational for the accelerated examination of patent applications. The Delegation stated that, along with the above, INAPI used the e-PCT platform for the processing of the PCT international applications, either as a Receiving Office or as an ISA/IPEA. It was foreseen that in the future, the platform would be very useful to share search and examination information among the offices. The Delegation encouraged other offices of the region that are Contracting States to the PCT to incorporate e-PCT into their operations, since it was a very efficient tool which considerably facilitated the administrative management of requests. Likewise, the Delegation stated that in order to integrate INAPI into international cooperation systems to share information related to search and examination, actions had been taken to incorporate international standards in that area. Thus, several digitalization processes of applications and patents had been carried out in INAPI, which had allowed the generation of an electronic file allowing those documents to be publicly available. Additionally, the Delegation stated that the standardization of the publication, examination and search formats had been promoted. Finally, the Delegation thanked International Bureau for the cooperation provided to its office with the implementation of the technological tools mentioned above.

137. The Delegation of Thailand wished to share its experience on the implementation and usefulness of the ASEAN Patent Examination Cooperation (ASPEC) system. Specifically, the Delegation stated that the purpose of that system was to share search results between the participating offices to allow applicants in participating counties to obtain corresponding patents faster and more efficiently. The Delegation continued that, the ASPEC system had begun in early 2013 and that it had proved to be one of the most effective tools for intellectual property offices in the ASEAN region in expediting their patent examination and registration procedures. In particular, the Delegation noted that the system had reduced the duplication of works among offices, the turnaround time of patent examination and backlogs, while preserving the country's authority in determining the patentability of the applications in accordance with its laws and regulations. Further, the Delegation stated that the Department of Intellectual Property of Thailand had so far received 113 ASPEC applications, mostly in the fields of electricity, physics and engineering. The Delegation noted that the examiners had learned about the principle of examination of other countries which could be considered as a channel to develop patent registration system of Thailand while applying its national law. Furthermore, the Delegation stated that Thailand had supported the new initiative to further improve the ASPEC system, namely, the e-ASPEC, and that it had been promoting the benefits of the system to Thai applicants through various channels.

138. The Delegation of the United States of America thanked the Secretariat for preparing documents SCP/27/4 Rev. and SCP/27/5 Rev. The Delegation stated that improving the quality of issued patents was one of the top priorities of the USPTO. The Delegation observed that the topic was also of great interest to many Member States. The Delegation was pleased by the increased number of responses to the questionnaire that the Secretariat had received, and was especially encouraged by the fact that responses had been provided by a wide variety of offices both large and small, as well as with different levels of experience and from different geographical regions. The Delegation continued to note that the response to the questionnaire reflected several common themes and views shared by many offices which could serve as a springboard for a more in-depth discussion and improving the quality of the patent system. The Delegation continued that those themes included improving the search and examination process, the timeliness of IP offices' actions and decisions, the hiring and training of examiners and communication with applicants and transparency of the processes. The Delegation stated that those four basic themes pointed out in document SCP/27/4 Rev. informed the Member States on the need to address those topics. Further, the Delegation stated that those themes were integral to work sharing programs and could be greatly enhanced by offices taking part in work sharing programs. The Delegation, therefore, expressed its hope that the Member States would agree to build upon those very important findings concerning patent quality. The Delegation stressed that the USPTO had been taking part in work sharing programs for many years, and had accumulated significant experience in working with other patent offices. The Delegation explained that those work sharing programs had demonstrated their benefits provided to offices and applicants. The Delegation stated that responses to the questionnaire from the Member States showed that various types of work sharing models between IP offices were cross-cutting and encompassed countries in different stages of development, IP offices of varying sizes and capabilities, and even legal systems with different traditions. The Delegation noted the widespread adoption of the PPH model across Asia, Americas and Europe. The Delegation also noted the widespread use of regional work sharing arrangement, such as PROSUR, CADOPAT, ARIPO and others, as well as the benefits that had been received in participating in those work sharing arrangements. The Delegation stated that it was becoming increasingly clear that work sharing offered to all offices, and especially to offices of more limited capabilities, the ability to carry out high quality searches and examinations which would otherwise be difficult or prohibitively expensive to carry out. The Delegation also observed that responses to the questionnaire showed that most countries did not see work sharing as infringing on their sovereignty or as imposing harmonization of laws upon

them. The Delegation reiterated that collaboration and work sharing played a major role in making patent offices more efficient and improving patent quality. In conclusion, the Delegation expressed its hope that the Member States would agree to continue working on developing better, more useful approaches to work sharing.

139. The Delegation of Japan expressed its appreciation to the Secretariat for preparing documents SCP/27/4 Rev. and 5 Rev. The Delegation wished to draw attention of the Committee to the following two issues regarding the quality of patents. First, the Delegation stated that it attached great importance to the topic of quality of patents. The Delegation was of the view that ensuring a high level of quality of patents was fundamental for achieving the objectives of the patent system, which was to encourage the creation of inventions and to contribute to industrial development. The Delegation agreed with the responses of some Member States reflected in paragraph 19 of document SCP/27/4 Rev., that the exclusive rights should be granted only to an invention that would meet prescribed patentability requirements such as, inventive step, to ensure the steady development of technologies and promote further innovation. Second, the Delegation wished to emphasize the effect of work sharing on patent offices. Specifically, according to Japan's experience, work sharing reduced the workload of the patent office and had a positive effect on the validity of granted patents. The Delegation observed that the same view was shared by other Member States in paragraphs 19 and 20 of document SCP/27/5 Rev.

140. The Delegation of South Africa aligned itself with the statement made by the Delegation of Senegal on behalf of the Africa Group. Noting the debate around the meaning of the term "quality of patents", the Delegation stated that it had become apparent that the term had different meaning to different delegations. According to its view, quality of patents related to the extent to which a patent would withstand any revocation attempts. The Delegation continued that, for that to be possible, a granted patent should meet the inherent requirements for patentability such as novelty, the inventive step and industrially applicability, which were the cornerstone of the patent system. The Delegation stated that, in addition, there should be a balance between the right granted and the disclosure of the invention to the public, which could be ensured through the requirement of sufficiency of disclosure in the patent application. Further, the Delegation stressed that various tools implemented by the office, i.e., search tools and databases for the searching of relevant prior art, the rigorous training of examiners, and the mechanisms for review of the office's work such as third party observations, appeal mechanisms and oppositions, were also important. The Delegation was of the view that the SCP's work on quality of patents should focus on enhancing the examination capacities of Member States, in line with their developmental imperatives. The Delegation also stated that the SCP should attempt to shed light on how to enhance the sufficiency of disclosure, the application of the inventive step, as well as opposition systems. Furthermore, while the Delegation understood that work sharing could ease the burden of patent examiners and avoid unnecessary duplication of work, it did not share the view that work sharing could necessarily be translated into a quality of patent and that patent quality could be simply improved by adopting the practices of other offices.

141. The Delegation of Cuba stated that the work products produced during the international phase of the PCT, such as international search and preliminary examination reports, helped to simplify the work of patent examiners by allowing them to take such reports into account in their examination according to their legislation at the national phase. Referring to the concept of patent quality, the Delegation stated that the requirement of inventive step and sufficiency of disclosure were absolutely vital for the quality of patents. The Delegation had informed the Committee that the Cuban patent office had implemented the quality control mechanism. The Delegation further stated that its office had been using the Support System for the Search of Patent Applications for Central American Countries and the Dominican Republic (CADOPAT) to support the search and substantive examination

of patent applications. In addition, the Delegation expressed its support to the proposals requesting further discussions on capacity building for patent examiners on search and examination and on the use of databases. The Delegation also expressed its support to a continuation of discussion on the topic of "quality of patents" within the Committee.

142. The Delegation of Mexico thanked the Delegation of Cuba for their kind words with regard to the CADOPAD system. Referring to its national experience with regard to the PPH, the Delegation supported the findings of other offices that such mechanisms for accelerated examination of patent applications did lead to a better quality of patents. The Delegation also stressed that such mechanisms did not oblige the office of the second examination to proceed in the same way as the initial examination. The Delegation explained that, while the work products of other offices helped the examiners to carry out the initial search more rapidly, it did not mean that that office did not carry out its own in-depth examination. The Delegation noted that according to the experience of its patent office, there had been some cases where a negative decision had been made on the applications where work products of other offices were available. Thus, the Delegation stressed that the offices would not necessarily come to the same conclusion as regards the patentability of a similar applications.

143. The Delegation of Australia stated that, like many offices, IP Australia sought to maximize the use of its examination resources by benefiting from the use of work products from other patent offices, and assisting examiners in conducting their examinations on similar patent applications that other patent offices might had examined. The Delegation stated that the ability to share the work products from its examinations and use of similar work products from other patent offices was an efficient way for managing patent workloads and pendency rates of applications. The Delegation noted that work sharing allowed examiners to focus their efforts on complex cases and to benefit from the knowledge and expertise of examiners of other patent offices. The Delegation stated that sharing of search and examination results provided a frame of reference as to from where to start their own examinations. In addition, from the experience of its office, utilization of those work products also helped their examiners to learn from other offices in conducting searches. The Delegation continued that that ultimately helped them to improve the patent quality, because examiners from across the world might uncover relevant prior art in foreign languages or specific technical fields that might be difficult to find. It was worth noting for the Delegation that using the work of another office did not mean that one office would simply accept the work of another office - each office needed to take into account its own laws and domestic requirements. At IP Australia, the examiners were required to validate the work products of other offices prior to using it, and to assess where further work might be required during the examination to satisfy their laws.

144. The Delegation of Estonia stated that the Estonian Patent Office was a small office and the number of national patent applications was also small. At that moment, there were 12 patent examiners in total. The Delegation stated that, despite that, the Office conducted a substantive examination of national patent applications in all fields of technology. Concerning the quality of patents and cooperation between patent offices in the field of search and examination, the Delegation stated that since 2002, Estonia had been a member of the EPO and that the majority of patents valid in Estonia were European patents, whose high quality was guaranteed by the EPO. The Delegation continued that, according to its view, even if the number of national patent applications was small, its substantive examination was very important for the quality of work product and the legal certainty of the granted patent. The Delegation stated that, in the case of the Estonian Patent Office, the performance of a quality substantive examination was entirely possible, as the office belonged to the European Patent Network and had access to the same databases and IT environment as the EPO. The Delegation continued that the exchange of information with

other patent offices, especially with the Nordic Patent Office, on both general issues regarding patent examination as well as on search and examination of specific applications had also been very helpful. The Delegation further stated that, lately, very close cooperation between the patent offices of EU took place in the area of supplementary protection certificates for pharmaceutical products (SPC). The Delegation also informed the Committee that, on July 6, 2015, the Estonian Patent Office had joined the Global Patent Prosecution Highway (GPPH) pilot program. One of the objectives of the program was a work sharing between patent offices in the field of search and examination. The Delegation noted that the procedure was used only if the patent applicant wanted it, and that a participation in the GPPH program did not force the participating patent office to accept the decisions taken by another office. Further, the Delegation stated that the Estonian Patent Office had used in some cases, on the request of the applicant, the decisions made by other offices in the framework of the GPPH pilot program. Based on the statistics published that year, the search and examination results of the Estonian Patent Office had been once used by such large offices as ROSPATENT, and six times by the USPTO. The Delegation stated that, according to the Estonian Patent Office, cooperation between patent offices in search and examination had enabled the applicants to receive patents faster and their quality was higher, and that it had allowed reducing the workload and optimizing the use of resources of the office.

145. The Delegation of Argentina stated that INPI Resolutions 56/2016 and 125/2016 empowered the use of search and examination results carried out by other patent offices under certain conditions. The Delegation clarified that those conditions were, for instance, that the foreign patent office which had carried out the initial search and examination of the corresponding patent application had applied the same standards for determination of patentability as in Argentina. The Delegation highlighted that the above-cited Resolutions and the PPH signed by Argentina enabled patent examiners to have a more precise “starting point” to conduct their own search and examination on patent applications to ensure that high quality patents were granted through access to more documents relevant to the state of the art. The Delegation, however, stressed that under no circumstances, INPI examiners were exempted from carrying out their in-depth search and substantive examination of applications in light of the patentability criteria set forth under the Patenting Guidelines of Argentina. On the basis of above, the Delegation concluded that higher quality patents were achieved without diminishing the rigor and level of analysis of the applications, without harmonizing or standardizing the patentability criteria between the different States, and without resigning national sovereignty. Finally, the Delegation mentioned that the Argentinian experience had been very positive. From October 2016 to that date, 915 applications had been filed based on equivalent patents examined by other offices, out of which 882 applications had resulted in expedited search and examination.

146. The Delegation of India reiterated that use of search and examination results of other offices should be carried out while respecting the sovereignty of participating offices. Noting that the technical capabilities and patentability requirements were different in different countries, the Delegation stated that the harmonization in that regard was not possible. The Delegation emphasized the need for further studies concerning the role of the sufficiency of disclosure requirement in the context of transfer of technology, since that requirement was linked to the patent quality. Further, the Delegation stated that as long as the work of the SCP remained within the studies, there was no risk to the patent system. In that context, the Delegation further reiterated that there should not be any attempt for harmonization of patent system and that the sovereignty of countries needed to be respected.

*A half-day information exchange session on cooperation between patent offices in search and examination*

147. The Delegation of Spain made a presentation on cooperation of the Spanish Patent and Trademark Office with other patent offices in search and examination. The presentation is available at:
http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_g_cooperation_spain.pdf.

148. The Delegation of Japan made a presentation on the JPO's initiatives on work sharing. The presentation is available at:
http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_h_cooperation_japan.pdf.

149. The Delegations of the Dominican Republic, El Salvador and Guatemala made a presentation entitled "quality of patents". The Delegations, *inter alia*, presented the Manual of Organization and Examination of Patent Applications of the Industrial Property Offices of the Central American Countries and the Dominican Republic. The presentation is available at:
http://www.wipo.int/edocs/mdocs/scp/es/scp_27/scp_27_i_cooperation_central_american_countries.pdf.

150. The Delegation of the United Kingdom made a presentation on collaboration of the Intellectual Property Office of its country with other patent offices in search and examination. The presentation is available at:
http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_j_cooperation_united_kingdom.pdf.

151. The Delegation of Singapore made a presentation entitled "Patent Work-Sharing Initiative". The Delegation focused on the ASEAN Patent Examination Cooperation (ASPEC) Program. The presentation is available at:
http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_k_cooperation_singapore.pdf.

152. The Delegation of the United States of America made a presentation on the United States Patent and Trademark Office (USPTO) international work sharing initiatives. The presentation is available at:
http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_l_cooperation_united_states_of_america.pdf.

153. The Delegation of Germany thanked the delegations which made presentations on cooperation between patent offices in search and examination. Furthermore, the Delegation provided an update regarding the activities of the German Patent and Trade Mark Office (DPMA) with other patent offices. The Delegation stated that since the year 2000, the DPMA had organized annual patent examiner exchanges with the patent offices of China, Japan, the Republic of Korea and the United Kingdom. In total, about 100 patent examiners of the DPMA had participated in those programs. The Delegation reported that all of those examiners had highly appreciated those exchanges and found them valuable. The Delegation further stated that, in 2013 and 2014, the DPMA had organized, in cooperation with WIPO, one week patent examination training course in the field of biotechnology in Munich. The Delegation stated that, in total, more than 30 patent examiners had taken part in the training representing examiners from the Patent Office of the Cooperation Council for the Arab States of the Gulf, Costa Rica, Cuba, Egypt, Georgia, Kenya, Macedonia, Nigeria, Pakistan, Ukraine, Vietnam and other countries. The Delegation continued that, in addition, over the previous five years, DPMA had organized with the patent offices of Brazil, China,

Malaysia and Singapore seminars and workshops for patent examiners. Further, the Delegation further stated that in 2008, the DPMA had also started participating in several bilateral PPH agreements, and in 2015, had joined the Global PPH. The Delegation also stated that PPH with China had been in place since January 2012.

154. The Delegation of Australia stated that the Vancouver Group had successfully demonstrated how similar-sized patent offices could operate collaboratively to help to improve efficiency in patent examination and the IP administration. The Delegation continued that, through that collaboration, participating offices had been aiming to contribute to an effective multilateral approach to the use and sharing of work products generated by each office. Further, the Delegation reported that a key new area of focus of the Vancouver Group offices would be in the area of searching of prior art during examination, and that they were in the process of starting a joint collaboration between the search specialist teams of each office. The Delegation noted that the new focus would consider how to best share and collaborate on information on best practices in searching techniques, databases and search tools. The Delegation stated that, in addition, the Vancouver Group offices would also investigate the sharing of information on the respective tools and techniques that each office used internally to assess the quality of their searches, and would also share information on the training materials on searching. In conclusion, the Delegation expressed its gratitude to the intellectual property offices of Canada and the United Kingdom for their continued participation in the Vancouver Group.

155. The Delegation of Ireland stated that, at the previous session of the Committee, it had reported that due to a small number of patent examiners in Ireland, the search reports had been established by the intellectual property office of the United Kingdom since 1992. Recalling its earlier statement that week, the Delegation stated that its office had reintroduced substantive examination as of May 2017. In that connection, the office had renegotiated with the intellectual property office of the United Kingdom to the effect that in addition to producing the search reports, they would provide the patent office of Ireland with the first written opinion on patentability, so that the applicant would get such opinion in conjunction with the search report. The Delegation stated that that would also facilitate moving to a substantive examination of its office. Referring to the trainings organized for their examiners, the Delegation expressed its acknowledgement and gratitude to the intellectual property office of the United Kingdom for its support to that new aspect of patent law in Ireland.

156. The Delegation of China thanked all the delegations which had shared their experiences on work sharing. The Delegation was of the view that by cooperating with other patent offices on search and examination, offices could reduce unnecessary duplication of work and improve the quality and efficiency of the examination. Recalling the statements of some delegations earlier that day, the Delegation stated that SIPO was carrying out various ways of cooperation in search and examination with other patent offices. Specifically, they included: pilot project on PPH in 23 countries and regions; provision of services for countries and regions, such as the GCC, Japan, the Republic of Korea; PCT collaborative search and examination projects; and other projects on sharing the search strategies. The Delegation looked forward to further enhancing the cooperation of the SIPO with other offices so as to enhance the quality of services and to increase the efficiency in search and examination to better serve its users.

*A sharing session on further examples and cases relating to assessment of inventive step*

157. The Delegation of Germany made a presentation on the German approach on the assessment of inventive step. In particular, the presentation focused on relevant decisions of the Federal Court of Justice (BGH). The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_m_inventive_step_germany.pdf.

158. The Delegation of Japan made a presentation on the practice of JPO in the assessment of inventive step. The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_n_inventive_step_japan.pdf.

159. The Delegation of Spain made a presentation on the assessment of inventive step. The Delegation focused on the issue of secondary indicia in the evaluation of inventive step. The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_o_inventive_step_spain.pdf.

160. The Delegation of Mexico made a presentation on the practice of the IMPI in the assessment of inventive step. In particular, the presentation was focused on the topic of juxtaposition vs. synergistic effects. The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_p_inventive_step_mexico.pdf.

161. The Delegation of the United States of America made a presentation on the practice of the USPTO in the assessment of inventive step/obviousness. In particular, the Delegation provided examples of determining obviousness under 35 U.S.C. § 103 in view of the decision of the Supreme Court in *KSR International Co. v. Teleflex Inc*. The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_q_inventive_step_united_states_of_america.pdf.

162. The Delegation of France thanked the Secretariat for the preparation of the working documents and for all the delegations that had made presentations during the SCP session. The Delegation reiterated its support for the proposal of the Delegation of Spain with regard to supplementary studies on the inventive step. The Delegation noted that the Intellectual Property Code L611-14 contained a provision regarding inventive step, which corresponded to Article 56 of the European Patent Convention, in particular, with respect to the definition of the prior art. The Delegation explained that while the French legislation did not define the term “person skilled in the art”, the national courts affirmed many times that “a person skilled in the art is someone who possesses the normal knowledge of the technology under question, and is capable, with the aid of his professional knowledge, of conceiving the solution of the problem which the invention proposes to solve”. The Delegation continued that it was therefore a specialist with the “average” qualification or capacity with normal knowledge in the field concerned, who could conceive the technical problem to which the invention responded. The Delegation noted that, according to French case law, a person skilled in the art did not possess professional knowledge belonging to any other specialty than his own: the person skilled in the art did not have any faculties of imagination or creation, but only abilities to associate the teachings of several documents if he was encouraged to carry out that association. The Delegation further stated that the French law did not define methods for assessing inventive step or threshold of inventive step. It explained that the assessment of the inventive step must, however, be as objective as possible, and in practice, both the INPI and the courts used the “problem-solution” approach in a manner similar to that of the EPO. In that approach, the Delegation stressed the importance of examining the incentive that a person skilled in the art might have to combine several documents in order to destroy the inventive step of a claim. In addition, the Delegation noted that the courts also used indices or

secondary criteria of inventive step (or non-obviousness), such as overcoming the prejudice of the skilled person or the time required to realize the invention. Referring to the French procedure, the Delegation stated that an opinion on the novelty and the inventive step of each patent application was made by INPI examiners with regard to 20% of the requests, and subcontracted to the EPO for the remainder. According to the Delegation, a written opinion on patentability, accompanying a preliminary search report, was formulated according to the "problem-solution" approach. The Delegation explained that, although that notice might mention a lack of inventive step, the Office could not reject the patent application on that ground in the absence of legislative provisions providing for it. The condition of patentability would, however, be taken into account when assessing the validity of the patent before the courts. The Delegation observed that the applicant was therefore informed of a possible defect of inventive step through the search report and the written opinion. In addition, the Delegation informed the Committee that INPI was currently working on setting up an opposition procedure on the ground of a lack of inventive step, based on which the Office would be allowed to offer an adversarial procedure, particularly on patents which involved a strong likelihood of disputes. In its opinion, the quality of French patents would therefore be strengthened.

163. The Delegation of the United Kingdom expressed its appreciation to other delegations for their informative presentations. The Delegation considered that sharing of experience and practice in the area of inventive step was very valuable. The Delegation noted that some of the examiners of the UKIPO had planned to watch those presentations in order to expand their understanding of inventive step practice in other jurisdictions. The Delegation stated that the inventive step was a crucial step in determining whether a patent could be granted. It recalled document SCP/22/3, in which the assessment on the inventive step, in particular, the definition of a person skilled in the art, methodologies for the assessment of inventive step and the level of the inventive step, had been examined as well as its presentation at the twenty-fifth session, during which the definition of a person skilled in the art and common general knowledge had been explained. The Delegation highlighted the importance of the transparency around the examination practice. It explained that the most up-to-date guidance on the United Kingdom's approach to inventive step can be found in the UKIPO's Manual of Patent Practice which was publicly available on the UKIPO's website. In addition, the Delegation thanked the Secretariat for producing the Questionnaire covering the aspects of quality of patents and cooperation between patent offices in search and examination. The Delegation also expressed its gratefulness to those additional Member States who had responded to that Questionnaire. As the responses to the Secretariat's questionnaire demonstrated, there were a variety of factors which influenced the quality of patents, including the underlying legal framework, office practices and procedures and the availability of mechanisms for challenging the validity of patents once granted. The Delegation observed that although the responses showed many ways of interpreting the term "quality of patents", they indicated that high quality patents were important to all Member States so that the patent system worked effectively. In its opinion, that initial fact-finding exercise was complete. Therefore, The Delegation suggested that the Committee further discuss other proposals relating to the quality of patents. The Delegation considered that while it might not be possible to reach a single common definition of the "quality of patents", there were two main concepts which had emerged from the responses as stated in document SCP/27/4 Rev.: the quality of a patent itself and a patent granting process within IP offices. The Delegation therefore was of the view that the Committee was in a position to pursue further work on how those two factors could be measured and how high quality patent rights could be achieved.

164. The Delegation of Portugal thanked the Secretariat for the compilation of the information gathered by the Questionnaire on the Term “Quality of Patents” and Cooperation between Patent Offices in Search and Examination. The Delegation considered that compilation very important, because it allowed sharing of information among Member States, providing a better understanding of how each Member State understood the quality of patents. 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. In addition, the Delegation expressed its support to the proposal by Spain, concerning a further study on inventive step. In that context, the Delegation thanked all the delegations that had made presentations on inventive step.

165. The Delegation of Australia thanked the Member States that had provided information on their systems and approaches to the assessment of inventive step. The Delegation informed the Committee of the recent developments in Australia with respect to inventive step. The Delegation noted that Australia’s Productivity Commission had conducted a wide ranging review of Australia’s IP arrangements and had released its report in December 2016. The Productivity Commission was the Australian government’s principal review and advisory body on microeconomic policy, regulation and a range of other social environmental issues. One of the recommendations it had made, which had been accepted by the government, was that the Australia’s inventive step criteria be amended in order to align it with that of the European Patent Office. According to the Delegation, that had been recommended to be implemented through raising the inventiveness threshold and introducing a requirement for applicants to disclose the technical feature of their inventions. The Delegation noted that it was consulting with the users of its system on how such a change could be implemented. It was expected that that would better align the Australia’s approach with the international standards. The Delegation looked forward to providing further updates on their proposed legislative changes, as its consultations and legislative processes would progress.

166. The Representative of APAA stated that the assessment of inventive step should be carried out objectively and be predictable in terms of quality examination. The Representative further noted that, as one of the core patentability requirements, subject matter eligibility should be differentiated from exceptions and limitations to patent rights, in the sense that substantial examination was required to assess the eligible subject matter, which had been understood to be distinct and independent from novelty and inventive step. In that regard, the Representative expressed her concern that the recent case law development in some jurisdictions, which were also very influential in the Asian countries as well, seemed to require prior art references in the description to be considered when assessing the subject matter eligibility, which had justifiably created considerable confusion among users. Taking those circumstances into consideration, APAA was of the view that an assessment of the subject matter eligibility should be clear, objective and predictable, and for that reason, prior art references should not be considered in the subject matter eligibility assessment, and should be left to the assessment of inventive step. In order to ensure an adequate balance between subject matter and the inventive step, the Delegation suggested that WIPO facilitate compilation of prior art references so that they would be sufficiently accessible for patent granting authorities and users so as to achieve quality examination.

167. The Representative of FICPI stated that FICPI recognized the fact that quality of patents was most important for a functioning patent system, advancing technological improvement and being beneficial for all societies. He observed that the quality of patents concerned not only the quality of a patent itself that meant a robust patent, but also the quality of a process, including the cost, time and efficiency of the process. The Representative noted that the diverse work groups within FICPI, such as CT3, CT7 and others, had focused on diverse issues related to the said elements of the quality. For instance, one aspect was the unity requirement which was handled in diverse ways worldwide, and other aspects were inventive step and legitimate interest in obtaining patent protection. The Representative noted that, at its Executive Committee held in China in March 2017, FICPI had prepared a Resolution, focusing on one aspect of the patent quality. The Resolution stated that: Observing that in the examination of patent applications, despite the continuing development of their document databases, patent offices do not have the resources to access all relevant disclosures that may have been made available to the public; Noted that a patent grant procedure should be of reasonable duration and without undue delay; further noted that there should be a balance between the interest of an IP right holder and third parties; acknowledged that numerous patent offices provide cost-effective administrative proceedings allowing a third party to file observations on the patentability of a pending patent application and/or an opposition against a patent application or recently granted patent utilizing the offices' expertise, FICPI urges and encourages authorities (i) to provide *inter-partes* opposition proceedings against a patent application or recently granted patent, including at least on the grounds of novelty, inventive step and lack of industrial applicability; (ii) to provide balanced procedural treatment of the parties in the opposition proceedings; (iii) to ensure that official fees for such opposition proceedings are kept on a reasonable level and that the parties should usually bear their own costs; (iv) to ensure that the time for completing such opposition proceedings is sufficient for resolving them with careful consideration of the issues, without an undue delay; and (v) to ensure that such administrative proceedings should not preclude a subsequent nullity or revocation actions between the same parties before a court or other relevant authority; further urges and encourages authorities to implement or retain existing pre-grant *ex parte* observation proceedings in addition to such opposition proceedings and to retain existing re-examination proceedings in addition to such opposition proceedings. Noting that FICPI was still working on that Resolution, and in view of the importance of quality of patents, the Representative strongly urged the Committee to keep that subject on the agenda for future sessions, focus on it and bring forward a resolution at the later stage, if possible. The Representative further stated that, due to lack of time, FICPI's resolution focusing on the formal requirements could not be finalized. The Representative informed the Committee that the focus of that draft resolution was on the user friendly system that made it possible to adapt claims when a PCT international application entered the national/regional phase, since in some countries, it was difficult, or impossible, to amend the claims and to save claim fees.

168. The Delegation of Senegal, speaking on behalf of the African Group, reiterated that the African Group could not support the idea of a study under that agenda item, since the Committee had not come to the consensus of the definition of "quality of patents". In its opinion, such a definition was absolutely fundamental for moving forward with that issue. The Delegation observed that, while there had been various discussions and presentations on that subject, Member States still did not have the same understanding of the concept of quality. The Delegation considered that the Committee needed to reach a consensus on the definition of the notion of quality before it could go into further depth on that issue.

169. The Secretariat presented the SCP webpage on opposition and other revocation mechanisms.

**AGENDA ITEM 10: CONFIDENTIALITY OF COMMUNICATION BETWEEN CLIENTS AND THEIR PATENT ADVISORS**

170. The Delegation of Iran (Islamic Republic of) expressed its belief that the issue of the confidentiality of communication between clients and their patent advisors was not a substantive patent law issue and could be governed by national laws. The Delegation was of the opinion that confidentiality of communications between clients and their patent advisors fell outside the scope of the patent law and should be treated at the national level, since it was a matter falling within the scope of private law and the regulation of professional services. The Delegation therefore stated that it did not see any added value for further discussion on that issue in the coming session of the Committee.

171. The Delegation of Georgia, speaking on behalf of the CEBS Group, attached a great importance to the continuation of work under that agenda item, and welcomed the decision of the previous session of the SCP 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 a soft law approach, which had been proposed during the previous Committee meetings, could be pursued and effectively applied in that area. The Delegation expressed its belief that the convergence of existing diverse systems in that particular area would benefit all users of the patent system.

172. The Delegation of Switzerland, speaking on behalf of Group B, stated that it attached a high importance to the topic of confidentiality of communications between clients and their patent advisors. Observing that patents were increasingly filed and granted in various jurisdictions, the Delegation pointed out that the issue between clients and patent advisors was strongly related to the patent filing procedures, patent prosecution and litigation in different countries. In its opinion, the issue had a significant impact on how the patent applications were filed, and how communications under those procedures were handled. The Delegation noted that patent applicants or owners needed to be able to receive cross-border legal advice without any risk of forced disclosure of confidential communication received from their patent advisors. The Delegation was of the view that unclear or lack of regulations in that area in countries had caused legal uncertainty and unpredictability, and thus, the users of the patent system – both patent applicants and patent advisors – were affected. The Delegation recalled that users of the patent systems from different regions, for example, Canada, Japan, Switzerland, Brazil and India, had emphasized the need to treat that subject at the international level, since they could not rely on national legislations to preserve the confidentiality of their information in cross-border situations. The Delegation therefore stated that Group B strongly expected the SCP to respond to that issue. The Delegation added that the protection of confidentiality would not affect the disclosure of an invention, since patent laws worldwide required that a patent application disclose the invention in a manner sufficient for a person skilled in the art to put that invention into practice. It stressed that such a patentability requirement was not compromised by a client-patent advisor privilege, and neither did the confidentiality of communication between clients and their patent advisors affected the level of available prior art for patent examiners. The Delegation stated 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 differences in their applicable legal systems. In that light, the Delegation urged that a soft law approach, which had been proposed during the previous SCP meetings, should be further pursued. In addition, the Delegation expressed its belief that court cases in different national legal systems in that field would provide resourceful materials for Member States and would contribute to further discussion. While Group B recognized that different opinions had been presented around that issue in the previous sessions, the Delegation reiterated its invitation to all Member

States, particularly to those opposing further work to tackle the problems, that they saw the SCP work in that area in a more objective manner in order to foster the discussion of what could be accomplished at the Committee. The Delegation suggested that a questionnaire in that area be conducted, and that the collection of court cases be continued so as to allow Member States to provide additional relevant court cases.

173. The Delegation of Estonia, speaking on behalf of the EU and its Member States, welcomed the decision of the previous session of the SCP that 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, would be held at the twenty-seventh session. The Delegation saw that as an opportunity to get valuable insight into the national practices supplementing the compilation of court cases with respect to patent advisor-client privilege, which had been prepared by the Secretariat (document SCP/25/4). The Delegation reiterated that the EU and its Member States would like to see further actions to be taken by the Committee. It expressed its belief that work on a non-legally binding instrument would be beneficial to all WIPO Member States. In its opinion, the potential soft law instrument should aim at conferring in Member States the same protection for communications between a client and its foreign patent advisor and for communications between a client and its national patent advisor, as applicable under the national law. The Delegation noted that it should be without prejudice to existing national legislation and should ensure optimal flexibility. It considered that the convergence of existing diverse systems in the area of confidentiality of communications between clients and their patent advisors among WIPO Member States would benefit users of the patent system, irrespective of the level of development of the individual Member States.

174. The Delegation of Senegal, speaking on behalf of the African Group, thanked the Secretariat for organizing a sharing session on experiences of Member States on implementation of confidentiality of communications between patent advisors and their clients. The Delegation reiterated the position of the African Group, and supported the statement made by the Delegation of Iran (Islamic Republic of). In its opinion, the issue was more relevant to private law than to patent law itself. The Delegation therefore was of the view that it should be addressed under national/regional legislation of the Member States. The Delegation did not consider that the issue was a substantive patent law issue, and therefore, it was up to each Member State to deal with it, as they saw fit under the national legislation.

*A sharing session on the experiences of Member States in implementing the confidentiality of communication between clients and their patent advisors through national legislation*

175. The Delegation of Denmark stated that the confidentiality of communications between clients and their patent advisors was a topic that was of great importance to the Danish user community. The Delegation was of the view that confidentiality of communications raised cross-border questions that posed an actual challenge to companies and IP advisors in their everyday work. In its opinion, the IP advisors that provided services to clients in other jurisdictions constantly had to find ways to work around such a challenge. The Delegation noted that it had been looking into how the situation of IP advisors could be improved. More concretely, it had been exploring whether IP advisors should be covered by client-patent advisor confidentiality before the national courts. The Delegation informed the Committee that it was expected that a legislative proposal to change the Danish Civil

Procedures Act would be presented to the Parliament in 2018, and expressed its readiness to share information on that issue at a later stage. Given the cross-border aspects of that topic and its importance to the user community, the Delegation remained dedicated to discussing that topic in the context of the SCP.

176. The Delegation of Hungary shared information on its relevant legislation with the Committee. The Delegation state that a patent attorney was a regulated profession: its law stipulated that only the members of the Hungarian Chamber of Patent Attorneys might act as a patent attorney. The Delegation explained that admission to that Chamber was subject to a number of conditions, some of which were the following: Hungarian nationality or a nationality of a country of the European Economic Area or domiciled in Hungary; having a master degree in natural sciences; having passed the relevant examination; having liability insurance valid in Hungary; and having appropriate residence or premises for carrying out the activities. The Delegation observed that as a consequence of those rules, the possibility of foreign patent attorneys acting as representatives before Hungarian authorities was rather limited in practice. Notwithstanding the above, the Delegation noted that patent attorneys were under a secrecy obligation with respect to all facts and data that came to their knowledge in connection with their activities, and that should remain confidential also after the termination of their activities. It further noted that the secrecy obligation extended to all documents that contained such privileged information. The Delegation considered that since those rules were applicable to both domestic and foreign clients of the attorney, they provided for confidentiality of communications even in cases that had a cross-border element. As another aspect that needed to be examined, the Delegation pointed out cases where members of the Hungarian Chamber of Patent Attorneys acted in patent proceedings abroad. It observed that the law, somewhat ambiguously, stated that in such cases, the relevant foreign law should be primarily applicable, but the Hungarian rules concerning the obligations of the patent attorney also needed to be applied correspondingly. The Delegation regretted that it could not report experience on their legislation's practical application, as there had been no court cases so far where the cross-border aspect of client-attorney relations had been relevant to the dispute. Nevertheless, in line with the positions of the CEBS Group and the European Union, the Delegation supported continuing work on that topic, with the possible long or mid-term goal of creating a soft law instrument.

177. The Delegation of Ireland stated that since 1992, its Patent Act provided for privileged communications. At that time, it had applied only to patent advisors who had been qualified under the Irish law to act as a patent advisor and also who had had to be registered in its national register of patent advisors, which was maintained by the Irish Patents Office. The Irish Patent Officer was responsible for setting the qualification examination which aspiring patent advisors must pass in order to get admission to practice before the Office and to be on the national register. In 2006, the Patent Act had been amended in order to include patent advisors from and European Economic Area countries who were qualified under their own national law to act as a patent advisor in their own jurisdiction. The Delegation strongly supported the statement made by the Delegation of Estonia on behalf of the EU and its Member States. The Delegation stated that it was very keen to see further work on that area, particularly with regard to the cross-border aspect. The Delegation was of the view that a non-legally binding instrument, such as a soft law approach, had a number of benefits for all Member States, and would help to remove much legal uncertainty which surrounded the cross-border communication between clients and their patent advisors. The Delegation observed that such communication had been increasing more and more, as the globalization progressed. While no case law existed in Ireland, should it be in the future, the Delegation expressed its willingness to report it to the Committee.

178. The Delegation of the United States of America stated that the consistent approach to cross-border protection for communications with patent practitioners remained an important topic to the United States of America. It noted that over the past year, there had been further developments in that area, which benefited all users of the United States patent system. The Delegation explained that in the United States of America, while attorney-client privilege had long protected communications with attorneys practicing in that country, such privilege had not been consistently recognized for foreign patent practitioners and non-attorney practitioners. The Delegation continued that courts used a variety of approaches to determine whether the privilege applied. The Delegation informed the Committee that although a 2016 ruling by the Court of Appeals for the Federal Circuit in the case *in re Queens University* had recognized the privilege of communication with non-attorney patent agents, such privilege did not apply to foreign non-attorney patent practitioners. While the USPTO did not have jurisdiction over US courts, it did have jurisdiction over several proceedings before the agency that operated under the rules similar to litigation. The Patent Trial and Appeal Board (PTAB) was an administrative tribunal within the USPTO which handled, for example, *inter partes* review, post-grant review and covered business methods review. Those proceedings had a discovery phase where the issues such as privilege could arise. In the past, the USPTO rules for those proceedings had not explicitly addressed privilege issues, defaulting to common law rules used in Federal courts. In October 2016, the USPTO had published a proposed rule in the Federal Register on privilege. It recognized privilege for all domestic and foreign patent practitioners who met professional qualifications to practice patent matters in at least one jurisdiction. The public comments had been due in December 2016. Responses received from legal associations, corporations, law firms and individual practitioners both in the United States of America and abroad had overwhelmingly supported the rule with a few suggestions for improvements to the language. On November 7, 2017, the final rule on privilege in the USPTO proceedings had been published. It had taken effect after 30 days. A few minor clarifications had been made in response to comments, but the thrust of the rule remained the same: to protect communications with any eligible practitioner acting within the authorized scope of their duties, whether domestic or foreign. The term “foreign practitioner” was defined under that rule as a person who was authorized to provide legal advice on patent matters in a jurisdiction outside the United States of America, provided that the jurisdiction established professional qualification and the practitioner satisfied them. The Delegation explained that the privilege did not alter the duties of disclosure, candor and good faith when practicing before the agency. It stated that communications were only protected from third parties during the discovery procedures, which did not apply to examination of patent applications. The Delegation clarified that the said rule only applied to the PTAB tribunal and did not change how the Federal and State courts handled questions regarding privilege. However, the Delegation noted that it might spur other courts to consider revisions of their own rules or legislation to the same end in light of those developments.

179. The Delegation of Germany sketched out the German legal framework of client-attorney privilege. The Delegation noted that the German law protected the confidentiality of communications between a patent attorney and his or her client. The patent attorney had to keep the communication with the client confidential, and had the right to refuse testimony. Those two principles created the client-attorney privilege for German patent attorneys admitted to the bar. The Delegation explained that such privilege also applied to any foreign attorney and patent attorney (or patent advisor) who, under the jurisdiction of his or her place of business, was obliged to keep confidentiality and had the right to refuse testimony. The Delegation further noted that since the beginning of 2016, the German law

had provided for the obligation of in-house attorneys and in-house patent attorneys to keep confidentiality of correspondence with the right to refuse testimony in civil legal procedures. The Delegation therefore supported the positions of the EU and its Member States as well as Group B concerning the issue of client-patent advisor privilege.

180. The Delegation of Japan reiterated its position that had been expressed during the previous SCP sessions. The Delegation considered that in order to ensure that patent attorneys and their clients could maintain honest and frank communication, such communication must be properly protected in every country. Furthermore, the Delegation was of the opinion that the attorney-client privilege issue needed to be addressed from a cross-border perspective. The Delegation expressed its belief that, to that end, the Committee should continue discussion towards establishing an international framework that could be accepted by a large number of countries.

181. The Delegation of China thanked the Secretariat for organizing an information sharing session. The Delegation considered that such a session could facilitate sharing of experiences by Member States on the subject under consideration, and could assist Member States to deepen their understanding of the issue. The Delegation considered that the issue of confidentiality of communication between clients and their patent advisors was of the interest for countries of different sizes. The Delegation observed that Member States had different degrees of knowledge on that issue: some countries had already advanced in that field, but in some other countries, patent advisors did not have privilege and lacked enough experiences in that area. In its opinion, the issue was closely related to national legal systems which were quite different from country to country. The Delegation explained that, with respect to the Chinese legislations, for instance, attorneys did not have a right to reveal any elements or contents requested by the clients. According to the Delegation, while it was a kind of norm and obligation, it was not privilege. The Delegation further observed that some other countries might not have such provisions in their national laws. Therefore, the Delegation was of the view that Member States had to respect the legal traditions of different countries to let the national law decide whether a country could apply the privilege system. In its opinion, the time was not mature for the Committee to solve that problem at that point.

182. The Delegation of the United Kingdom stated that cross-border aspects of the topic under discussion were of particular importance to the United Kingdom and to its users. For that reason, it supported the statements made by the Delegation of Estonia on behalf the EU and its Member States and Group B. The Delegation noted that in response to the recent Circular, No. 8653, inviting Member States to submit information, it had submitted updated information on existing UK law. It explained that in summary, the wording of Section 280 of the 1988 Copyright, Designs and Patents Act meant that patent attorney privilege was confined to communications with patent attorneys registered in the United Kingdom and with European patent attorneys. The Delegation clarified that privilege was not extended to other foreign patent attorneys, but patent attorneys who were lawyers were covered by solicitors privilege. The Delegation welcomed further work on a comprehensive review of case law from other jurisdictions, and further studies on that matter.

183. The Delegation of Switzerland stated that, in its country, patent attorneys had been subject to professional confidentiality since entering into force of the Federal Act on Patent Attorneys on July 1, 2011. The Patent Attorneys Act was part of the broad reform of patent law in Switzerland started in 1998. The Delegation noted that the new legislation had significantly improved the standing of patent attorneys in Switzerland and abroad by means of regulating the use of the professional title, and introduction of a statutory client-patent attorney privilege. The Delegation explained that before the enactment of the Patent

Attorneys Act, the training and qualification of patent attorneys had not been regulated in Switzerland. It further noted that since even unqualified persons could perform the actions of a patent attorney and carry that title, their clients had been put at risk of receiving incomplete and incompetent advice and representation with existential consequences. The Delegation further explained that the Swiss legislators also noted the increased demand of quality advice and representation due to the massive international linkages in patent prosecution and enforcement. The Delegation observed that the lack of professional regulations had put Swiss patent attorneys and their clients at risk to be obliged to disclose secret documents during the court proceedings in other jurisdictions, while their counterpart was able to claim professional secrecy. To resolve that problem, it was prescribed that courts in other jurisdiction accepted the professional secrecy of a foreign patent attorney, provided that his country of origin had similar level of secrecy protection, or the patent attorney had equivalent function and qualification as a patent attorney in the country of the court proceeding. Enshrining that into law, the Swiss legislators sought to improve the initial position of a Swiss patent attorney and the clients in cross-border situations. The consultation of the draft of the Patent Attorneys Act took place in 2006. While it had been widely supported, critics had been the negative impacts on the freedom to pursue professional activity. According to the Delegation, concerns about higher costs for professional advice and representation that would burden small and medium sized companies were raised. The Swiss Parliament adopted the Patent Attorneys Act in 2007, which underlined the understanding that qualified expert advice in patent matters was key for Switzerland and innovation. Under the Swiss Patent Attorneys Act, only persons with proven expertise were allowed to use the professional title of a patent attorney. Before taking up that occupation, they must register themselves in a patent attorney register and prove that they possessed the required professional qualifications. The Delegation explained that such rules allowed the public to choose a professional and competent service provider. In addition, it served to protect concerns of the person being advised by imposing an obligation of professional secrecy on patent attorneys. The Delegation observed that the secrecy obligation reflected the fact that patent attorneys received highly confidential information during consultation and representation, which included information on inventions before patent application or business secrets associated with the invention. The Delegation explained that, for the client, it was of great economic importance that such information was protected. In its opinion, the client needed to unreservedly trust in the confidentiality of the patent attorney in order to disclose all relevant information. With the view to increasing international trade and related IP questions, according to the Delegation, the Swiss provision on professional secrecy was to improve the situation in the cross-border court proceedings in other jurisdictions, involving a Swiss patent attorney. Noting some positive impact of the statutory Swiss patent attorney-client privilege, the Delegation referred to the case before the District Court of New Jersey, where the court had applied the US privilege to a Swiss patent attorney, with a reference to the amended Swiss Patent Law and Article 160 of the Swiss Code of Civil Procedure. The Delegation noted that prior to the enactment of the Patent Attorneys Act, another court had denied such privilege, and a Swiss patent agent, his client and a Swiss in-house council had not been protected by professional privilege. The Delegation highlighted that although the professional secrecy had a national character, it could not be maintained in the cross-border situations. In its opinion, the present situation at the international level showed that adequate regulations for the protection of confidentiality did not exist in every country. The Delegation was of the view that in many countries where it existed, the protection was not always applied to foreign patent attorneys or did not apply to them to the same extent as to the domestic professionals. The Delegation therefore stated that such a situation was unsatisfactory with respect to legal certainty and predictability, and did not provide the safeguard for sensible information and trust in the client-patent attorney relationship. The Delegation believed that a full and frank conversation between the patent agents and their clients under that circumstance was not possible. In its view, that compromised the quality of legal advice

with an impact on patent prosecution and the quality of patents. The Delegation reminded the Committee that it had proposed to pursue future work based on soft law regarding the cross-border aspect of the client-attorney privilege, which might contain general definitions of key terms, such as patent advisor or privileged information, and the minimum standard of the privilege. The Delegation considered that such a soft law framework might serve as a template for national laws, and would provide a flexible approach that allowed adapting national legislations in accordance with the national legal background and needs. As a way forward, the Delegation stated that the work of the Committee could focus on how foreign patent attorneys were protected in other jurisdictions.

184. The Delegation of the Republic of Korea emphasized the importance of the client-patent advisor privilege, particularly when it came to cross-border lawsuits, since international disputes over patent rights were globally being increased. The Delegation considered that in order to have an invention to be protected effectively in the global market, a full consideration should be given to confidentiality-based communication between a patent advisor and his/her client and preservation of confidentiality. The Delegation expressed its belief that the subject under the present agenda item could be effectively and desirably discussed in the SCP meetings. In its view, even though each Member State operated different legal systems, confidentiality of communication between a patent advisor and a patent applicant with good will should neither be harmed nor invaded due to the different legal systems. The Delegation expressed its hope that each Member States would make efforts to get involved in the discussion constructively with open mind.

185. The Delegation of India noted that the attorney-client privilege did not apply to patent agents in India. It explained that the patent agents were not necessarily advocates, and that persons who had the degree in science or engineering could practice before the patent office as authorized patent agents, once they passed the qualification examination. The Delegation stated that the Indian Evidence Act only provided protection for advice from lawyers or advocates from being disclosed during the court proceedings, and that patent agents having scientific or technical background did not qualify for such protection. The Delegation therefore considered that no requirements in that regard should be required at the international level.

186. The Delegation of Australia stated that its legislative provisions afforded foreign innovators privilege, and thus communications with patent attorneys in their own country and with Australian patent attorney were privileged when they sought protection in Australia. The Delegation however noted that when the Australian clients sought protection of their intellectual property overseas, they could not be confident that their confidential communications, even with their local patent attorneys in Australia, would be protected from disclosure in foreign court proceedings. The Delegation explained that Australia had made revisions in its law in 2012: the Raising the Bar Act of 2012 had introduced the cross-border recognition of privilege for advice from non-lawyer patent and trademark attorneys, which had come into effect on April 15, 2013. According to the Delegation, those amendments to the Patents Act and the Trademarks Act extended privilege to overseas attorneys who were authorized to provide intellectual property advice, and better aligned privilege communications between lawyers and their clients with those between patent and trademark attorneys and their clients. The Delegation expressed its belief that free and frank communication between clients and their patent attorneys was essential to good, clear, and well-articulated patent applications. In the context of the global patent system, the Delegation was of the view that high quality professional representation led to well drafted specifications, greater certainty in the validity of granted patents, and importantly, an increase in the quality of information disseminated to the public for the purpose of further innovation.

187. The Delegation of Chile reiterated that the regulation of the subject under discussion was a question that corresponded to the domestic legislation of each country. The Delegation noted that, in Chile, the confidentiality between clients and their patent advisors, whether they were lawyers or not, was covered by the mutually agreed terms between them. It explained that such "confidentiality contract" was one of those that were called "unnamed contracts" i.e., it was not expressly regulated and was governed by the principle of the autonomy of the will, typical of private law. The Delegation further noted that in terms of confidentiality between clients and their patent advisors, certain ethical obligations for lawyers, which were found in the Professional Code of Ethics of the Bar Association, including provisions for both confidentiality and the professional secrecy, were also applicable. According to the Delegation, the Political Constitution of Chile stated that professional associations should be empowered to hear complaints against the ethical conduct of their members, and their decisions might be appealed to the respective Court of Appeals. The Delegation further clarified that with respect to lawyers who were not associated, it was stated that they would be tried by the ordinary courts. Furthermore, the Delegation informed the Committee that the jurisprudence of the Supreme Court of Justice had guaranteed in its rulings the reserved nature of the documents that were exchanged under the professional secrecy of the lawyer. The Delegation stated that it was available to share more information on how the topic was addressed in Chile, if it was of interest to other delegations.

188. The Representative of UNION stated that the Committee should continue exchange of experiences on that issue, which would lead to positive results of the better understanding of the matter. The Representative noted that UNION was an association of practitioners from different European countries in the field of intellectual property, that was, individuals whose principal professional occupation was concerned with patents, trademarks and designs and who carried on their profession independently or as employees. The Representative stressed that UNION represented IP practitioners from all European countries, including Ukraine and the Russian Federation, and not only from the European Patent Convention (EPC) Member States. The Representative further noted that, most importantly, UNION did not represent simply the clients who were IP owners, but was concerned about the public interest, which was always a goal in its studies. The Representative noted that it had produced a position paper on client-attorney privilege for patent advisors. She stated that client-attorney privilege in the IP context should be considered as the right to resist requests from authorities or other parties to disclose communications between a person and that person's IP advisor. Based on its experience, UNION considered it unacceptable that IP professionals who were obliged to keep information confidential under one national law might face even criminal prosecution in other countries for complying with that obligation. With regard to the WIPO study on the patent attorney privilege, the Representative stressed that any further discussion would enhance the issues at hand. The intension of UNION, she stated, was to stress practical issues so as to help finding the best possible formulation for a common agreement. The Representative endorsed the position that had been taken by AIPPI. Referring to the joint proposal that had been prepared by the AIPLA, AIPPI and FICPI, the Representative produced some specific comments on practical points, as follows. Firstly, as regards the notion of intellectual property advisor, the Representative noted that the qualification of an IP advisor could be clarified further, and that the following should be taken into account: (i) contrary to common law countries, in many civil law countries, there was generally no protection for in-house counsels, since they were considered to be a separate profession and did not enjoy the same status and protection as an independent patent attorneys. Secondly, the Representative stated that in some countries, it could be unclear whether a patent attorney was a qualified professional or not. For instance, in Sweden, the title "patent attorney" was not protected, thus anyone might say that he/she was a patent attorney, even though they had not possessed relevant education at all. The

Representative further noted that in other countries, communications with third parties might be covered by privilege. For instance, in the United Kingdom, the privilege covered communications between a lawyer or client and a third party which came into existence for the dominant purpose of being used in connection with actual or pending litigation (litigation privilege). The Representative explained its position that the IP advisor should be a qualified professional duly authorized in accordance with domestic law and to whom there was adequate regulation. In that respect, the Representative considered it beneficial If each country could provide WIPO with the specific categories of advisors whose clients benefited from privilege under that standard. The Representative then commented on the second issue, i.e., which intellectual property rights were covered by the client-attorney privilege. The Representative expressed her belief that the expression "any matters relating to such rights" could be clarified, and could be enhanced by including some examples that would allow the reader to understand the full scope of that definition. Thirdly, as regards the issue of communication, the Representative commented that the wording could be enhanced as follows: communication includes any communication made by any means (for example, oral, written or electronic record), irrespective of the country of origin of that communication, whether it is transmitted to another person authorized to receive such communication or not. Concerning professional advice, the Representative suggested that the reference to "mere statements of fact" could be further explained in order to avoid misinterpretation of the scope of the exception. Furthermore, the Representative highlighted that there were already specific limitations which covered communications from patent attorneys. For instance, in the contents of the future Unified Patent Court (UPC), the Proposed Rule 287 provided that advice from lawyers and non-lawyer patent attorneys were privileged, from proceedings before the UPC. In addition, Rule 153 of the Implementing Regulations under the European Patent Convention (EPC) provided that advice from professional representatives to client were privileged from disclosure in proceedings before the European Patent Office. The Representative then presented two examples of specific cases regarding the application of that specific rule. The first example was that Article 64-3 of the EPC made reference to the national law in case of infringement of a European patent, and therefore, that provision expanded significantly the scope of such protection by national laws. The second example was that Rule 153 had been amended under the French law on October 21, 2008, and the amended version had entered into force on April 1, 2009. Consequently, in the view of the Representative, it was unclear if the privilege was applicable to communications/advice given before that date. Considering the above, the Representative was of the opinion that it would be very difficult to implement the system which prevented States from limiting or varying the scope of the privilege. The Representative believed that the weakest protection which could not be abolished by the State in any circumstances would be the best solution, provided that it did not reduce the protection provided in clause 2 of the joint proposal by the AIPLA, AIPPI and FICPI.

189. The Representative of FICPI referred to the joint proposal that had been brought forward together with AIPPI and AIPLA, and expressed its appreciation for the statement made by the Representative of UNION. The Representative stated that he clearly saw the cross-border impact of the issue on his everyday practice, especially in relation to clients of patent attorneys. The Representative noted that the impact was very grave, regardless of the location of patent attorneys and of patent owners. In addition, the Representative expressed its appreciation to the Delegation of the United Kingdom for bringing its position forward.

190. The Representative of JPAA expressed his strong belief that the so-called attorney-client privilege was a very important legal concept, as it protected important trade secrets from disclosure to third parties. Noting that the privilege was not used to hold the important prior art from patent offices, the Representative explained that under the Japanese Civil

Procedure Code, patent attorneys were not forced to give testimony, if a given question was related to confidential information known through the course of his/her work. The Representative also noted that patent attorneys could also reject the production of documents which related to such confidential information. Furthermore, the Japanese Patent Attorneys Act prescribed the confidentiality obligation of patent attorneys. The Representative highlighted that the purpose of those provisions was, in essence, to protect clients' confidential information. Given the importance of the issue, the Representative hoped that the discussion on client-patent advisor privilege would continue further in the SCP with all Member States participating in the discussion. The Representative expressed his belief that a so-called soft law approach, or setting minimum standards, would be a good way to resolve the issue.

191. The Representative of AIPPI, supporting the statements made by the Representatives of UNION and FICPI, stated that AIPPI maintained its position that the SCP should continue its consideration on the question under discussion. In his opinion, the issue was important, because it was about trust between the client and his patent advisor. He observed that if there was no certainty of confidentiality, there would be no trust between the client and his patent advisor. In his view, that would go against the transparency that every SCP member and observer desired to see.

## AGENDA ITEM 11: TRANSFER OF TECHNOLOGY

192. The Delegation of Switzerland, speaking on behalf of Group B, stated that it acknowledged the utmost importance of transfer of technology and WIPO's work regarding that matter. The Delegation was of the opinion that intellectual property helped to promote transfer of technology on voluntary and mutually agreed terms, which led to wide dissemination of technologies for society's benefits. The Delegation observed that for a number of years, WIPO had been engaged in a multitude of transfer of technology-related activities that had benefited low and middle income countries, which had been extensively considered at the CDIP. At the twentieth session of the CDIP, a list of WIPO activities and resources related to technology transfer had been discussed. Likewise, a compilation of technology exchange and licensing platforms had been submitted to the CDIP. The Delegation further recalled that the joint proposal by Australia, Canada and the United States of America, which showed how WIPO should proceed in that field in order to ensure sustainability of results of the Project on IP and technology transfers, had been approved at the earlier session and had been the subject of further discussion at the twentieth session of the CDIP. Group B believed that concrete issues and activities related to the role of WIPO in technology transfer should be discussed at the CDIP, rather than during the SCP sessions. In its opinion, the CDIP was more competent to handle concrete projects, and the SCP should avoid duplication of work. Moreover, the Delegation stated that Group B did not want to prejudge the CDIP's outcome.

193. The Delegation of Georgia, speaking on behalf of the CEBS Group, reiterated the importance it attached to Agenda Item 11 and acknowledged the role of WIPO in promoting the technology transfer. The Delegation therefore welcomed the decision to hold a sharing session on patent law provisions that had contributed to effective transfer of technology. The Delegation expressed its belief that while the transfer of technology was an enabling factor in fostering development, the CDIP was the space where the issues should be discussed, taking into consideration the recent successful developments with respect to the technology transfer issue at the CDIP. In its view, the Committee needed to avoid any duplication.

194. The Delegation of Estonia, speaking on behalf of the EU and its Member States, stated that transfer of technology was an important factor in fostering development. The Delegation therefore welcomed the decision of the SCP at its twenty-sixth session to hold a sharing session on patent law provisions that had contributed to effective transfer of technology. However, considering that the CDIP had produced an excellent overview of the work that WIPO had been performing in that area, the Delegation stated its position that the SCP should avoid duplicating the efforts of the CDIP in that respect. The Delegation noted that during the twentieth session of the CDIP, the Secretariat had introduced the compilation of technology exchange and licensing platforms contained in document CDIP/20/10 Rev. The Delegation considered that such information was extremely useful in obtaining an overview of the situation and informing WIPO's work in that area, and was glad to see the relatively big number of national, regional and international platforms covered in that non-exhaustive compilation. The Delegation drew attention of the Committee to the fact that out of the five relevant regional networks and platforms covered in that compilation, two were located in Europe and hosted by the European Commission, which, in its view, indicated the importance attached by the EU to the issue of technology transfer. In addition, the Delegation took note of the various changes related to technology transfer and licensing platforms identified in the document, and acknowledged the need to keep in mind that those challenges posed particular difficulties in developing countries and LDCs. The Delegation continued to support updating WIPO's web page regarding information on national, regional and international technology exchange and technology licensing platforms.

195. The Delegation of Costa Rica, speaking on behalf of GRULAC, reiterated that the SCP should continue considering the agenda item on transfer of technology, looking at cases in which patent law provisions had contributed to effective transfer of technology and the forms that would make patent information available to the public.

196. The Delegation of Senegal, speaking on behalf of the African Group, supported the agenda item on transfer of technology. The Delegation considered that transfer of technology played a catalyst role in the development, and promoted innovation as well as skills and know-how in developing countries and LDCs. The Delegation recalled that the WIPO Development Agenda had a whole chapter on transfer of technology from Recommendations 24 to 32. The Delegation was of the opinion that in accordance with Recommendation 25 the Committee should study regulations on intellectual property required for transfer and dissemination of technology for the benefit of developing countries, and appropriate models that would enable those countries to fully understand the various different provisions with regard to flexibilities in international agreements from which they might benefit. As the SCP dedicated to study patent issues, the Delegation considered that it had an important role to play with respect to the issues relating to transfer of technology, independent from what other bodies or Committees did under their own mandate and their own methodologies of work. It observed that the approach of the SCP was not a project-based approach, but was ongoing work unlike that of the CDIP. In its view, the SCP was the perfect place to have an ongoing study on transfer of technology regarding patents, and thus transfer of technology needed to remain on the agenda of the SCP. The Delegation encouraged the SCP to go into depth on the issue of transfer of technology that related to patents. In that light, the Delegation welcomed the sharing session and thanked the Secretariat for its work.

197. The Delegation of Brazil expressed its belief that the topic on technology transfer opened many avenues of opportunities for the Committee to explore. The Delegation observed that the creation of intellectual property rights, particularly the patent system, had been supported by sound economic theory: creative work and innovation had characteristics of public goods; therefore, in the absence of intellectual property protection,

there was a risk of underinvestment in socially beneficial creative and innovative work (so called “market failure”). The Delegation noted that the patent system allowed market-driven decentralized decision-making, which ultimately contributed to the creation and dissemination of technology and consequently, the increase in standards of living. The Delegation however considered that the system was not perfect, particularly in areas where the market alone might not provide adequate incentives, such as the cure of neglected diseases. The Delegation further highlighted that although IP was one of the tools available in the development of new technologies, they were not synonymous. In its opinion, the patent system was only a proxy of innovation, one that had to be evaluated case-by-case. The Delegation noted that the state of the art literature highlighted that the development of new technologies hinged upon the establishment of an effective tailor-made IP law in tandem with other appropriate regulatory policies. It pointed out that studies showed that the right balance and fine tuning among those policies produced a positive correlation between R&D expenditures and innovation. Notwithstanding the great strides made by developing countries and LDCs in the last decades to improve their innovation systems, the Delegation observed that high-income countries still represented approximately 65% of the world total R&D investments. In that light, the Delegation considered that the SCP could play an important role to bridge the remaining gap between developed and developing countries. The Delegation stated that Brazil was aware that the term “technology transfer” encompassed a whole host of mechanisms, which went far beyond the licensing of patents, such as cross-border trading, mobility of skilled labor, foreign direct investments (FDI), international licensing, R&D alliances, etc. The Delegation further noted that WIPO, as a specialized agency of the United Nations, should take into consideration the language reflected in the Agenda 2030, adopted by all UN members at the highest level: “Promote the development, transfer, dissemination and diffusion of environmentally sound technologies to developing countries on favorable terms, including on concessional and preferential terms, as mutually agreed (SDG 17.7). Moreover, the Delegation believed that Articles 7 and 66.2 of the TRIPS Agreement should serve a basis for the discussion in the SCP, i.e., “Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members in order to enable them to create a sound and viable technological base.” In its opinion, the Committee should not forget Recommendations 25, 28, 29, 30 and 31 of the WIPO Development Agenda, which all pointed to the same direction of highlighting the transfer and dissemination of technology in a manner conducive to social and economic welfare, to the benefit of all countries, without exception. In that regard, the Delegation welcomed the sharing session on the contribution of patent law provisions to technology transfer, based on a GRULAC’s proposal. The Delegation expressed its belief that the SCP session should further continue promoting sharing sessions on that issue, in accordance with the Committee’s mandate.

198. The Delegation of Iran (Islamic Republic of) stated that transfer of technology was a signature subject in the agenda of the SCP. Consequently, the Delegation considered that the SCP should understand the opportunities and the challenges faced by technology transfer through holding discussions and sharing information in order to enhance free and efficient flow of technologies and to promote science and technology innovation. The Delegation was of the view that in order to strike a balance between the rights and obligations of right holders and third parties, and the protection and enforcement of patent rights *vis-à-vis* disclosure of inventions in the patent specifications, patent systems should be conducive to the social economic development. In its view, the requirement of sufficiency of disclosure had the potential to play a basic role in national innovation systems, and it was a crucial component of transfer of technology and proper functioning of the patent systems. Having in mind the differences between the subject of transfer of

technology in the CDIP and the SCP, the Delegation, along with GRULAC, the African Group and the Delegation of Brazil, supported the topic of transfer of technology in the agenda of the SCP. The Delegation further noted that it looked forward to the sharing session on patent law provisions that had contributed to the effective transfer of technology.

*A sharing session on patent law provisions that contributed to effective transfer of technology*

199. The Delegation of the United Kingdom believed that the global exchange and development of technologies was crucial to the economic growth and the wellbeing of societies in all countries. The Delegation considered that the relevant provisions of the 1977 Patents Act, which related to sufficiency of disclosure in patent applications, helped to ensure the transfer of technology by making valuable information about new developments widely available. The Delegation informed the Committee that the details of the UK law and practice in that area were summarized in document SCP/22/4 and available on the SCP website. The Delegation explained that the examiners in the United Kingdom used sufficiency as a tool to ensure the scope of protection of granted patents corresponded to the patentees' contribution to the art. It further noted that its examination guidance was provided in the Manual of Patent Practice and other guidelines, which were publicly available on its website. The United Kingdom third party observation service had also been expanded to cover the question of sufficiency, providing third parties in the United Kingdom with a low cost route to challenging a patent if they believed that it did not explain an invention clearly and completely enough. Furthermore, the Delegation stated that another mechanism for encouraging the sharing and exploitation of patented technology was through the licensing of patents. The Delegation highlighted that the license of rights scheme in the United Kingdom, provided for in the United Kingdom Patents Act, was an important way of supporting that aim. In its opinion, the license of rights encouraged voluntarily licensing of technology and knowledge exchange, as the patent owners were offered a significant reduction of renewal fees. The Delegation explained that third parties were able to search information on such licensing on its website. Since the introduction of that database, the Delegation continued, the increase in the license of right requests filed had been observed. Around 2% of in force patents in the United Kingdom were currently available for license of rights. The Delegation stated that the information on over 8,200 patents was currently being shared in that way. The Delegation observed that an effective IP system was essential to knowledge exchange between businesses and universities, and patents could help universities to secure business partners and funding. In its view, they were also a vital tool for commercializing ideas. It highlighted that the UKIPO provided a whole range of tools for universities and businesses, wanting to make the most of their IP and to commercialize their inventions. For example, in the United Kingdom, the Lambert Toolkit, which had been developed with a number of bilateral partner countries, provided guidance and model agreements for IP generated in collaborative exchanges.

200. The Delegation of France referred to a new user service which had been established in 2017 by the French national patent office. It explained that an electronic platform, "*bourse brevets*", helped to put into contact possible licensors and licensees. The Delegation informed the Committee that if a holder of a patent wanted to exploit the patent through a technology transfer licensing, the *bourse brevets* could assist them in finding potential licensees. Similarly, if there was innovative technology which was sought, the tool could help to find those technologies that had been available for licensing. It also had a teaching component about granting licenses, a confidentiality agreement model and other things. In addition, the Delegation clarified that the aim of such a system was providing further impetus to small and medium sized businesses.

201. The Delegation of China stated that since free flow of technologies worldwide played a very positive role for the economic growth and social development, the Chinese government had paid high attention to the use of technologies and to the supportive role played by the patent system. Thus, China had enacted the law on promotion of technologies, in which there was one provision that provided use of technology and IP related information as well as the public service related to the search tool and the management of IP, which was considered as the criteria for the establishment of projects. With respect to the IP laws, the Delegation stated that there were also provisions regarding transfer of technology and licenses, and that some new recommendations on the complete use of technologies, which had been still under consideration and had not been established as the formal regulations yet, were contained in the fourth revision of the China's patent law. The Delegation explained that they related to the open licenses, the basic framework of which was as follows: firstly, if a right holder wanted others to use his patented technology, the right holder could use a platform, declaring that he/she was willing to license his/her patent under the declared royalty fee. If the person who was interested in that patented technology and accepted the requested licensing fee and other conditions, that person should notify the rights holder in written form. The Delegation expressed its hope that, in such a manner, the cost of licensing could be reduced and the linkage between the patented technology and the use of it could be promoted, so that the patent system could play a positive role in transfer of technology. While it required more consultations and discussions, the Delegation hoped that the said recommendations could be included in its patent law. With regard to the use of technology, the Delegation expected the SCP to focus on the difficulties faced by developing countries and seeking solutions through sharing experiences and successful cases. The Delegation considered that the SCP should work on an operational model law for reference to Member States, which, in the view of the Delegation, was also within the mandate of the SCP. In its opinion, in comparison with the CDIP, the SCP had more experts in the field of patent law, and therefore could have discussions in the area of transfer of technology.

202. The Delegation of Chile stated that transfer of knowledge was one of the principal functions that the intellectual property system had. It noted that the patent system was a repository for accumulated knowledge, and that such accumulated information needed to be conveyed to the rest of society for its use. The Delegation stated that, in Chile, there were a number of law provisions which encouraged transfer of technology, for example, the publication of an extract from a patent application, once it had gone through the official examination of the admissibility. The Delegation noted that the presentation of a descriptive coverage of the patented invention and drawings (if necessary), which included a description of the embodiments that were the examples of the application of the claimed invention, should allow people to reproduce the claimed invention without having a need to have any other background. The Delegation continued that the example of a description consisted of a detailed explanation of at least one way of implementing the claimed invention, and it needed to be illustrated or supported by the use of drawings, if applicable. At the same time, the Delegation noted, the patent application should be accompanied by an abstract, which contained a summary of the invention, an indication of the technical sector and the industrial areas of application. The Delegation explained that it should be presented in a format which the patent office provided to the public as a template. The abstract essentially covered the technical problem, its solution and its application, and could also include a representative figure of the invention. As to the drawing of the invention which might be presented, if applicable, the Delegation noted that they should be submitted separately in sufficient details for the inventions to be reproducible. The Delegation finally stated that a patent application should also include some bibliographic facts, which allowed for prior art search using key words from the title, inventor or patent holder. The Delegation stated that INAPI was responsible for protection of industrial property and had the duty of dissemination of information it had generated. It further

observed that the law creating INAPI stated that it should carry out the dissemination of knowledge under industrial property. The Delegation informed the Committee that, through those functions, INAPI had developed a series of initiatives which were directly linked to the effective transfer of technology. In that connection, the Delegation highlighted the following activities: distance learning courses on industrial property; the periodic publication of bulletins with technologies that were in the public domain; and recently, the opening of two regional offices located in important industrial centers in the country in order to meet the needs of its users more directly. Finally, the Delegation reported on its two electronic platforms. The *INAPI Proyecta* dealt with transfer of technology and dissemination of information, providing opportunities to innovate and create through the use and management of industrial property. On another platform, national institutions and innovators could find information about industrial property, and they could connect with people who were interested in using inventions commercially. The Delegation considered that those tools allowed for technology transfer, because they raised not only the visibility of the patent registry but also the usefulness of those patented inventions.

203. The Delegation of Australia referred to the activities under the WIPO/Australia Funds in Trust (FIT), which were aimed at supporting technology transfer and building collaborative linkages between stakeholders. The Delegation noted that, through the FIT, it was helping support the WIPO Re:Search program. While that did not specifically relate to patent law provisions for enabling transfer of technology, the Delegation stated that it sought to use the WIPO Re:Search partnerships and knowledge sharing to help combat global health challenges with respect to neglected tropical diseases, malaria and tuberculosis, which affected many LDCs. In the area of technology transfer, the WIPO/Australia FIT, through a partnership with BIO Ventures for Global Health (BVGH), was helping to place further eight research scientists from Bangladesh, Papua New Guinea, Tanzania, Indonesia, and Kenya into leading Australian medical research institutes so that they could take the knowledge and skills back to their home countries. The Delegation further stated that, through the FIT, there had been other activities on using IP to facilitate technology and knowledge transfer, including training courses on successful technology licensing, patent drafting, IP valuation and creation of a tool box for technology transfer offices at universities and research and development (R&D) institutions. The recipients of those trainings so far included Vietnam, Thailand, Indonesia, Malaysia, the Philippines and Cambodia. In addition, the Delegation explained that the WIPO/Australia FIT had also been supportive of activities for WIPO GREEN which was a green technologies platform that connected technology and service providers with those seeking innovative solutions to the environmental challenges they faced. The Delegation expressed its support to those initiatives, and considered that those and similar approaches helped to support the facilitation of innovation and the transfer of technology in a broad and practical manner, in line with the needs of the participating countries.

204. The Delegation of the United States of America stated that, in its country, the federal government spent billions of dollars every year for funding research and development conducted by universities, government research institutions, private businesses and individuals. As an example, in 2016, the federal government had spent about 70 billion on non-defense research and development. The Delegation informed the Committee that about 50% of the academic research was funded by the federal government, as university research was very important for advancing science, for expanding the knowledge pool and for its economy. The Delegation observed that that was an important place where technology transfer came into play. In its opinion, voluntary technology transfer from universities and other research institutions to industry on mutually agreed terms, and ultimately to the public, was vital for maximizing the benefits of research. Since university research was usually carried out in the early stages of development of the technology, without transferring such research from public research institutions and forming

partnerships with private companies for further development and commercialization, the public might not be able to benefit from the research. It therefore considered that technology transfer was good for the economy of the United States of America, helping to create new jobs, new products and new companies. In its view, technology transfer promoted local and state economic development and encouraged maximum participation of small businesses and non-profits in federally funded R&D efforts. Furthermore, it encouraged innovation and helped the United States of America maintain its competitive edge. The Delegation observed that such technology transfer was also good for the public. In the United States of America, the Delegation noted, hundreds of new products and technologies, including life-saving medicines originated from public research, were developed and placed on the market through public and private partnerships. The Delegation explained that the technology transfer was made possible in large part by the legislation, commonly called the Bayh-Dole Act, which was codified in the US Code Title 35. It had passed in 1980 and had become effective on July 1, 1981. The Delegation noted that it represented a fundamental change in the US government innovation policy, giving the power to the universities and the small companies to own inventions that they developed with federal funding and to grant exclusive licenses on those inventions so that universities were encouraged to collaborate with industry to translate their research results into products that would benefit the public. The Delegation noted that universities often obtained licensing income from the inventions, which was typically invested in more research, in rewarding university scientists, and in supporting the cycle of innovation. Because the funding was derived from the US taxpayers, the government policy was to give preference to small businesses. The Delegation further stated that the Act included a number of safeguards designed to protect the public interest, including the obligation to disclose each new invention to the federal funding agency and to file an initial patent application within a certain time period. Furthermore, the government retained under very narrow circumstances an option to require the patent holder to grant a license to a third party, or the government might take title and grant licenses itself, which was called the march-in right. The Delegation, however, noted that no US federal agency had ever exercised such march-in right. It observed that customized research coupled with enabling legal environment created by the Bayh-Dole Act had helped to create entirely new industries, such as biotechnology, where the United States of America upheld a leadership role. Prior to the passage of the Bayh-Dole Act, the Delegation explained, the federal government had generally held and retained title to inventions created with federal funding, and licenses granted to private companies had usually been non-exclusive, as the federal government itself had not commercialized the inventions. The Delegation noted that, at the time the law had passed in 1980, the US federal government had held title to approximately 28,000 patents, of which fewer than 5% had been licensed to industry for development of commercial products. In its view, that meant that American taxpayers had not been getting the full benefit from the billions of dollars invested in research. The Delegation informed the Committee that in the past 25 years, more than 11,000 start-ups had been formed, based on the results of the university research. A majority of those had been located in close physical proximity to the university, contributing to the local and state economy and development. It noted that in 2016 alone, 1,024 start-ups had been formed, and 800 new products had originated from university research and had been introduced into the marketplace by companies in the private sector. Furthermore, according to the Delegation, over 200 medicines and vaccines had been developed through public-private cooperation since the Bayh-Dole enactment. The Delegation noted that university technology transfer had billions of dollars of direct benefit to the US economy and supported millions of jobs every year. In its opinion, the successful example of the United States of America

demonstrated the importance of having an efficient patent system and clear IP laws that were conducive to technology transfer and technology commercialization. In addition to the Bayh-Dole Act provisions, the Delegation noted that the US patent law and patent regulations provided for patent fee reductions for universities and small or micro entities, which encouraged licensing by those entities.

205. The Delegation of Nigeria aligned itself with the statement made by the Delegation of Senegal on behalf of the African Group. As a general statement relating to the agenda item, the Delegation expressed its belief that transfer of technology was an important issue for Member States and should be maintained in the agenda of the SCP. The Delegation reiterated its position that a discussion on transfer of technology and its relationship with the patent system should progress beyond the preliminary stage, particularly on the issue of sufficiency of disclosure with respect to transfer of technology.

206. The Delegation of Colombia pointed out that its new law No. 1838 of 2017, which aimed at promoting research in public universities, had been made available on the WIPO Lex website. That new law, which was called a spinoff law, made it possible to develop technologies associated with basic or applied science in the academic environment to products having a commercial use in order to benefit the society. According to that law, the Delegation explained, spinoff companies which came about from higher education institutions could own intellectual property rights to ensure that their developments could be protected through mechanisms such as patents or trade secrets. The Delegation highlighted that professors or researchers from those higher education institutions could be part of such a company, without having any kind of conflict of interest in receiving remunerations from the company, which was not possible in Colombia under the previous law.

**AGENDA ITEM 12: OTHER ISSUES: INFORMATIVE SESSION ON LEGISLATIVE ASSISTANCE IN THE FIELD OF PATENTS AND RELATED CAPACITY BUILDING**

207. The Secretariat presented its activities regarding legislative assistance in the field of patents and related capacity building.

208. The Delegation of Colombia expressed its appreciation to WIPO for the assistance provided to inventors. Noting that Colombia was the first beneficiary country of the Inventor Assistance Program (IAP), it noted that it had been very successful and had enabled inventors in Colombia to navigate the patent system with clear guidance from the lawyers undertaking that initiative. The Delegation noted that Colombia had many times used the legislative assistance by WIPO, particularly since 2000. The Delegation observed that it had requested specific assistance, which had been bilateral, neutral and absolutely confidential. Noting that not only in Colombia did it have WIPO assistance for issues with regard to patent rights, the accelerated patent procedures, utility model rights and other substantive issues related to IP rights, the Delegation stated that when Colombia had decided to bring in international trade standards, WIPO had provided legislative assistance for implementation of those criteria and many elements that were part of the international patent law. In its view, interpretation of the law was not the issue, but assistance within the international framework was valuable. In addition, the Delegation highlighted the fact that any Member States could benefit from the legislative assistance.

209. The Delegation of Belarus stated that in 2015/16, the Republic of Belarus had been working on an amendment of its patent law, and had received a number of requests and questions from patent attorneys and stakeholders. On the basis of those questions, the Delegation explained that WIPO had organized a regional seminar in Minsk, during which

delegates from other countries of the region had shared their own experiences with regard to their implementation of the Patent Law Treaty (PLT). The Delegation observed that the seminar was very useful for its country and was significant in its accession to the PLT, since the experts from Belarus who had participated in the seminar had gained knowledge as to how they could adapt their law to the requirements under the PLT. The Delegation further stated that in order to bring the PLT into its national legislation, Belarus had used WIPO's very detailed comments on its legislation in relation to the PLT. Furthermore, the Delegation noted that additional in-depth consultations had been held with the WIPO Secretariat in relation to limitations to patent rights. The Delegation expressed its appreciation for the high quality work of the WIPO Secretariat, and appreciated the legislative advice given in its national language, which had helped better understanding of the content of the advice.

210. The Delegation of the Dominican Republic expressed its appreciation to WIPO for the assistance it had provided and for the guidance on normative issues. The Delegation explained that in response to its request for technical assistance, the Dominican Republic had received a WIPO mission in 2011, and an analysis of legal provisions had been undertaken in 2016.

211. The Delegation of Iran (Islamic Republic of) stated that it attached great significance to the technical assistance provided by the Secretariat to Member States as a useful tool for capacity building and increasing knowledge to address their national needs and priorities. The Delegation noted that it had already benefited from such programs, and looked forward to receiving more benefits. As regards the IAP, the Delegation requested more information about that program.

212. The Delegation of Switzerland, speaking on behalf of Group B, welcomed the opportunity for WIPO's legislative assistance in the field of patents and about related programs and tools that each individual Member State might use. It observed that WIPO was the competent organization to provide legal policy and technical expert advice on intellectual property, including patents. It was of the view that, where necessary, WIPO was in the position to consult or cooperate with other UN agencies or intergovernmental organizations in order to provide thorough advice and assistance. In its opinion, WIPO's legislative assistance was tailor-made and demand-driven, taking into consideration the individual needs of a country. In that respect, the Delegation considered that it complied with the principles of the Development Agenda, and that the assistance provided wide flexibility for developing projects and activities. The Delegation emphasized that the active participation of a country was crucial for a successful implementation of the technical support. As the solid patent system functioned as a driving force in creativity, the Delegation believed that the assistance provided by WIPO in establishing or improving patent systems helped countries and their stakeholders in the global economy.

213. The Delegation of Senegal, speaking on behalf of the African Group, expressed its appreciation to WIPO for the activities it carried out in the area of legislative assistance to Member States. While many African countries had benefited from such activities, the Delegation highlighted that the technical assistance and legislative assistance had not been sufficient to enable LDCs and other countries to overcome the challenges they had been facing. The Delegation explained that, in that light, the African Group had formulated its proposal in document SCP/24/4, which contained, as the third pillar, a technical assistance, including legislative assistance. The Delegation believed that the simple fact of having legislative provisions in a national legislation was not enough to overcome the challenges that those countries had been facing.

214. The Delegation of Indonesia, speaking in its national capacity, expressed its gratitude for the capacity building programs that had been conducted in cooperation with WIPO, and looked forward to strengthening the cooperation with WIPO in the field of patents. The Delegation reiterated that the capacity building activities should be development oriented. It also highlighted that such technical or legislative assistance in developing countries and LDCs should make full utilization of the flexibilities available to them under the legal framework that had evolved after 1979 when the WIPO Model Law for Developing Countries on Inventions had been published. The Delegation raised the issue of the revision of the WIPO Model Law, and stated that it would be a useful exercise that could help WIPO to implement its Development Agenda. In its opinion, the revision of the Model Law should be oriented towards development and give policy options for developing countries and LDCs in taking full utilization of the flexibilities available to them under the international legal framework. The Delegation further stated that such a revision should also consider the different levels of development and to avoid substantive harmonization or a one-size-fits-all approach.

215. The Delegation of China stated that China had been a beneficiary of the legislative assistance provided to developing countries. Noting that China had got the assistance from WIPO when it had developed its first patent law in 1970s, the Delegation took the opportunity to express its appreciation for WIPO's assistance on behalf of China. The Delegation recalled that, at that time, the WIPO Secretariat had conducted many times consultations and discussions with the Chinese delegation: in total, 13 times and more than 30 hours. The Delegation hoped that such kind of legislative assistance activities could continue to play an important role for developing countries. The Delegation highlighted that, at present, China was conducting examiner exchanges with the neighboring developed countries, and had also conducted training courses. It noted that in 2016, China had provided training courses for more than 80 examiners from foreign countries, and more than 100 other officers from developing countries had come to China for the training. The Delegation explained that in all of those activities, it had also presented in detail the Chinese patent law. In addition, the Delegation stated that China had conducted many seminars and workshops to share its experiences with participants from foreign countries, for instance, the countries of ASEAN and of the African Union. Based on those practices and experiences, the Delegation considered that the legislative assistance could help developing countries to better understand the patent system and to help them to improve their patent system. As each country was in a different situation, the Delegation believed that Member States needed to strengthen the cooperation among them, and that the SCP could particularly play a more important role in that regard.

216. The Delegation of Azerbaijan expressed its appreciation to WIPO for the legislative assistance it had provided to its country. The Delegation noted that in the end of November 2017, there had been a seminar on the topic of the PLT and its practical implementation in Baku, which had been organized by WIPO in cooperation with the authority of Azerbaijan. The Delegation observed that that seminar had provided an excellent opportunity to clarify issues relating to the implementation of the PLT in its country, and also to exchange experience with participants from countries that had implemented that Treaty. The Delegation noted that the seminar was welcomed by the Azerbaijan authority and all other stakeholders. Furthermore, the Delegation took the opportunity to thank the delegations that had made interesting and useful presentations about the inventive step.

217. The Delegation of Ecuador expressed its appreciation to WIPO for its legislative assistance program. The Delegation informed the Committee that the IAP was launched in Ecuador on November 13, 2017. It noted that the program had generated great interest in the general public, and that the establishment of the national committee had involved

representatives from academia, research, the state and the private sector. To its surprise, great interest in the program had been expressed by lawyers working in the field of intellectual property. The Delegation invited other delegations to visit its IAP platform available at: www.paiecuador.ec.

218. The Delegation of Costa Rica, speaking in its national capacity, stated that it had benefited from WIPO's legislative assistance program for the development of the relevant legislation in the area of patents. The Delegation noted that it had helped them to work together with other countries in the region, through which it sought harmonization and worked on policies for the development and innovation. The Delegation observed that a demonstration of those efforts was a Central American agreement with the Dominican Republic on patent examination.

**AGENDA ITEM 13: FUTURE WORK**

219. The Delegation of Georgia, speaking on behalf of the CEBS Group, stated that the agenda of the Committee reflected the priorities of different regional Groups. The Delegation recognized that the Member States had a complex task ahead in order to retain the delicate balance. The Delegation reiterated that its Group attached a great importance to the issue of quality of patents. It believed that the issue was at the core of the patent system. With respect to the topic of confidentiality of communication between clients and their patent advisors, the Delegation wished to continue work and see advancement on the recognition of foreign patent advisor's privilege through a soft law instrument. The Delegation was ready to continue deliberations on the five main core topics under the agenda and looked forward to reaching a balanced work program.

220. The Delegation of Indonesia, speaking on behalf of the Asia and the Pacific Group, referred to the position of its Group on various items on the agenda expressed during that week. The Delegation highlighted the importance of the work of the Committee, and looked forward to reaching a future work program satisfactory to all Member States.

221. The Delegation of Costa Rica, speaking on behalf of on behalf of GRULAC, welcomed the development of a balanced agenda. The Delegation stated that there were two priorities for its Group: exceptions and limitations to patent rights, and patents and health. At the same time, the Delegation welcomed the information exchange sessions, which it had found very useful.

222. The Delegation of Switzerland, speaking on behalf of Group B, as regards the future work, referred to its statements made under each agenda item. The Delegation looked forward to seeing the balanced agenda on future work and fruitful discussions to end that session of the Committee.

223. The Delegation of Senegal, speaking on behalf of the African Group, stated that it had expressed the position of its Group during the discussions of the respective agenda items during that week. Noting the importance of the Committee for its Group, the Delegation reiterated that the main issues for its Group were the issues of exceptions and limitations to patent rights, transfer of technology, and patents and health. Expressing its wish to continue to work on those issues, the Delegation stressed that their priority was on the issue of patents and health, and specifically on the activities contained in its proposal (document SCP/24/4). Looking towards the development of work program based on that proposal, the Delegation expressed its commitment towards reaching a balanced work program.

224. The Delegation of the Russian Federation, speaking on behalf of the Caucasian, Central Asia and Eastern European Countries (CACEEC), stated that for its Group, the quality of patents was one of their priorities. Therefore it supported further discussion of that issue in the Committee. In addition, the Delegation expressed its support to the proposal of the Delegation of Spain to conduct a study on inventive step requirement. The Delegation also proposed that the Committee would continue discussions on cooperation between patent offices in search and examination. The Delegation further stressed the importance of continuing to update the webpage on opposition and administrative revocation mechanisms for development of such systems in various countries. As regards the issue of exceptions and limitations to patent rights, the Delegation suggested the Secretariat to develop a draft reference document on the topic of experimental use/research exception. Further noting that the issue of access to medicines was of particular importance for its Group, the Delegation stressed the necessity of international cooperation on the issue. However, the Delegation also stressed that the work on the issue of patents and health should be carried out within the mandate of the Committee and any overlap of work with other bodies of WIPO be avoided. As regards the issue of confidentiality of communications between clients and their patent advisors, the Delegation supported further work to be conducted focusing on cross-border aspects. Finally, as regards the issue of transfer of technology, the Delegation suggested that patent-related impediments to transfer of technology be studied.

225. The Delegation of China with regard to future work expressed its belief that it would be beneficial to carry out thematic research on various topics and collect the legal provisions and practices of various countries at that stage. The Delegation further stated that it would be helpful to pay attention to the activities carried out by other international organizations and to conduct a wide range and extensive information exchange and experience sharing. The Delegation stated that that would help to deepen understanding and mutual learning among Member States. With regard to exceptions and limitations to patent rights, the Delegation noted a high quality of the draft reference document on exception regarding acts for obtaining regulatory approval from authorities prepared by the Secretariat, and stated that the document was an important reference for understanding each country's system. Regarding the topic of patents and health, the Delegation supported the proposal of the African Group (document SCP/24/4) and it also welcomed the revised proposal by the Delegations of Canada and Switzerland (document SCP/27/8). The Delegation stated that those two proposals had demonstrated that that topic was of common interest to many countries and that they would be a good basis for future work on the topic. On the issue of transfer of technology, the Delegation supported the statements made by the Delegations of Senegal on behalf of the African Group, and Brazil. Specifically, the Delegation was of the view that the work of the SCP and of the CDIP were not overlapping but complementary, and that the SCP could have its own focus and develop related work plans. In conclusion, the Delegation stated that as countries' national situations and stages of development were different, their priorities and interests were also different. Therefore, the Delegation stated that all delegations needed to take a more flexible stand and work together to develop a work program, reflecting the interests and concerns of all countries, to the extent possible.

226. After some consultations conducted by the Chair, 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*

– The Secretariat will continue working on a draft reference document on exceptions and limitations. It will submit a second draft reference document on exception regarding acts for obtaining regulatory approval from authorities to SCP/28. In this regard the Secretariat will invite Member States to send any additional inputs with respect to, for example, challenges faced by Member States in implementing the exception and results of the national/regional implementation. The Secretariat will prepare a first draft reference document on the research exception, and will submit it to SCP/29.

*Quality of Patents, including Opposition Systems*

– The Secretariat will prepare a further study on inventive step, giving a particular attention to the topics suggested in paragraph 8 of document SCP/24/3 (Proposal by the Delegation of Spain).

– A sharing session on opposition and administrative revocation mechanisms will be held at SCP/28. The session will address national/regional experiences, challenges encountered and possible solutions, among others.

– Member States will continue to share their experiences on cooperation between patent offices in search and examination, including sharing of information concerning the corresponding foreign applications and grants, at SCP/28. Member States may address challenges encountered and possible solutions, among other issues.

*Patents and Health*

– The Committee will continue exchanging information on publicly accessible databases on patent information status and data, on medicines and vaccines at SCP/28, taking the issues addressed in paragraphs 18 and 19 of document SCP/24/4 (Proposal by the African Group for a Work Program on Patents and Health) into consideration.

– The Secretariat will update the feasibility study on the disclosure of International Nonproprietary Names (INN) in patent applications and patents (document SCP/21/9), and submit it to SCP/28.

– Member States will share their experiences with respect to enhancing examiners capacity, particularly in small and medium-sized offices at SCP/28. The Secretariat will report its technical assistance activities in this area at SCP/28.

– The Committee will continue discussion on the revised proposal by the Delegation of Canada, cosponsored by the Delegation of Switzerland (document SCP/27/8 and SCP/27/8 Add.), at SCP/28.

*Confidentiality of Communications between Clients and Their Patent Advisors*

– Member States will continue sharing their experiences and court cases in implementing the confidentiality of communication between clients and their patent advisors through national legislation, including cross-border issues.

*Transfer of Technology*

– Member States will continue sharing information on patent law provisions that contributed to effective transfer of technology.

**AGENDA ITEM 14: SUMMARY BY THE CHAIR**

227. The Chair introduced the Summary by the Chair (document SCP/27/9 Prov.).

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

229. 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 15: CLOSING OF THE SESSION**

230. The Secretariat noted that the success of the session was a tribute to the leadership of the Chair, as well as to all the delegations that had participated in that session in a very vigorous and constructive way.

231. The Chair thanked the regional coordinators, all other delegates, the Secretariat and the interpreters for their excellent work towards getting a consensus.

232. The Chair closed the session on December 15, 2017.

*233. The Committee unanimously adopted this report at its twenty-eighth session on July 9, 2018.*

[Annex follows]

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