

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

**Twenty-Fourth Session**  
**Geneva, June 27 to 30, 2016**

DRAFT REPORT

*prepared by the Secretariat*

### **INTRODUCTION**

1. The Standing Committee on the Law of Patents (“the Committee” or “the SCP”) held its twenty-fourth session in Geneva from June 27 to 30, 2016.
2. The following States members of WIPO and/or the Paris Union were represented: Afghanistan, Algeria, Angola, Argentina, Australia, Azerbaijan, Bahamas, Brazil, Cameroon, Canada, Chile, China, Colombia, Costa Rica, Cuba, Cyprus, Democratic Republic of the Congo, Dominican Republic, Egypt, El Salvador, Estonia, Finland, France, Germany, Ghana, Greece, Guatemala, Hungary, India, Indonesia, Iran (Islamic Republic of), Ireland, Italy, Japan, Kuwait, Latvia, Lebanon, Mali, Mexico, Morocco, Myanmar, Netherlands, Nicaragua, Nigeria, Norway, Oman, Pakistan, Panama, Paraguay, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Senegal, Singapore, Slovakia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Thailand, The former Yugoslav Republic of Macedonia, Turkey, Uganda, Ukraine, United Kingdom, United States of America, Uruguay, Viet Nam (73).
3. Representatives of the following intergovernmental organizations took part in the meeting in an observer capacity: African Intellectual Property Organization (OAPI), African Union (AU), Eurasian Patent Organization (EAPO), European Union (EU), Patent Office of the Cooperation Council for the Arab States of the Gulf (GCC Patent Office), South Centre (SC), United Nations (UN), World Trade Organization (WTO) (8).

4. Representatives of the following non-governmental organizations took part in the meeting in an observer capacity: Asian Patent Attorneys Association (APAA), Association of Spanish Attorneys before International Industrial and Intellectual Property Organizations (AGESORPI), Cámara Industrial de Laboratorios Farmaceuticos Argentinos (CILFA), CropLife International (CROPLIFE), European Law Students' Association (ELSA International), Innovation Insights, Institute of Professional Representatives Before the European Patent Office (EPI), International Association for the Protection of Intellectual Property (AIPPI), International Center for Trade and Sustainable Development (ICTSD), International Chamber of Commerce (ICC), International Federation of Intellectual Property Attorneys (FICPI), International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Japan Intellectual Property Association (JIPA), Japan Patent Attorneys Association (JPAA), Knowledge Ecology International. Inc. (KEI), Latin American Association of Pharmaceutical Industries (ALIFAR), Medicines Patent Pool Foundation (MPP), Médecins Sans Frontières (MSF), Open Knowledge Foundation (OKF), and Third World Network Berhad (TWN) (20).

5. A list of participants is contained in the Annex to this report.

6. The following documents prepared by the Secretariat had been submitted to the SCP prior to the session: "Draft Report" (SCP/23/6 Prov.2); "Draft Agenda" (SCP/24/1 Prov.); "Report on The International Patent System: Certain Aspects of National/Regional Patent Laws" (SCP/24/2); Proposal by the Delegation of Spain (SCP/24/3); and "Proposal by the African Group for a WIPO Work Program on Patents and Health" (SCP/24/4).

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 Group of Latin American and Caribbean Countries (GRULAC)" (SCP/22/5); and "Proposal by the Delegation of the United States of America on the Study of Worksharing" (SCP/23/4).

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

## **GENERAL DISCUSSION**

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

9. The twenty-fourth session of the Standing Committee on the Law of Patents (SCP) was opened by the Director General, Mr. Francis Gurry, who welcomed the participants. The session was chaired by Ms. Bucura Ionescu (Romania). Mr. Marco Aleman (WIPO) acted as Secretary.

## AGENDA ITEM 2: ADOPTION OF THE AGENDA

10. The SCP adopted the draft agenda (document (SCP/24/1 Prov.) with inclusion of a new document SCP/24/3 under agenda items 6.

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

11. The Committee adopted the draft report of its twenty-third session (document SCP/23/6 Prov.2) as proposed.

## GENERAL DECLARATIONS

12. The Delegation of Greece, speaking on behalf of Group B, stated that Group B strongly believed that the SCP, a multilateral forum in the field of patents, had a responsibility to provide a venue for technical discussion on substantive patent law issues, in a manner responding to the evolving real world. The Delegation also expressed its Group's readiness to engage constructively in the discussion on what the Committee should do in the future. The Delegation noted, nevertheless, that during the previous sessions, the SCP had spent a disproportionate amount of time on deliberations on the future work program. Further, the Delegation noted that during the previous session, its Group had supported the delicate balance reached in the Chair's proposal and expressed its disappointment that the Committee had not reached an agreement at that session. Further, the Delegation reiterated its Group's strong support for the SCP to engage in discussions which would address the needs of the real world. The Delegation stated that, for example, with respect to the agenda item "quality of patents, including opposition systems", Group B expected that the Committee could build future work focusing on international work sharing and substantive patentability requirements, such as inventive step. The Delegation stated that, at the previous session of the SCP, the great interest of Member States in the subject had been demonstrated across regional boundaries when national experts from various countries and regions had shared their experiences on the evaluation of inventive step requirement. In addition, the Delegation stated that a proposal from the United States of America on work sharing had also received a wide support from the Member States. In the view of the Delegation, the Committee should build on the importance many Member States placed on that subject and intensify its work on those technical topics in order to ensure and increase the quality of issued patents worldwide. Further, the Delegation noted that the importance of protecting the communication between patent advisors and their clients had been extensively discussed in the Committee. It recalled that users of the patent system had stressed the need to address the subject at an international level. Group B, therefore, believed that the Committee should take a step forward towards a regulative solution at the international level, for example, in the form of a soft law. The Delegation expected that the Committee would be able to agree on some concrete and substantive works for the future, which could substantively contribute to that perspective. The Delegation further stated that Group B supported the work of the SCP and attached great importance to its mandate. The Delegation expressed its hope that all delegations had come prepared to engage in the existing five agenda items. In that regard, the Delegation noted that the GRULAC proposal on the revision of the Model Law, included under agenda item 10, was not part of the five subjects forming the body of the agenda and that its continued discussion would create a significant imbalance which could not be accepted by its delegation. In conclusion, the Delegation stated that it was ready to engage in discussions on the five agenda items from the perspective of future work and assured that Group B would be engaged in the work of the Committee with a constructive spirit and in a forward looking way.

13. The Delegation of India, speaking on behalf of the Asia and Pacific Group, expressed its confidence in the leadership of the Chair and its hope that she would be able to guide the twenty-fourth session of the SCP in the desired direction. The Delegation also expressed its appreciation for the hard work of the Secretariat in preparing the meeting, including the organization of informal consultations for the Regional Coordinators. The Delegation further noted that the work of the SCP was critical 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-related flexibilities. Noting that those flexibilities were critical for policy makers in drafting and amending domestic patent laws in accordance with national development priorities and socio-economic realities, the Delegation stated that the TRIPS flexibilities took into consideration those differences and played an important role in achieving the requisite balance. In particular, the Delegation stated, the flexibilities allowed governments, especially in countries with limited resources, a necessary policy space to meet their health needs and at the same time to foster innovation. Members of the Asia and Pacific Group were ready to participate and contribute towards a productive discussion on that important developmental issue. Further, the Delegation expressed its hope that exchange of Member States' experiences and case studies on the effectiveness of exceptions and limitations would provide guidance to improve and further enhance the efficiency of the current patent system in a manner sensitive to the diverse needs of the Member States. The Delegation requested the Secretariat to continue updating the document SCP/23/3 by inviting submissions from research institutions, civil society organizations and domestic industries in developing countries so that they could share their practical experiences on effective use of the exceptions and limitations to patent rights under their relevant national legislations. In relation to the issue of International Nonproprietary Names (INN), the Delegation requested the Secretariat to revise the study contained in document SCP/21/9 by addressing the question about feasibility of disclosure of INN in patent applications, specifically where the INN was known to the applicant. The Delegation further supported the idea that SCP should have discussions on the opposition systems, which was an important issue for its Group. Particularly, the Delegation stated that the Committee could consider devising a work program on opposition systems that could comprise a survey questionnaire on different kinds of opposition mechanisms available in a country, the procedures and modalities for their use, constraints in using the opposition system effectively and how such opposition systems could be strengthened and their constraints removed. Further, the Asia and Pacific Group was of the view that the SCP should arrive at a common understanding on the meaning of the term "quality of patents". In particular, the Delegation questioned whether the term meant efficiency of patent offices in disposing patent applications, or whether it meant the quality of patents granted, i.e., how to ensure that patent offices did not grant patents of questionable validity. In addition, the Delegation requested the Secretariat to provide regular information to the Member States about the outcome of patent applications in different jurisdictions as well as outcomes of opposition procedures. Finally, the Delegation expressed its support for the proposal of GRULAC on the Revision of the 1979 WIPO Model Law for Developing Countries on Inventions, and stated that such revision should emphasize legislative and policy options for the Member States. The Delegation emphasized that that agenda item was, by no means, at a lower level of priority, even when it was placed under "other items" and therefore it should be given equal importance as the other substantive agenda items.

14. The Delegation of Nigeria, speaking on behalf of the African Group, noting that the work of the SCP was critical for development and balanced use of the international patent system, stated that it was looking forward to an agreement on the future work of the SCP and a more ambitious work program thereafter. The Delegation expressed its readiness to work with all interested parties to ensure that such a result would be achieved during the twenty-fourth session. The African Group reiterated its commitment to work towards an international patent system which would be balanced and progressive and which would take

into account the different levels of development of WIPO Member States and the priorities attached to different issues in the field. The Delegation expressed its belief that a more accessible and balanced patent system was crucial in facilitating the knowledge dissemination and in fostering innovation for the broader human and societal development. The Delegation noted that the five issues under consideration had already been debated at several SCP sessions without satisfactory results. In that regard, the Delegation expressed its hope that every Member State and stakeholder reflected deeply and came to that session with a readiness to advance on the important issues for the diverse WIPO membership. The Delegation stated that its Group's priority was on the subject of patents and health, and it was looking forward to sharing its views on that subject. In its view, the seminar, on the relationship between patent systems and, *inter alia*, challenges related to availability of medicines in developing countries and least developed countries (LDCs), held during the twenty-third session of the SCP provided useful resources with regard to the barriers to the affordable and safe medicines, and technology transfers in the field. The Delegation further noted that it was also interested in the subjects of exceptions and limitations to patent rights and transfer of technology, and expressed its hope that the SCP would significantly advance the work in those fields before the end of the session. The African Group equally looked forward to constructive discussions on the issue of quality of patents, including the opposition systems and confidentiality of communications between clients and their patent advisors. In conclusion, the Delegation reiterated its support to the GRULAC proposal to review 1979 WIPO Model Law for Developing Countries on Inventions and expressed its hope that the SCP could define a clear path forward on that agenda item.

15. The Delegation of Pakistan aligned itself with the statements made by the Delegation of India, on behalf of the Asia and Pacific Group and the Delegation of Nigeria on behalf of the African Group. The Delegation noted that the SCP was an important Committee, especially with regard to issues having implications for many sectors such as public health, technology transfer and patent-related flexibilities. The Delegation stated that it was unfortunate that the Committee could not agree on its future work program at the previous session. The Delegation highlighted that deliberations at the SCP were inclusive and cognizant of the differences in the socio-economic and technological development of the Member States as well as the TRIPS flexibilities while respecting the needs of all Member States. The Delegation noted the case studies and experiences on the effectiveness of the exceptions and limitations in addressing the development issues contained in document SCP/23/3 and requested the Secretariat to update the study by inviting submissions from a broader audience, including civil society organizations, research institutions and local industries developing countries about their practical experience on the matter. The Delegation stated that new diseases and epidemics caused global health threats challenging developed and developing countries. The Delegation continued that the basic human right to health was denied to increasingly large population globally because they could not afford the treatment. It noted that the revised WHO Model List of Essential Medicines included medicines for treating Hepatitis C, cancer and others, most of which were unaffordable to a large population. The Delegation supported the proposal of the African Group and the Development Agenda Group (DAG) contained in document SCP16/7 and SCP/16/7 Corr. The Delegation stated that there was a need to analyze specific challenges to the availability of medicines arising from the patent system in developing countries and LDCs, the impact of patent systems on the facilitation of innovation on medicines for the treatment of diseases predominantly prevalent in those countries and whether the patent system had facilitated transfer of technology and local manufacturing of medicines in developing countries and LDCs. The Delegation supported the GRULAC proposal regarding the revision of the 1979 WIPO Model Law for Developing Countries on Inventions, contained in document SCP/22/5, and stated that such revision was in line with the Development Agenda recommendations for WIPO's technical and legislative assistance and that it would be

important to ensure that developing countries were able to fully utilize available flexibilities in an updated manner.

16. The Delegation of the Bahamas, speaking on behalf of the Group of Latin American and Caribbean States (GRULAC), stated that GRULAC viewed the work of the Committee as very important to its region, and there were items on the agenda on which they wished to place particular emphasis. Specifically, the Delegation stated that, as regards agenda item 5, which related to exceptions and limitations to patent rights, GRULAC requested the Secretariat to prepare an analysis of those exceptions and limitations that had proven effective to address development concerns. Further, based on such analysis, it proposed the development of a non-exhaustive manual on the topic, as a reference for WIPO Member States. With regard to agenda item 7, on patents and health, the Delegation was interested in the discussions that would take place within that agenda item, as the members of its Group consisted of developing countries and LDCs, which faced challenges related to the availability of medicines, the promotion of innovation and fostering of the necessary technology transfer to facilitate access to generic and patented medicines. GRULAC was also very interested in the discussions that would take place on transfer of technology, under agenda item 9. Further, with regard to agenda item 10, GRULAC reiterated its proposal that there was need for a complete revision of the 1979 WIPO Model Law for Developing Countries on Inventions. In that regard, noting the support given to that proposal at the previous session, the Delegation expressed its wishes to continue the discussion on such revision. The Delegation stated that a revised document should take into account international legal framework, such as the WTO Agreements, and the WIPO Development Agenda recommendations. The Delegation expressed its hope that there would be a productive discussion on that matter at the appropriate time, and urged other delegations to review the current version of the Model Law to appreciate how outdated it had become, and therefore, no longer served its intended purpose. Finally, the Delegation encouraged all delegations to work towards agreeing on a future work program, so that the important work of the Committee could continue for the benefit of all WIPO Member States.

17. The Delegation of the Netherlands, speaking on behalf of the European Union and its Member States, stated that the program of the twenty-fourth session reflected the balance of different regional priorities and should provide opportunities to all to make much needed progress. The Delegation stated that it came to that session with a constructive spirit and with concrete proposals. The Delegation noted that at the previous sessions, the members of the Committee had spent a disproportionate amount of time on deliberations on the future work program and expressed its hope that at the current session, consensus would be found. In that regard, the Delegation noted the importance of retaining a delicate balance in the current work program. Specifically, regarding the agenda for that week, the Delegation noted that inclusion of discussions on the 1979 WIPO Model Law for Developing Countries on Inventions would take the SCP members further away from a balanced work program. The Delegation highlighted the areas of interest for its Group, in particular, on the topic of quality of patents. The Delegation reminded the Committee that several proposals on work sharing, assessment of inventive step and improving the quality of search and examination had been made by the Delegations of Canada and the United Kingdom, Denmark, Spain and the United States of America and had been endorsed by all other Member States of the European Union. The Delegation remained convinced that the work in that area would be beneficial to all WIPO Member States as it would enhance international cooperation and improve the knowledge of patentability requirements thus ensuring a more efficient, effective, and higher quality patent system to all. Secondly, in relation to the topic of confidentiality of communications between clients and their patent advisors, the Delegation stated that the time was ripe to consider a concrete mechanism to address the recognition of foreign advisors' privilege. The Delegation was convinced that a compilation of court cases with respect to cross-border aspects of client-advisor privilege would be of benefit to all users of

the patent system. Further, the Delegation expressed its commitment to discussing key aspects of substantive patent law, with the aim of international patent law harmonization. The Delegation noted, however, that if the SCP would make no progress on the future work program during that session, they would need to reconsider the frequency and duration of meetings of the Committee. Finally, the Delegation wished to highlight the significance of the work undertaken by the European Union under its enhanced cooperation procedure on the European Patent with unitary effect and the creation of the Unified Patent Court.

18. The Delegation of China stated that it attached great importance to the work of the SCP which provided platform for discussing the patent-related issues and expressed its hope that all Member States would make joint efforts to allow the patent system to play a more important role with regard to incentivizing innovation and promoting social, economic and technological development. The Delegation stated that it would engage in discussions in constructive manner, especially it looked forward to the discussions on the topics of quality of patents, patent and health and confidentiality of communication between clients and their patent advisors. The Delegation was of the view that information sharing and experience exchange among Member States would bring better understanding of the key issues. Noting further that countries had different national conditions, priorities and interests, the Delegation stated that flexibilities were required and that the SCP should work together to take into account the interests of all parties to promote the progress of the Committee. The Delegation looked forward to constructive and fruitful discussion at the twenty-fourth session.

19. The Delegation of Latvia, speaking on behalf of the Central European and the Baltic States (CEBS Group) expressed its confidence in the guidance of the Chair and expressed its thanks to the vice-chair for her engagement in the work of the Committee, and to the Secretariat for preparing the session. Noting that at the previous session, the SCP had failed to agree on the future work program, the Delegation welcomed the possibility to have an in-depth discussion on different proposals made during previous sessions under the five longstanding agenda items. The Delegation further expressed its disapproval for the tremendous amount of efforts and time dedicated for the discussion of the future work program during the previous sessions of the SCP. In the view of the Delegation, the five agenda items accommodated the interests of all Member States in a delicate balance. As the interest of each individual Member State lay in at least one of those five topics, the CEBS Group would encourage the Member States to bear that in mind when engaging in discussions on the future work. The Delegation stated further that the areas of interest of its Group were in the work on the quality of patents and on confidentiality of communications between clients and their patent advisors. The Delegation expressed its belief that it was crucial to continue the work on improving quality of patents and in that regard, it supported the proposal to launch a questionnaire and the proposal by the Delegation of Spain. In the area of confidentiality of communications between clients and their patent advisors, the Delegation supported the work on a soft law approach. Further, with regard to the proposal to review the 1979 WIPO Model Law for Developing Countries on Inventions, the Delegation stated that that might disturb the achieved balance in the agenda. Moreover, in the view of the Delegation, such revision would not necessarily reflect the various needs of countries that were supposed to benefit from it. Finally, the CEBS Group believed that the SCP should focus its efforts on a substantive discussion based on different proposals put forward during the previous sessions or on any new proposals and to achieve an agreement on the future work of the Committee. Nevertheless, the Delegation disapproved the excessive amount of time being spent on the discussions on the future work. In conclusion, the Delegation expressed the readiness of the CEBS Group to engage in those discussions in a constructive manner.

20. The Delegation of Oman associated itself with the statement made by the Delegation of India on behalf of the Asia and Pacific Group. The Delegation considered the Committee's

work being extremely important in order to find a balance between the public interest and the interest of the right holders with regards to health, transfer of technology and patent flexibilities. The Delegation stated that it was important to find such a balance taking into consideration the differences in economic and social development and respecting the interests of all Member States. The Delegation also stated that such approach would enable countries with limited resources to guarantee the health needs of their people while encouraging innovation. The Delegation expressed its hope that discussions at the twenty-fourth session would achieve the goal of improving the patent quality while taking into account the interest of all Member States. Further, the Delegation associated itself with the statement made by the Delegation of India on behalf of the Asia and Pacific Group, as regard to the disclosure of INN in patent applications. With regard to the agenda item on quality of patents, including opposition systems, the Delegation reiterated the importance of finding a definition of the term "quality of patents". In its view, the absence of such definition made it impossible to define and fully understand the various proposals on the table. Regarding the topic of opposition systems, the Delegation stated that there was a need to examine all the existing systems to ensure that they were to the benefit of all as regards to health issues and the availability of medicines at an affordable price, and that factor was extremely important for developing countries. In conclusion, the Delegation expressed its support for the GRULAC proposal on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions.

21. The Delegation of Iran (Islamic Republic of) expressed its hope that the Chair would be able to guide the twenty-fourth session in the desired direction and to lead the meeting to a successful outcome. It also expressed its thanks to the Secretariat for its hard work in preparing for this session. Further, the Delegation associated itself with the statement made by the Delegation of India on behalf of the Asia and Pacific Group. The Delegation attached great importance to the work of the SCP for substantive discussions and advancing norm-setting. The Delegation believed that the deliberations on exceptions and limitations, technology transfer and patents and health would help the Committee to better understand the challenges encountered by developing countries in their economic and social development and explore the ways to better adapt the patent system to meet the needs of the national development. The Delegation stated that, in that context, international harmonization of patent laws without giving account to the differences in the levels of social, economic and technological development would not benefit the Member States. The Delegation considered that the international patent norms under a single one-size-fits-all would be unworkable and inappropriate. In its opinion, strengthening the fundamental balance between private interests of right holders and public interest was necessary, especially in the patent system. Accordingly, the Delegation believed that the activities of the SCP should facilitate the dissemination and transfer of technology and ensure that the patent system contributed to the promotion of progress and innovation. The Delegation considered that the Committee should set out a balanced work which would provide the opportunity for fruitful exchange of views on a wide range of topics related to patents. The Delegation looked forward to having substantial discussions on proposals that had been tabled by the developing countries on exceptions and limitations, patents and health and the revision of the 1979 WIPO Model Law for Developing Countries on Inventions. The Delegation expressed its hope that the Committee would make significant progress in advancing discussions on issues of particular relevance to both developed and developing countries.

22. The Delegation of Senegal associated itself with the statement made by the Delegation of Nigeria on behalf of the African Group. The Delegation stated that the agenda was very promising, and it hoped that the members of the SCP would have fruitful exchanges of national experiences with regard to patents, particularly on the subjects of patents and health and exceptions and limitations. Noting that, to achieve that, the delegations should show a constructive approach to the work, the Delegation expressed its readiness to cooperate.



Finally, the Delegation supported the proposal by GRULAC on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions.

23. The Delegation of South Africa supported the statement made by the Delegation of Nigeria on behalf of the African Group. The Delegation stated that the work of the Committee was very important, as it related to the critical aspect of the patent system and its effectiveness in addressing critical public policy issues, such as health. The Delegation looked forward to a concrete, balanced work plan that could provide a structure and guide the SCP discussions to make a meaningful contribution to the broader work undertaken by WIPO. The Delegation stated that South Africa confirmed its commitment to the longstanding issues in the Committee. The Delegation placed importance on the issue of patents and health and wished to see some of the work in the African Group proposal operationalized within the Committee to get a better understanding of the challenges and constraints faced by developing countries in making full use of public health-related patent flexibilities. The Delegation stated that if public health was a major concern for all countries, an appropriate balance between private and public interests needed to be struck when human lives were a factor. The Delegation also looked forward to working on the issue of exceptions and limitations, more specifically on how effective they had been in addressing public policy issues. The Delegation expressed its support to the statement made by the Delegation of India on behalf of Asia and Pacific Group, which was to revise document SCP/23/3 and invite submissions from research institutions, civil society organizations in order to provide more practical examples. Further, the Delegation stated that maintaining patent quality was critical and attention should be paid to the patentability criteria as patent quality could not be improved by simply adopting other patent offices' practices. In the view of the Delegation, the capacity constraints in developing countries required further attention. Finally, the Delegation wished to reaffirm its support for the GRULAC proposal on the 1979 WIPO Model Law for Developing Countries on Inventions and looked forward to constructive discussions on issues that had a direct bearing on how the patent system could be effectively utilized to foster innovation and provide creative solutions to developmental challenges.

24. The Delegation of Paraguay thanked WIPO for organizing a joint seminar on patents and innovation in April 2016, in Paraguay. The Delegation stated that the seminar was organized on the basis of the work of the Committee and dealt with issues, such as patents and health, exceptions and limitations, transfer of technology and quality of patents. The Delegation wished to highlight, once again, the importance of the discussions in the SCP and expressed its hope that that session would make it possible to continue to make progress on each of the items on the agenda as well as on the basis of new proposals that would strengthen the role of the Committee as the only multilateral forum on patents.

25. The Delegation of India aligned itself with its statement made on behalf of the Asia and Pacific Group. The Delegation reiterated that patent systems had been created in the interest of national economy and that, consequently, patent offices had to act as a steward of the public interest so as to protect the public against issuance of frivolous patents that added unnecessary costs and confer unwarranted market distortions. The Delegation reaffirmed that harmonizing patent laws across countries with asymmetric distribution of IP assets served the interests of rent seekers rather than that of the public in developing countries and LDCs. The Delegation expressed its belief that the policy flexibility is a *sine qua non* if enlightened societies were to ensure that intended beneficiaries, the public in each country, would not be worse off as a result of such protection. The Delegation stated that India attached great importance to the work of the SCP and reaffirmed its views expressed at the previous sessions of the SCP, particularly on the topic of exceptions and limitations to patent rights, quality of patents, including opposition systems, patents and health, confidentiality of communications between clients and their patent advisors and transfer of technology. In particular, on the issue of exceptions and limitations to patent rights, the Delegation recalled the mandate of Synthesis Report of the Secretary General of the United Nations, The Road

to Dignity by 2030: On the Post-2015 Agenda. The Delegation stated that, accordingly, the mandate of its delegation was to ensure that the global intellectual property regimes and the application of the TRIPS flexibilities had been fully consistent with and contributed to the goals of sustainable development. Therefore, it reiterated that the information on exceptions and limitations and flexibilities of the patent system to be properly analyzed to distil out the contribution of exceptions and limitations and flexibilities of patent system to the socio-economic development. On the issue of quality of patents, including opposition systems, the Delegation expressed its belief that work sharing had nothing to do with the quality of patents and quality of examination needed to be improved substantially in conformity with the national policy objective of a country so that high social cost of granting patents to insignificant improvement was avoided, which would only create barriers for dissemination of knowledge and transfer of technology. Instead, the Delegation stated, experience sharing might improve the quality of patents and also would improve the skill and technical expertise of patent offices. On the issue of patents and health, the position of the Delegation was that in order to meet the public health requirements with respect to patented drugs and to provide them on affordable prices in developing countries, there was a need to study the TRIPS flexibilities, effective utilization of compulsory licensing provisions under the patent laws and the consequential impacts of grant of compulsory licenses on the availability and prices of patented drugs. The Delegation reaffirmed its view on document SCP/21/9 concerning feasibility study on the disclosure of INN in patent applications and/or patents and on the proposed study on overbroad Markush claims under the agenda items “patents and health” and “quality of patents”. On the issue of client-attorney privilege, the Delegation reiterated its view that the issue was of substantive nature and could be governed by national laws, and expressed its concern over the manner in which the matter had been progressing towards a soft law approach for the harmonization. On the issue of transfer of technology, the Delegation recalled the objectives of the TRIPS Agreement and its mandate as far as transfer of technology and dissemination of knowledge were concerned. The Delegation stated that in order to create balance of rights and obligations, the protection and enforcement of patent rights *vis-à-vis* technological content of patent specifications should be conducive to the socio-economic development. On the proposal by GRULAC, the Delegation reiterated that any revision of 1979 WIPO Model Law for Developing Countries on Inventions should be fully and adequately development-oriented and should provide the legislative and policy options for developing countries to fully utilize TRIPS flexibilities.

26. The Delegation of the Russian Federation thanked the Chair and expressed its hope that under her leadership, the SCP would be able to succeed in reaching a work program for its next session. The Delegation stated that the SCP should be focused on resolving new practical issues relating to substantive patent law. Specifically, the Delegation noted that discussions should be on practical matters relating to innovative developments. The Delegation stressed that issues which were particularly important for its delegation were exceptions and limitations to patent rights, quality of patents, including opposition systems and patents and health. Further noting that the Secretariat had collected voluminous information relating to different aspects of patent law, the Delegation proposed a further work forward by compiling such information and provision of specific recommendations on specific topics.

27. The Delegation of Uruguay thanked the Secretariat for its support in organizing a seminar on the role of patents in development and innovation in Uruguay which was held in April, 2015. The Delegation stated that the seminar provided a good opportunity to discuss the importance of the patent system in the development of its country. In relation to the work of the SCP, the Delegation expressed its hope that delegations would be able to reach an agreement on future work.

28. The Delegation of the Republic of Korea emphasized the importance of the SCP as the only multilateral forum in the field of patents. The Delegation stated that the Committee should play a greater role by providing substantive and technical discussions to improve the patent system. The Delegation encouraged Member States to show more flexibility and cooperative spirit to cover the interests of all Member States in producing a future work program acceptable to all. The Delegation expressed its strong belief that enhancing quality of patents should be a core topic of the SCP. The Delegation stated that high quality of patents was essential to avoid unnecessary socio-economic costs and to achieve innovation and economic development of countries. Therefore, the Delegation reiterated that the Committee should study and exchange views on the issue of work-sharing since that was one of the most effective solutions to obtain tangible output in enhancing the quality of patents. In addition, the Delegation expressed its hope for progress in discussions to be achieved in other issues, such as confidentiality of communications between clients and their patent advisors, patents and health and transfer of technology.

29. The Representative of OAPI expressed its hope that some progress would be made at the twenty-fourth session of the SCP. Noting the importance of the patent system in the development of countries, the Delegation expressed its commitment to participate actively in the work of the SCP.

30. The Representative of TWN stated that the work program of the SCP and the activities of the Secretariat in the area of patents should be driven by realities and evidence rather than the blind promotion of patent protection as a magic way to fix development and innovation problems. He stated that the work program of the SCP should also reflect the reality and effort towards reforming the patent regime to fit its original purpose rather than a mechanism for rent seeking. The Representative believed that the first step, in that regard, was to eliminate the negative externalities of patents on the public and development policies. The Representative continued that it was important to discuss the limitations of patents in inspiring innovation rather than pursuing a patent maximalist agenda. He further stated that some studies had found that the main problem of patents was that they inhibited innovation rather than promoted it. The Representative continued that the current patent system was distorted by pursuing the interests of a few multi-national corporations. He also stated that according to The Economist magazine, the pharmaceutical companies had conducted 30 times more clinical trials for recurrent cancer drugs than for preventive drugs. He further stated that another publication showed that the firms were taking the expenditure away from more curable localized cancers and focusing on incurable metastatic recurring cancers instead. The Representative stated that the patent system encouraged pharmaceuticals to pump out drugs aimed at those that had almost no chance of surviving the cancer anyway. He continued that such patent distortion cost the economy of the United States of America around 89 billion a year in lost lives. He stated that the one-size-fits-all patent system did not cater specific innovation even in the pharmaceutical industry, and that evidence showed that patents failed to attract R&D investment, not only in neglected diseases but also in communicable diseases, such as Ebola virus. The Representative stressed the importance of examining the implications of patents on the transfer and dissemination of technologies relevant to the achievement of the UN 2030 Sustainable Development Goals. He regretted that, since 2008, there had been no substantive progress in the SCP on a development-oriented work program based on empirical evidence. In his view, although issues identified by the SCP in 2008 had offered that possibility, a systematic objection from some developed countries against making any progress in those areas had been observed. The Representative looked forward to a constructive engagement based on the WIPO Development Agenda recommendations during the twenty-fourth session of the SCP.

31. The Representative of KEI wished to reiterate its support for the inclusion of the GRULAC proposal on the revision of the 1979 WIPO Model Law for Developing Countries on

Inventions to the work program of the Committee as he had expressed in the previous session of the Committee.

32. The Representative of Innovation Insights noted the importance of bringing innovators from a range of countries to discuss their practical experiences with the patent system at the SCP. She further stated that Innovation Insights was dedicated to sharing the perspectives of innovators, across sectors and jurisdictions, with policymakers and other stakeholders. She continued that their experience showed that, across fields of technology, patents were useful tool that could be used differently depending on the context and business model. She stated that patents were especially important in the context of collaboration, or open innovation. Further, the Representative informed the SCP about recent patent-related discussions that Innovation Insights had hosted in Geneva. In particular, she stated that on the margins of the CDIP, Innovation Insights had organized a discussion featuring technology transfer officials from research institutes in South Africa, Turkey and Switzerland where the speakers had shared their experiences in setting up frameworks for technology transfer, including IP management. The speaker from the government of South Africa had underscored the important role that IP management played in ensuring that publicly funded research outcomes were transformed into products and services that improved people's lives on the ground. The other speakers, the Representative stated, had identified their common objective in using patents: which was ensuring that research could be turned into offerings that improved lives. Further, she stated that in June 2016, Innovation Insights had co-hosted a discussion featuring the experiences of Colombian research institutes, companies, and universities in setting up technology transfer and IP management systems. The speakers at that event, the Representative stated, had presented a network in Antioquia called SECOPIND, which had been formed to enable 15 organizations to enhance their use of IP tools, by sharing costs. The speakers had explained how patent management was enhancing their organizations' ability to collaborate with others and ensure they benefited from their research. She noted that a speaker from the Colombian government body "Colciencias" had explained how the activities presented fit into broader Colombian plans for economic development, and investment in science technology and innovation. Before concluding her statement, the Representative wished to reiterate their support for bringing the voices of more and more types of innovators, from more countries, to share insights and their experiences with the Committee. That, she said, could enrich the work of the Committee by helping to connect the SCP discussions with the real economy. As an initiative, Innovation Insights would try to present a diversity of views about IP management and technology transfer to Geneva discussions.

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

33. Discussions were based on document SCP/24/2.

34. The Secretariat noted that since the twenty-third session of the SCP, no information concerning certain aspects of national/regional patent laws had been received from Member States. The Secretariat invited Member States and regional patent offices to share information on any recent development of national/regional patent laws under that agenda item.

35. The Delegation of India wished to inform the SCP on the latest developments in the Indian Patent Act. The Delegation stated that it was continuous efforts of India making amendments in the patent procedures periodically to meet the international obligation and promote indigenous inventions. In particular, the Delegation stated that the following amendments had been introduced to the Patent Rules: (i) to facilitate the "Indian Startup",

the Government had considered several incentives including reduced official fees, filing and prosecution assistance by empaneled patent and trademark agents and expedited examination of patent applications; (ii) reduction in the time period for filing a response to examination reports had been reduced from twelve months to six months and the deadline could be extended by three months, if an appropriate request along with prescribed fee was submitted prior to the six-month period; (iii) hearings was proposed to be conducted through video-conferencing or audio-visual communication devices with limited timelines for adjournments and written submission; (iv) the possibility to amend the claims before national phase entry had been introduced; (v) the possibility to get refund of up to 90% of examination fees had been introduced, if the applicant withdrew the application before the issuance of the first examination report; (vi) expedited examination became possible for a PCT applicant by selecting Indian Patent Office as International Searching Authority (ISA) or as International Preliminary Examining Authorities (IPEA). A possibility of converting a regular request for examination into request for expedited examination on satisfying the above requirement had been introduced; (vii) in the pre-grant opposition, the opponents and the applicants shall submit a copy of their representations and replies to each other; (viii) the Power of Attorney (PoA) shall be submitted within 3 months from the date of application or date of filing of relevant document; (ix) the reference to a deposit of biological material in the specification shall be made within 3 months from the date of filing of the application or on or before the date of making a request for early publication, whichever was earlier; and (x) obligation for patent agents to communicate electronically with the Patent Office.

36. The Representative of OAPI stated that some amendments to the Bangui Agreement Relating to the Creation of an African Intellectual Property Organization, Constituting a Revision of the Agreement Relating to the Creation of an African and Malagasy Office of Industrial Property (Bangui (Central African Republic), March 2, 1977) had been introduced, and said that it would submit it in writing in response to the formal request by the Secretariat. The Delegation stated that modifications were related, for instance, to examination as to substance, the procedures and the role of the supreme appeal tribunal, and the opposition procedures.

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

37. Discussions were based on documents SCP/14/7 and SCP/19/6.

38. The Delegation of Brazil fully associated itself with the statement made by the Delegation of the Bahamas on behalf of GRULAC. The Delegation stated that, as had been illustrated by the Secretariat, the topic of exceptions and limitations to patent rights had a long history in the SCP. The Delegation stated that the discussions held since the 14<sup>th</sup> session of the SCP had allowed the Committee to explore how the exceptions and limitations were implemented by the Member States at the national level. That, the Delegation stated, related to the first phase of the proposal, contained in document SCP/14/7, which should be followed by the analysis of those exceptions and limitations that had proven effective to address the development concerns. The Delegation reminded the SCP that the third phase of that document proposed the elaboration of an exceptions and limitations manual, in a non-exhaustive manner, to serve as a reference to WIPO Members. The Delegation further stated that after all the work that had been carried out by the Committee, it was time for the Secretariat to prepare an analysis of the exceptions and limitations that had proven to be effective to address the development concerns. The Delegation noted that such studies would take into account not only the document discussed at the previous sessions of the SCP, but also other rich materials produced at the sessions before. That would include the responses by 72 Member States to the questionnaire on exceptions and limitations to patent rights, debates held in previous sessions of the SCP and

Experts' Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights circulated at the 15<sup>th</sup> session of the SCP. The Delegation continued that other inputs could be found from elsewhere such as the discussions held in UNCTAD and the WHO. Furthermore, the Delegation stated that inviting submissions from all stakeholders, such as scholars, research institutions, civil society organizations and local industries with practical experiences on that matter, would bring the points of view of the actual users of the exceptions and limitations. Additionally, the Delegation stated that a compilation of court cases with the exceptions and limitations could be an interesting exercise that it wished to bring for consideration of Member States. The Delegation continued that, on the basis of that analysis and the study, the development of a non-exhaustive manual on the topic should be followed. Noting that exceptions and limitations to patent rights were relevant to an adequate and balanced system and that Member States had developed different approaches to their implementation, the Delegation expressed its belief that a flexible policy space was necessary to allow Member States to develop and adapt the sets of exceptions and limitations more adequate for their realities, independent of whether it was a developed country or a developing country. The Delegation noted that existence of the exceptions and limitations was not sufficient to evaluate the benefits or obstacles faced by Member States in their implementation. The Delegation explained that that was the reason underpinning the second phase of its proposal, aiming at investigating which exceptions and limitations were more effective in addressing the development concerns. Emphasizing that those concerns were not only restricted to the developing countries, and that every Member State had a crucial interest in advancing its technological, economic and social development for the benefit of its population, the Delegation stated that it was a matter of interest to all members of the SCP to agree on the continuation of work on that matter.

39. The Delegation of the Bahamas, speaking on behalf of GRULAC, as well as in its national capacity, expressed support to the proposal made by the Delegation of Brazil.

40. The Delegation of Iran (Islamic Republic of) expressed its support to the statement made by the Delegation of Brazil on the topic of exceptions and limitations to patent rights. The Delegation stated that it attached great importance to the flexibilities in the IP system which recognized the need to adapt national legislations on patents to countries' economic and social situations. The Delegation further stated that the mandate given to the Secretariat in preparing the studies on exceptions and limitations had been limited to input received from Member States and they had to be prepared without evaluating the effectiveness of those exceptions and limitations. The Delegation continued that, accordingly, there was no wider assessment of whether any of the exceptions and limitations was being used for the purpose of meeting public policy goals and society needs such as, development needs, public health goals or competition, as found in the proposal by the Delegation of Brazil, contained in document SCP/19/6. The Delegation stated that, in fact, the studies provided very limited focus on implementation challenges and practical constraints faced by countries in using those exceptions. Therefore, the Delegation stated that the findings made in those studies did not necessarily adequately reflect many countries' particularities and differences in the level of development. In that context, in the view of the Delegation, it would be important for the SCP to consider undertaking the work as stated under phase two of the proposal by the Delegation of Brazil and to undertake an analysis of how various exceptions and limitations were utilized by different countries in addressing various public policy objectives. In conclusion, the Delegation stated that the Secretariat should invite submissions from civil society organizations, research institutions, and local industries in developing countries to submit information on their practical experiences on effective use of the exceptions and limitations to patent rights under their relevant national legislations.

41. The Delegation of Pakistan noted that exceptions and limitations to patent rights were essential for providing the requisite flexible policy space to all countries and, therefore, it expressed its strong support to the proposal by the Delegation of Brazil.

42. The Delegation of the Netherlands, speaking on behalf of the European Union and its Member States, noted that, for that agenda item, there had not been any new contributions from Member States, beside the documents from previous sessions, namely documents SCP/14/7 and SCP/19/9. The Delegation referred to document SCP/23/3 on Member States experiences and case studies on the effectiveness of exceptions and limitations, discussed at the previous session of the SCP, and stated that the European Union and its Member States considered that that document would serve as a useful reference. The Delegation continued that, in order to have a meaningful outcome on exceptions and limitations, it was essential that the Committee could learn from practical experiences on the effectiveness and challenges of exceptions and limitations in addressing development issues and stimulating innovation. Therefore, the Delegation could consider, as part of the future work program, a sharing session among Member States on case studies with respect to exceptions and limitations to patent rights, as had been proposed at the previous session. Further, as regards exceptions and limitations in general, the Delegation highlighted that exceptions and limitations to patent rights maintained an appropriate balance between the interests of rights holders and the general public. Taking that balance into account, it was important to address both sides at the same time; on the one hand, exclusions from patentability or exceptions and limitations to patent rights, and on the other, the corresponding legal standards used to determine whether an invention was patentable, such as novelty, inventive step, and industrial applicability.

43. The Delegation of China thanked the Delegation of Brazil for its statement. The Delegation stated that the Secretariat had summarized countries' legal provisions on exceptions and limitations, prepared the detailed analysis of implementation of various exceptions and limitations in Member States, and shared Member States' experiences and case studies on the effectiveness of exceptions and limitations. The Delegation stated that all that information was important for the countries' reference and learning and that it had laid a solid foundation for detailed discussions on exceptions and limitations. The Delegation believed that exceptions and limitations to patent rights constituted a very important support for a good functioning of a patent system as they provided a balance between interests of the public and the right holders. The Delegation welcomed effective and fruitful discussions on that issue and encouraged Member States to continue sharing the information on exceptions and limitations, since that would be a valuable reference for Member States to improve their patent laws. Further, the Delegation suggested that the Secretariat continued to collect and compile, update the information submitted by countries and to make further analysis of exceptions and limitations so that the SCP could identify how countries were using them in their jurisdictions, the public policy goals of those exceptions and limitations as well as the obstacles that they had encountered in applying those exceptions and limitations.

44. The Delegation of India reaffirmed its support for the work proposed in document SCP/19/6 on exceptions and limitations to patent rights. The Delegation stated that the proposed study might focus upon the use of some exceptions such as, compulsory licensing, parallel imports, government uses and the Bolar exception, which were extremely important from the perspective of accessibility and affordability of medicines and also in other areas of socio-economic importance, namely the environment and technology transfer to developing countries. In that regard, the Delegation recalled the mandate given in the Synthesis Report of the Secretary General of the United Nations, *The Road to Dignity by 2030: On the Post-2015 Agenda*, that: *"We must facilitate access to the benefits of technology for all, including the poorest, while ensuring that intellectual property regime creates the right incentives for the technological innovation needed for sustainable development. The urgency is*

*particularly great in the case of low-carbon technologies as part of our efforts to mitigate human-induced climate change*". The Delegation stated that, therefore, its mandate was to ensure that the global IP regimes and the application of the TRIPS flexibilities were fully consistent with, and contributed to, the goals of sustainable development. The Delegation noted that, in order to protect the public interest, Articles 7 and 8 of the TRIPS Agreement allowed the WTO members to enact the exceptions and limitations in their legislation. The Delegation considered that, like any rights, patent rights could not be absolute and that they also carried the accompanying obligations that had to benefit public at large, and that those rights and obligations would balance each other. Having said that, the Delegation appreciated the thorough work by the Secretariat in collecting the information on exceptions and limitations to patents rights, but at the same time, it wished to reaffirm that it was time that such information to be properly analyzed to understand the contribution of those exceptions and limitations to the development. In that regard, the Delegation suggested that since scientific and research institutes could be a good place to use research exceptions and civil societies involved in public policy could be good sources of information regarding the use of exceptions, the Secretariat should take into account the experience of those institutions in compiling such information.

45. The Delegation of Latvia, speaking on behalf of the CEBS Group, stated that its exceptions and limitations to patent rights represented a balance between the rights of patent owners and those of the public at large. The Delegation considered that, therefore, the question of the exceptions and limitations should be discussed at the same time as the patentability criteria used in determining whether the invention was patentable or not. In particular, the Delegation noted that discussions on novelty, inventive step and industrial applicability were necessary for a holistic approach. The Delegation saw the merits in sharing national experiences and case studies on implementation of exceptions and limitations to patent rights, and stated that the CEBS Group would be willing to consider it as the part of the future work.

46. The Delegation of South Africa, speaking on behalf of the African Group, observed that, as it had been indicated in the statement by the Delegation of Brazil, exceptions and limitations had a long history in the Committee and much work had been done. The Delegation was of the view that rich quantitative data had been already produced, it was important that the SCP proceeded to qualitative analysis. Specifically, the Delegation questioned how effective those exceptions and limitations had been; whether they achieved intended purpose; what the benefits of exceptions and limitations were; and whether they could be imitated by other countries facing the similar challenges. The Delegation suggested that the study should be extended to certain societies and research organizations. The Delegation noted importance of taking the steps forward and ensuring that the ultimate goal of promoting socio-economic development in the broader context of the 2030 Agenda for Sustainable Development would be achieved.

47. The Delegation of the United States of America thanked the Secretariat for preparing the non-paper on proposals, studies, seminars and other activities and issues which had taken place between the sixteenth and twenty-third sessions of the SCP on the issue of exceptions and limitations to patent rights and noted a large amount of work which had already been carried out by the SCP on that topic, such as studies and seminars. The Delegation stated that, thus, a very large body of information could be used by Member States without further elaboration by the Secretariat. Noting that the proposals by the Delegation of Brazil, regarding exceptions and limitations to patent rights, raised several complex questions that had not been clarified, the Delegation stated that such clarification was necessary before the Committee could consider any additional action, in particular with respect to the phase two of the proposals. Specifically, the Delegation stated that some of those clarifications related to how the effectiveness of exceptions and limitations to address



development concerns would be defined; how the effectiveness of the exceptions and limitations would be measured and what the indicators of such effectiveness were. The Delegation further stated that, assuming that there was a universally acceptable methodology to measure the effect of implementing or not implementing certain law provisions on the country's level of development, the Delegation was of the view that such socio-economic analysis fell outside of the scope of the competence of the Committee and of WIPO in general. Accordingly, the Delegation stated that it was outside of the Secretariat's competency to draw conclusions on the effectiveness of the exceptions and limitations in reaching public policy objectives and society needs as a whole. The Delegation continued that an attempt to carry out such analysis would likely entail an enormous amount of work since every Member State had different public policy objectives and societal needs and different strategies in meeting those objectives. The Delegation stated that one-size-fits-all approach was contrary to the spirit of the Development Agenda. The Delegation continued that each Member State was sovereign and should make its own policy decisions which may include the adoption of the intellectual property provisions which were designed to attract foreign direct investment. Noting that providing reliable incentives for the innovation through the patent system was the best method to achieve the development and public policy objectives, the Delegation stated that there was ample evidence to show that the patent system was a key component in industrial development. Finally, the Delegation was of the view that WIPO should not be placed in the position of making qualitative judgments or criticizing other international agreements, some of which might be administered by WIPO, on the grounds that they could be viewed in some situations as constraints or obstacles in the implementation of flexibilities. The Delegation concluded that, for the above reasons, it did not support the analysis to be carried out by the Secretariat on exceptions and limitations to patent rights as had been proposed by the Delegation of Brazil.

48. The Delegation of Brazil thanked for the interventions made during the plenary which underscored the relevance of the work done by the Committee on the subject, as well as the importance of a firm understanding of exceptions and limitations in order to adequately balance the patent system. The Delegation further elaborated on the two points made by it in its first intervention. The first concerned the invitation for all stakeholders to make submissions. The Delegation reiterated its belief that it was important to learn from practical experiences and that the patent system responded to the evolving real world. The Delegation also believed that open invitations from all stakeholders would generate concrete information on obstacles and opportunities faced by the actual users of those exceptions and limitations, and it could bring first-hand accounts on benefits from the use of the exceptions and limitations. The second point made by the Delegation related to a compilation of court cases that involved the use of patent exceptions and limitations. The Delegation explained that there was very rich experience from members of every region and level of development and that the court cases had a direct impact on the understanding and practice of uses of the patent system. The Delegation specified that they included decisions related, for instance, to the Bolar exception or compulsory licensing. The Delegation made a suggestion that such compilation could include matters related to the application of the research exemption, also acknowledging that some questions could arise on the use of that exception, for example whether it included the exportation of a patented invention to be tested in another country or whether a patented invention could be imported without the authorization of the right holder for research purposes. The Delegation further noted that decisions on other issues could also shed light on the understanding of the judicial authorities on evolving subjects regarding the patent system. The Delegation believed that the approval of such proposals would bring additional useful information for members of the SCP.

49. The Representative of TWN stressed the importance of exceptions and limitations to patent laws for safeguarding the public interest, and noted that developing countries had been asked to use flexibilities to safeguard the public interest from the hardship of common

minimum intellectual property standards since the conclusion of the TRIPS Agreement. When it came to the patent protection, the Representative stressed that the political consensus of using the TRIPS flexibilities to address public health concerns was clearly reflected in the Doha Declaration on the TRIPS Agreement and Public Health, and that since the adoption of the Doha Declaration, many UN declarations and resolutions have referred to the Doha Declaration, most recently, the Sustainable Development Goals, in particular the means of implementation of goal three, to ensure access to affordable health products. The Representative emphasized that many Member States, especially the developing countries, nevertheless, were facing difficulties in using the flexibilities in an international patent regime. The Representative remarked that there were legal, institutional and policy constraints in the effective implementation of flexibilities and that, apart from those constraints, developing countries were facing bilateral pressure from developed countries against the use of flexibilities. The Representative stated that the bilateral pressure was manifested in the form of political pressure and aggressive trade and investment obligations through free trade agreements and investment agreements. In the view of the Representative the statements from the officials of Switzerland and United States of America against Colombia's plan of using a compulsory license to facilitate affordable access to Imatinib, a crucial life-saving medicine for leukemia patients, clearly showed how the developed countries were pressuring developing countries against the use of flexibilities. The Representative stated that such political pressure went against the UN Declaration on the Inadmissibility of Intervention and Interference in the Internal Affairs of States, and quoted Article I (b), which recognized: "the sovereign and inalienable right of a State freely to determine its own political, economic, cultural and social system, to develop its international relations and to exercise permanent sovereignty over its natural resources, in accordance with the will of its people, without outside intervention, interference, subversion, coercion or threat in any form whatsoever." The Representative continued by stating that bilateral trade pressure was used as a tool to threaten trade sanctions, such as the Special 301 Report on the Intellectual Property Rights. The Representative stated that such bilateral pressure constituted a violation of the international obligations and the various human rights treaties. The Representative further emphasized that the international human rights obligations also obligated Member States to refrain from actions which would prevent the enjoyment of human rights in a third country. Against that background, the Representative called upon Member States to engage in a constructive discussion on exceptions and limitations. In the view of the Representative, the first step towards such discussion was to entrust the Secretariat to carry out a qualitative analysis of the exceptions and limitations.

50. The Delegation of the Russian Federation noted a number of issues dealing with exceptions and limitations to patent rights, namely that the national legislation of the majority of Member States had implemented the TRIPS provisions on exceptions and limitations. The Delegation reminded of its earlier statement that the legislation of the Russian Federation also foresaw a number of limitations and exceptions from patent monopoly. At the twentieth session of the SCP, the Delegation had brought in some examples with regard to the legislation of the Russian Federation and also some practical approaches, which could be found in the documents from the twentieth session. As to the issue of innovation, in view of the Delegation, the main task of Member States in using exceptions and limitations was the balance of rights between the right holder and the society as a whole. The Delegation therefore concluded that while the flexibilities were already foreseen in the TRIPS Agreement, the balance of interests needed to be found depending on the area of technology and the access of society to new technologies, and not only in the pharmaceutical and medical areas but in other significant areas as well. With regard to the work of the Committee on exceptions and limitations, the Delegation stated that the Committee had already some rich information available with regard to the legislation of Member States and also their experience and their practice in use of exceptions and limitations. The Delegation reiterated its proposal, that the Secretariat establish a consolidated list of exceptions and

limitations. The Delegation suggested that such kind of a list could be a manual and actually have, for instance, case law examples and the problems that different Member States had encountered when trying to implement those exceptions and limitations. The Delegation expressed the desire to continue the consideration of the practical aspects of the implementation of limitations and exceptions at a national level and called on members to share their experience particularly with regard to compulsory licensing. The Delegation suggested that one of the practical aspects could be the issuance of the obstacles that Member States came up with and also members of the civil society in trying to actually use compulsory licensing and other uses without the agreement of the rights holder. The Delegation emphasized that in order to overcome such problems, it would be useful to have such information. The Delegation confirmed that it was in favor of continuing the discussion on the topic and keeping the topic on the agenda of the SCP.

51. The Delegation of South Africa on behalf of the Africa Group took note of the various options put forward by the Delegation of Brazil, such as broadening the audience to have a more comprehensive view of the exceptions and limitations, as well as collecting existing court cases. The Delegation believed that such options would be useful when the Committee would consider Future Work.

52. The Representative of KEI, in relation to limitations and exceptions, recalled the proposal by the Delegation of Brazil (document SCP/14/7), which had called attention to the lack of policy coherence in a world where in certain international fora, countries endorsed the use of compulsory licensing to promote access to medicines for all, while in other fora, they criticized developing countries for actually considering or issuing such compulsory licenses. The Representative then quoted paragraph 15 of the submission of the Delegation of Brazil, which stated: "During the post WTO period, after a long period of negotiations, the government of Brazil decided in May 2007 to sanction the compulsory licensing of an antiretroviral drug in order to address urgent public health problems. Our country then suffered an intense campaign to discredit us, led by some international actors, as if it were ignoring the rules agreed by all WTO Members, with which we fully complied". The Representative continued by stating that in November 2015, the United Nations Secretary General Ban Ki-moon convened the High Level Panel on Access to Medicines with the objective of reviewing and assessing "proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies." The Representative emphasized that if the compulsory licensing of medicines was truly supported, it should not be subject to bilateral and unilateral trade pressure. The Representative further stressed that the Committee should address what role, if any, WIPO could play in addressing such lack of policy coherence. In the opinion of the Representative, in developing modules on state practice for limitations and exceptions, the International Bureau should examine how certain countries, such as the United States of America, implemented limitations and exceptions to remedies associated with the exclusive rights of patents, with a focus on the flexibilities found in Articles 44.1 and 44.2 of the TRIPS, including cases where non-voluntary authorizations to use patents replaced injunctions to enforce exclusive rights (see for example, the U.S. Supreme Court decision *eBay v MercExchange*, or 28 USC 1498). The Representative drew the Committee's attention to the United States Affordable Care Act, which had created a limitation on remedies for infringement of patents when a company selling a biologic drug failed to provide timely disclosure of patents to potential suppliers of biosimilar products. The Representative finally concluded that KEI supported Brazil's call for the Secretariat to create a compilation of court cases related to exceptions and limitations to patent rights.

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

53. Discussions were based on document SCP/24/3.

54. The Secretariat presented a summary of the work done by the SCP on the agenda item since the twentieth session of the SCP. The Secretariat made a presentation on the new WIPO web page regarding work sharing and collaborative activities as well as on the WIPO CASE system.

55. The Delegation of Mexico made a presentation on CADOPAT, a support system for patent applications management, created in 2007 with the aim of: (i) fostering innovation protection in Latin America; (ii) strengthening cooperation between the offices in Central America and the Caribbean; and (iii) providing a service by the Mexican Intellectual Property Organization for offices that required support with examination on the substance or the form of patent applications.

56. The Delegation of Japan congratulated the Chair and expressed appreciation of the informative presentations that had been made by the Secretariat about work sharing, including the PPH and WIPO CASE. Noting some concerns on work sharing that had been expressed in the previous session of the SCP, the Delegation stated that business activities had been becoming more and more globalized and the number of patent applications filed by non-residents had been increasing. In the view of the Delegation, such increase indicated that the number of patent applications filed in multiple offices was also on the rise. The Delegation, therefore, observed that the increase in global patent applications created more duplication of work, and thus there was growing demand for work sharing. The Delegation explained that, in response to heavy workloads, one idea might be to hire more people to deal with them. However, hiring more examiners would place more demand on human resource management and costs, and therefore, in its view, the possibility of such increase would be limited. As a result, the Delegation continued, another solution was work sharing, which had been growing in importance and becoming an effective means. The Delegation noted that the PPH, as one of the examples of work sharing, was a program that made use of other offices' examination results and therefore reduced the workload for conducting prior art searches and speeded up the examination process. The Delegation further noted the dossier sharing system as the other example of work sharing, which enabled IP offices to access other offices' examination results. The Delegation stated that neither of the initiatives impacted the independence of examinations at the offices. If necessary, the Delegation proposed to provide explanations in a more detailed manner during the ongoing session or bilaterally. The Delegation also expressed its appreciation to the Delegation of Mexico for sharing its interesting work sharing program.

57. The Delegation of the United States of America thanked the Secretariat and the Delegation of Mexico for the presentations on WIPO CASE and the CADOPAT system. The Delegation noted that WIPO CASE was similar to the Global Dossier system that the IP5 Offices had been working on. The Delegation explained that the IP5 Offices included the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO) and the State Intellectual Property Office of the People's Republic of China (SIPO) which together had formed a cooperative initiative to work together. The Delegation further noted that the Global Dossier was one of those tools that the Offices were trying to build. The Delegation stated that, in addition to the IP5 Offices, a Global Dossier task force had been formed, and comprised various legal and business groups from the IP5 countries, also in partnership with WIPO. The Delegation specified that those groups were working together to establish the Global Dossier and that in many ways, it was similar to WIPO CASE. The Delegation further explained the U.S. patent application information retrieval system – the PAIR system.

Through the PAIR system, if one was aware of a U.S. reference of a U.S. application, one could see the entire dossier for that application once it had been published, namely, what references had been cited against it and the actions that the examiners had issued against it. The Delegation compared the Global Dossier in many ways to the public PAIR on steroids. The Delegation explained that through the Global Dossier system, one could go into the U.S. application and then see every related application, filed by that time in the IP5 Offices, and access every dossier for each of those applications. Recalling the words of the Chair, the Delegation observed that patent examination had changed dramatically, because previously the examiner had to flip through paper patents one at a time. The Delegation explained that now, if an examiner was looking at an application, while knowing a related application filed in one of the IP5 Offices, and needing certain pieces of art to complete his examination, that examiner could go into the Global Dossier system, see every reference cited against every related application in that patent family, and then find what was missing. The Delegation concluded that it was a bold, brave, and wonderful new world for examiners. The Delegation named some of the services that the Global Dossier system offered, for example, a patent family list: one could click on the application that one was initially aware of and see every related application. In addition, the Delegation continued that there was a quick view system that allowed to see the documents cited in each of the dossier of other related applications, the dossier view that allowed to see the entire dossier, and the classification and citation view, that would allow one to see each citation of every reference and then access those references through the Global Dossier system. The Delegation provided some statistics, stating that the Global Dossier system was being accessed by the public at a rate of 25,000 accesses per day; and by examiners at various offices worldwide at a rate of 3,000 accesses per day. The Delegation reassured that such numbers were continually growing as more and more members of the public and examiners worldwide were becoming aware of the system. The Delegation mentioned, in the future, it hoped to offer an enhanced Office action indicator in the system and an ability to filter the desired documents within the system. The Delegation revealed that members from the IT Section had been in Geneva the previous week and talked with the Secretariat about a connection with the WIPO CASE, which would expand the Global Dossier beyond the IP5 Offices to every providing office under the WIPO CASE. The Delegation stated that one of the things that it was most excited about was the document exchange pilot which would allow the various IP5 Offices to exchange documents, references, cited papers, filed papers amongst one another. In the view of the Delegation, that would be a first step towards cross filing, where an applicant could file in a first office and then indicate that he/she wanted to cross file in numerous other IP5 Offices, and they could all be taken care of through the Global Dossier system. The Delegation was also looking for stakeholder input and promised to give out a couple of website addresses. It suggested providing the Secretariat with the specific addresses so that people would not have to furiously write them down. The Delegation reiterated that it was looking for stakeholder input; therefore if someone wanted to make suggestions on how the system could be bettered, he/she could go to: <http://www.uspto/globaldossier.ideascale.com> or email the USPTO's Global Dossier team at: [globalDossier@USPTO.gov](mailto:globalDossier@USPTO.gov). The Delegation clarified that one could access the Global Dossier system through portals at four of the five IP5 Offices. So, at that time, everyone except for Japan had a public portal, which in the understanding of the Delegation, would be active either later in that summer or certainly before the end of the year. As a concluding remark, the Delegation proposed to provide a live demonstration and a more in-depth presentation on the Global Dossier system at a future session, how it worked and how it could be used by the examiners worldwide to improve their examination processes.

58. The Delegation of Argentina was pleased to see the Chair chairing the meeting and stated that it trusted that the Chair would guide the meeting in a way that would be productive. The Delegation believed that, in terms of improvement of the quality of patent applications and patent examinations, the issue was of high interest for all Member States,

irrespective of their level of development, because it would result in benefits not just for the users but also for society as a whole. Furthermore, the Delegation emphasized that to ensure that the patent system worked properly and that it promoted innovation, knowledge and wellbeing of populations in access to health, it was fundamental to have a system that granted patents of high quality. For that reason, the Delegation agreed with the proposal by Denmark with regard to the fact that the objective should not be to harmonize the national patent system, because there was nothing that prevented collaboration between offices in order to create a better patent system with high quality patents and reduce operating costs for states. The Delegation further noted that it was obvious that sharing of search results on the same invention would be beneficial for the examiner at a later stage irrespective of which office was issuing the patent. The Delegation concluded that carrying out the work on work sharing did not impede the independence of Member States in determining patentability criteria.

59. The Delegation of the Netherlands, speaking on behalf of the European Union and its Member States, thanked the Delegation of Mexico for its useful presentation. The Delegation believed that work sharing and international cooperation could be powerful tools that contributed to making the work of patent offices more efficient and effective, and could be instrumental in helping offices to grant high quality patents. In the view of the Delegation, it was clear that many offices around the world, both large and small, were taking advantage of work sharing in order to avoid duplication of work, reduce backlogs, and improve the overall efficiency of the search and examination process. The Delegation suggested that the Secretariat could assist Member States in benefiting from existing tools and practices by, for instance, providing a dedicated page on the WIPO website where Member States could collect information on existing work sharing programs and educate themselves. The Delegation added that conferences in the margins of SCP sessions on that topic would also be beneficial. Furthermore, the Delegation believed that a study on how work sharing could amplify the efficiency of patent offices worldwide would be useful. In the view of the Delegation, as all patent professionals knew, the inventive step was the most difficult patentability requirement to assess and its proper evaluation was a key to guaranteeing a high quality patent system. The Delegation, therefore, expressed the wish to see further studies of the assessment of the inventive step within the Committee. The Delegation recalled that several constructive proposals had been made by the Delegations to that effect. The Delegation reiterated support for the proposals made by the Delegation of the United States of America (documents SCP/19/4 and SCP/23/4), the proposal made by the Republic of Korea, the United Kingdom and United States of America (document SCP/20/11), the Spanish proposal of studies on inventive step (document SCP 19/5 Rev.) – and earlier proposals made on improving the efficiency of patent offices by Denmark, Canada, the United Kingdom and United States of America (documents SCP/17/7, 8, 10, and SCP/18/9). The Delegation noted that key elements of those contributions were well reflected in the proposal for a work program which was elaborated on during the previous session of the SCP. The Delegation confirmed that it fully subscribed to those elements under “quality of patents” in the work program and was ready to commence its work to the benefit of all Member States.

60. The Delegation of the Republic of Korea expressed its belief that the advancing of the work on quality of patents was an important issue to ensure that the patent system operated properly. The Delegation emphasized that further work in that area was beneficial to all WIPO Member States. The Delegation further specified that among the many sub-topics related to the patent quality, work sharing was particularly important, since it could be one of the most effective solutions to enhance the quality of patents. The Delegation emphasized the fact that large offices, as well as small offices, had difficulties during the examination process. By way of an example, the Delegation stated that searching prior art all over the world was not easy even for the large patent offices, particularly when the prior art was

written in foreign languages. Since a small number of examiners handled a large number of technical fields in small IP offices, it caused more serious difficulties. In the view of the Delegation, various work sharing programs had been launched, mainly focusing on sharing information of prior art search results. The Delegation expressed the belief that, due to the successful programs, thanks to which examiners in different offices could cooperate with each other, duplicated work had remarkably decreased. In its opinion, the SCP was an ideal forum to share the successful experiences so that Member States could choose the most appropriate ones for them and collect new ideas to improve existing programs. The Delegation further emphasized that work sharing would give advantages to all Member States, regardless of the economic situation or the capacity of national IP offices. The Delegation recalled that during the previous sessions, some Member States had raised their concern that work sharing might weaken the examination process and the capability of IP offices in developing countries. Nevertheless, in view of the Delegation, developing countries with small offices could benefit from work sharing by utilizing resources from other countries. Further, the Delegation recognized that CADOPAT which had been introduced by the Delegation of Mexico was a good example of such benefit, and expressed its gratefulness to the Delegation of Mexico for their excellent presentation. The Delegation also believed that work sharing could be a very useful way for developing countries to strengthen their capacity through cooperation with more experienced countries. The Delegation also noted that work sharing was only for helping the decision making of each country according to its own law. In that context, the Delegation supported the proposal by the Republic of Korea, the United States of America and the United Kingdom to organize annual conferences (document SCP/20/11 Rev.) and the proposal by the United States of America to conduct a study on work sharing (document SCP/23/4). Finally, the Delegation briefly shared its experience in the Global Dossier, and noted that in August 2013, KIPO had implemented the One-Portal Dossier (OPD), for examiners, which had been one of the most significant achievements of the Global Dossier project and it had been opened to the public since March 2015. The Delegation further explained that KIPO examiners had accessed to the documents from other IP5 Offices approximately 183,000 times via the OPD in 2015, and the Korean documents had been accessed by examiners of the other four IP5 Offices about 496,000 times. The Delegation also affirmed that the OPD had been widely used by applicants and the public: in particular, in 2015, Korean users had accessed to the documents of other IP5 Offices around 133,000 times. The Delegation specified that according to an internal survey in 2015, KIPO examiners had confirmed that the OPD had substantially enhanced the deficiency of patent examination, in particular they had given 91 points out of 100 in the satisfaction survey of the service. According to the Delegation, in order to further improve the OPD, KIPO kept focusing on enhancing machine translation quality in minimizing the maintenance time and improving user interface. In concluding, the Delegation invited other Member States to share more information, experiences and new ideas on various supporting tools for work sharing in order to reduce workload and enhance efficiency of patent examination.

61. The Delegation of India reiterated the view that the patent quality was not finally determined by instrumental efficiencies, but by appropriate application of formal and substantive issues of respective States commensurate to their laws. In the opinion of the Delegation, the problem with the deterioration of quality was not mainly due to inadequate infrastructure, but to the lowering standards of patentability and examination practices. The Delegation, thus, drew the conclusion that to advance the discussion on quality of patents, the Committee needed, first, to advance a common understanding on what was meant by “quality of patents”, since the terminology might have many different meanings. In the view of the Delegation, the concept of work sharing had nothing to do with the patent quality; and the quality of search and examination needed to improve substantially in conformity with the policy objective of a country so that no huge social cost of granting patents to insignificant improvement, which only created barriers for dissemination of knowledge and transfer of

technology, were created. The Delegation restated that mere arithmetical application of standards applied in one country could not be a solution in another, and automatic validation of patents granted in other jurisdictions would not enable India to grant patents in conformity with the standards described in the statute. The Delegation explained that India resisted any attempt of harmonization of patent laws in the name of work sharing under the pretext of quality of patents, and expressed concerns for the norm setting in future. The Delegation reiterated its proposal for further studies on different thresholds in national patent legislations for “sufficiency of disclosure” as a problem linked to the patent quality leading to patent backlogs requiring further work by the examiners. The Delegation specified that the study might further be enhanced to probe the role of “sufficiency of disclosure” in the context of transfer of technology, since the transfer of technology *vis-a-vis* the sufficiency of disclosure was also linked to the patent quality. With respect to document SCP/23/4, the Delegation drew the attention to the fact that the Delegation of the United States of America reiterated in the twenty-third session that the reuse of search and examination results under the PPH was carried out, while respecting the national sovereignty of participating offices, since the search and examination of the application continued to be performed by each office, according to its national law and no deference was given to patentability determinations that were reached by the other offices. The Delegation further recalled that the Delegation of the United States of America had expressed the opinion that because of those safeguards, the concerns that the PPH called for the automatic acceptance of patentability decisions reached by another office were unwarranted. The Delegation also remembered that a nearly similar opinion had been expressed by other delegates, such as the Delegation of the United Kingdom. The Delegation further added that, although the India Patent Office utilized the report of foreign patent offices, their examiners were duty bound to do the searches and examinations by themselves. In the end, the Delegation stated that, as long as the work of the SCP remained within studies and as long as there was no attempt of any harmonization, there was no threat to the patent system. Therefore, the Delegation was of the opinion that the work sharing should be bilateral, or trilateral, or so on, but any proposed study should not be construed as a tool for harmonization of patent laws or for norm setting in future. Nevertheless, the Delegation stated that on several occasions in the past, it was observed that certain forms of the PPH were recommended by different offices, in which a third office remained obligated to validate the grant, if the first two offices gave a favorable report. Therefore, the Delegation stated that it had its apprehensions on the proposed study. With regard to the U.S. proposal on a study analyzing the benefits and possible impediments of making national collections of prior art available to all patent offices through an IT portal, the Delegation referred to the concerns by the Representative of TWN on the traditional knowledge related databases, and stated that opening of the databases, such as the Indian TKDL used by the India Patent Office, to the public would cause rampant bio-piracy, although India already shared its TKDL database with the leading patent offices for the search and examination. The Delegation hoped that there would be a separate round of discussions and interventions regarding the proposal by Spain on the inventive step.

62. The Delegation of Ireland noted that discussions had been held from the perspective of a number of very large patent offices, which were indeed extremely large from the view of the Delegation, since in Ireland the staff constituted three patent examiners, who were expected to examine patents across the entire technical spectrum. The Delegation expressed its satisfaction to the Secretariat’s presentation on the work sharing web page, because it had also looked at some of those modalities which were available to offices, and particularly to small offices. The Delegation explained that in 1992, Ireland ratified the European Patent Convention so that the vast majority of applicants would obtain patents by that route. Nevertheless, Ireland received a small number of national applications each year: at that moment, the number ran between 150 and 200 patent applications. The Delegation explained that although one would expect three examiners to be able to handle that number of applications, it was a problem because of the range of subject matter concerned. The



Delegation described what had been done since 1992: first of all, an applicant could ask the Ireland Patent Office to commission a search report on their behalf – Ireland had a cooperation program with the United Kingdom Intellectual Property Office (UKIPO) that did the searches on their behalf. As an alternative, the Delegation explained that, instead of requesting a search report conducted by the Ireland Patent Office, applicants could submit a search report from either the UKIPO, the German Patent and Trade Mark Office (GPMA), the EPO, or from WIPO; or instead of supplying a search report, the applicant could submit a granted patent from the UKIPO, the GPMA, or the EPO. The Delegation explained that was the way how the workload was managed with such a limited number of patent examiners. The Delegation noted that the point it was trying to make was that there were different modalities and different work sharing. The Delegation observed that while it was great to hear that the large offices were cooperating so closely, offices such as Ireland had very, very limited options open. In its view, the only way that Ireland could guarantee the quality of the patents was to be clever in the way the limited resources were used.

63. The Delegation of Latvia, speaking on behalf of the CEBS Group, expressed its view that the issue of quality of patents was at the core of the patent system, and that high quality patents enabled the intellectual property system to fulfill its function. In its opinion work sharing was one of the instruments allowing the patent offices to deliver high quality patents, and at the same time helped them to avoid duplication of work. The Delegation believed that the work would benefit all patent offices, and therefore, the Delegation supported the proposal to launch a questionnaire on the quality of patents, as had been outlined by the Delegations of Denmark, Canada, United Kingdom and United States of America. The Delegation further supported the proposal made by the Delegation of Spain. It believed that better understanding of the assessment of the inventive step would increase the quality of patents.

64. The Delegation of Australia stated that, like many other patent offices, it had limited resources, while in line with global trends, the demand for patents in Australia had been growing. The Delegation viewed work sharing as an efficient way of managing the existing workloads, because it allowed examiners to use work products of another office as a head start in examination. The Delegation noted that it also helped to learn from the experiences of other offices in conducting searches, and allowed the examiners to focus their efforts on complex cases first filed in Australia. The Delegation further explained that work sharing did not mean that one office simply accepted the work of another office – each office needed to take into account its own laws and domestic requirements. The Delegation further specified that at the intellectual property office of Australia, the examiners were required to validate the work of other offices prior to their use, and assess where further examination work might be required to satisfy the Australian law. The Delegation also explained that work sharing simply meant that a second office could look at the work of another office in order to assist it to conduct more efficient searches and examinations. In the view of the Delegation, work sharing produced better quality patents, because examiners from across the world might uncover relevant prior art in foreign languages or in a special technical field, which might be difficult to find. The Delegation observed that the two key elements that were required to support effective work sharing were access to search and examination information, such as WIPO CASE, and trust in that information. In its opinion, having trust in the work of another office was also a key element underpinning effective work sharing. It believed that making available details of how examiners searched prior art, such as sharing an examiner's search strategy, would lead to an increase in trust in a search conducted by another office. The Delegation further stated that it would also help offices to learn from the experiences of other offices in conducting searches. The Delegation considered that trust could be established through bilateral or multilateral benchmarking or auditing exercises, such as the auditing activities of the Vancouver Group, where the Canadian Intellectual Property Office (CIPO), UKIPO and IP Australia used a common framework and agreed Quality Standards to audit a

small number of each other's recently granted patents every six months and discussed the findings of those audits. In the Delegation's view, that had helped to recognize differences in laws and practices, which could be considered in determining the areas in which future work might be required. In that regard, the Delegation welcomed studies that would look at the benefits and possible impediments to making national collections available. It was also the view of the Delegation that it was important that offices had access to as much of the relevant prior art as practical.

65. The Delegation of Iran (Islamic Republic of) recalled that many delegations, including Iran, had reiterated in previous sessions that a precise definition of the concept of "patent quality" was highly necessary for further discussions in the SCP on the issue. In its view, the lack of common understanding on the meaning of the concept made it difficult to fully comprehend the proposals on the topic. As regards the work sharing, the Delegation expressed its strong belief that, first of all, work sharing was not in the agenda of many countries, and in fact, it was a bilateral issue and cooperation between few patent offices. The Delegation noted that secondly, work sharing and the PPH would make the national offices of developing countries exclusively rely on search and examination reports of the offices of developed countries in the future. In addition, the Delegation stated that taking into account the diversity of the legal frameworks and the resources of patent offices in developed and developing countries, the PPH could undermine the autonomy of national offices to conduct a comprehensive search and examination to ascertain that a patent application meet the substantive requirements of the applicable national law. The Delegation continued that it was wondering how work sharing was workable between the national offices without having a precise definition of the concept of "patent quality". The Delegation then stated that work sharing in general and the PPH in particular would lead national laws to harmonization in practice. In the view of the Delegation the major difficulty in addressing the issue of quality of patents was that there was no agreed understanding among SCP members of what was meant by "quality of patents". The Delegation further pointed out that patent quality could not be improved by simply adopting the practice of other offices or by collaborating with other offices through work sharing arrangements. The Delegation stressed that work sharing was a matter of procedure which fell outside the mandate of the SCP as a substantive Committee. The Delegation concluded that it did not support any proposal on further discussion about that issue in the SCP, but expressed support for further discussions on opposition systems and preparing a compilation of models on opposition and administrative revocation systems. The Delegation was also in favor of developing a work program in the SCP to enhance examination resources of patent offices through technical infrastructure development, improvement of patent office administrative processes, and address how patent offices could cooperate and collaborate in conducting search and examination work in order to improve patent granting processes. Finally, the Delegation thanked the Delegation of Spain for the new proposal on additional studies on the assessment of inventive step. The Delegation believed that such a proposal could be a good basis for further discussions on the issue, and stated that it could go along with that proposal.

66. The Delegation of the United States of America stated that while it had not been able to study the improved web page yet, based on the presentation by the Secretariat and on a cursory preview of the website, the Delegation believed that those improvements were very useful and would be welcomed by all the users of the patent system. The Delegation also believed that the improved web page would provide up-to-date comprehensive information on work sharing collaborative programs that were relevant and useful. The Delegation stated that many of such programs were constantly evolving and expanding; thus the need to provide up-to-date information was real, and the information pertaining thereto needed to be updated on a regular basis. The Delegation believed that every Member State had an interest in improving the efficiency of the patent system in granting high quality patents as defined by their national objectives and economic considerations. Referring to a second

aspect of their proposal developed in document SCP/20/11, the Delegation stated that there was a need to conduct regular conferences on work sharing and collaboration between offices. In its view they would be designed to share national and regional experiences and best practices and to find ways to improve the usefulness of those programs to IP offices, to users of the IP system and to the general public. The Delegation also took the opportunity to briefly address some of the other proposals on work sharing which had been presented in previous sessions and had been also mentioned at least in some of the statements made by other Member States, for example by the Delegation of the Netherlands on behalf of the European Union and its Member States. The Delegation further specified that one of the proposals could be found in document SCP/19/4, which had been presented a couple of years ago. The conclusion of the Delegation in that document was that, in view of the demonstrated improvements obtained by work sharing programs, it proposed that Member States collaborate in several activities, some of which had been already partially accomplished. The Delegation further elaborated that the proposals in that document were, first, to carry out an inventory of work sharing programs that were or had been taking place between offices bilaterally, multilaterally and regionally and evaluate their benefits for the IP offices, for users of the IP system and for the general public. The Delegation thanked the SCP for having conducted at least part of that work, as far as compiling an inventory of work sharing programs and making them available in an SCP document. The Delegation further stated the second point, which was to explore ways to further refine and increase the usefulness of the work sharing programs, such as by determining best practices that could be adopted by participating offices on a voluntary basis. The third aspect of the Delegation's proposal was to explore the tools that could facilitate effective work sharing programs between participating offices. The Delegation recalled the presentations on WIPO CASE, for example, and the Global Dossier, which were indeed tools that could be used to facilitate work sharing. The Delegation, however, stressed that there were other possible tools and other improvements that could be brought about and it would be interesting to explore them. Furthermore, the Delegation explained that in document SCP/19/4, it proposed to conduct workshops on how work sharing programs could be effectively implemented by patent offices. Although the Secretariat had already carried out an inventory of work sharing programs, the Delegation was interested in following up with the remaining elements of the proposal that had not yet been completed. The Delegation noted that during the twenty-first session of the SCP, the Delegation had had the opportunity to share its experiences in international work sharing and collaboration, on which the positive comments from a variety of offices had been received. In the twenty-third session of the SCP, the Delegation had introduced the proposal, contained in document SCP/23/4. Since the relevance of the topic continued to grow with increased cooperation among offices, in the view of the Delegation, work sharing had the potential to significantly improve the efficiency of patent offices and the quality of granted patents. The Delegation explained that on a basic level, work sharing was a tool for the patent offices to limit the amount of repeated work that they carried out by reusing, to the extent possible, the work that was previously generated in related patent applications by other offices. The Delegation further explained that after the first office carried out the search and examination of a patent application, those results could be used by other offices to facilitate their own later search and examination of a related application. Focusing on its proposal to study the effect of work sharing on quality and efficiency and to amplify the capabilities of patent offices, the Delegation pointed out that it was increasingly apparent that work sharing and international cooperation could be powerful tools that contributed to make the work of patent offices more efficient and potentially more effective, and could be instrumental in amplifying the abilities of offices to efficiently grant high quality patents. The Delegation praised the presentation made by the Delegation of Mexico on CADOPAT, which had been addressing some of such work sharing elements. The Delegation observed that the benefit of work sharing could be especially significant if offices involved had different capabilities and strengths, for example, offices which operated in different languages or had special expertise in different technical fields could help each other

conduct a better search and examination. The Delegation also noted that the same could be true for small offices, as stated by the Delegation of Ireland. The Delegation further stressed that in many cases, searching the prior art relevant to certain patent applications might be simpler and more efficient for some offices than for others, because access to national collections of prior art or search tools available to patent examiners were different, and the availability of examiners having special technical expertise or language skills might not be uniform across all offices. Therefore, the Delegation was of the opinion that since some offices may be able to evaluate certain applications in an easier and efficient manner than other offices, those other offices might be able to amplify their capabilities by taking advantage of the work which had previously been carried out in the earlier searches and examinations. The Delegation emphasized that even large offices like the USPTO could have difficulties in finding prior art that was in a foreign language and/or which was located in national collections of other offices. In the view of the Delegation, developing every capability in every office might be difficult or impossible and might be prohibitively costly. Therefore, the Delegation reiterated the proposal that it had made in the previous session of the SCP: first, in order to better understand the potential of work sharing on the operation of patent offices, it requested the Secretariat to conduct a study of whether, under what circumstances and how the implementation of work sharing and international cooperation programs between patent offices could assist the collaborating offices in conducting more efficient searches and examination and in granting high quality patents by leveraging the work carried out in other offices. The Delegation suggested that for such study, the Secretariat collect information from Member States on their experiences with work sharing programs and also collect information on how work sharing had been applied between offices and how it had impacted the search and examination of patent applications in those offices. As a matter of example, the Delegation suggested that the focus be on how limited capabilities of an office could be amplified through the use of work sharing. The Delegation further explained that the study would also address the tools that had been used by offices to share information, for example, WIPO CASE, the Global Dossier or other electronic dossier systems. Once that study was completed, the Delegation also requested that the Secretariat present the study and organize a practical demonstration of those tools during a future session of the SCP. On the second aspect of the proposal addressing the sharing of examiner's search strategies, the Delegation explained that when performing automated searches of prior art, examiners prepared a set of search queries to discover the most relevant prior art and the search terms and related logic used were generally preserved in an application file. In its opinion, it could be beneficial for national offices to have access to the search logic used by other offices that had already carried out the examination of related applications on a voluntary basis. The Delegation proposed that the SCP conduct a study on the views of Member States concerning sharing search strategies which could involve, for example, a survey of the Member States. Finally, the Delegation referred to the third aspect of its proposal regarding prior art collection availability. The Delegation highlighted the fact that access to as much of the relevant prior art as practical was fundamental to carrying out a high quality search. The Delegation explained that some prior art was only found in certain national collections, which were not available to other offices. The proposal of the Delegation was that the Secretariat study the benefits and possible impediments to making national collections of prior art available to all offices, for example, through an IT portal.

67. The Delegation of South Africa, speaking on behalf of the African Group, reiterated the African Group's belief that disclosure was the bedrock of the patent system, and that a lack of transparency compromised patent quality, stifled knowledge creation and its dissemination. With regard to work sharing, the Delegation acknowledged that work sharing could ease the burden of patent examiners and avoid duplication of work, but it did not necessarily translate into high quality patents. The Delegation did not believe that patent quality could simply be improved by adopting the practices of other offices, and that it could serve the developmental interests of countries, as each country had its own particular socio-

economic considerations. The Delegation further stated that it was, thus, important that patent offices retained their discretion to determine patentability criteria in line with national legislation and developmental concerns and that they were fully capacitated to do so. The Delegation took note that the Committee did not have a common understanding on the term “quality of patents”.

68. The Delegation of China expressed its belief that since improvement of patent quality was beneficial for the effective functioning of the patent system, it would have positive significance having work sharing under the agenda item. The Delegation stated that Member States could learn from each other's experiences regarding work sharing. In the view of the Delegation, first, the Committee needed to identify the definition and scope of the study, which was important and necessary for an in-depth and effective discussion in the future. The Delegation further suggested that under the agenda item, Member States focus on the Office's capacity building, exchanging prior art the information databases, search and examination tools and the utilization of IT facilities, as well as information on technical assistance provided for developing countries on how to enhance the training and exchange of examiners. The Delegation concluded that those issues were the essential infrastructure for raising the quality of patents.

69. The Representative of TWN took the opportunity to remind Member States that one size did not fit all. In his view, that was applicable in the case of not only exceptions and limitations on patent rights, but also on patent protection, especially on patent examination. The Representative pointed out that since Member States had used flexibilities related to the scope of patentability as per the public policy objectives, the scope of patent protection was different from one Member State to another. The Representative was of the opinion that the work sharing indirectly interfered with that diversity, leading to substantial harmonization of patent laws. Noting that many Member States, especially developing countries did not have enough examiners, the Representative considered that work sharing arrangements in a way were the burden: first, to look at the examination reports from other offices, and second, to evaluate the patent application as per their national law. The Representative noted that the proponents of work sharing were yet to offer a satisfactory explanation on that problem. The Representative suggested that the SCP address the root causes of pending patents applications instead of treating the symptoms through work sharing. In his view, the root causes of pending patent applications were the large number of patents emanating from certain Member States due to the lowering of the patentability criteria, especially in developed countries, and as a result, there was an incentive to file patent applications on trivial or frivolous inventions. Therefore, the Representative considered that the first step to address the issue of pending patent applications was to set a high threshold level for the patentability criteria to create disincentives in the system against filing patent applications for non-genuine inventions. The Representative observed that instead, the work sharing proposal was forcing countries to grant patents by eliminating the existing flexibilities with regard to the scope of patentability. The Representative further stressed that that was an attempt to bring back the harmonization agenda through back doors. Without prejudice to his position on work sharing, the Representative also stated that since the PPH was a bilateral or plurilateral initiative outside the multilaterally system, while WIPO SCP was a multilateral forum, it should not legitimize such initiatives. The Representative viewed that as legitimizing norm setting activities without the participation of most of the WIPO Member States. Against that background, the Representative called upon Member States to focus the discussion on high threshold level of patentability criteria, instead of work sharing, because there was no merit to conduct a study on work sharing without discussing the concerns related to work sharing.

70. The Delegation of Romania thanked the Delegation of Spain for its proposal to conduct a study on the most difficult and complex tasks in patent practice, i.e. inventive step. The

Delegation supported the proposal, as it found it extremely useful for the offices' work. In that regard, the Delegation expressed its willingness to participate in sharing sessions by giving practical case examples. The Delegation shared the view that an effective system for the protection and enforcement of intellectual property rights represented an essential element for the growth of economies that were based on the generation and exploitation of new scientific and technological knowledge. The Delegation emphasized that in the most straightforward way, the concept of patent quality could be defined along two major dimensions: the techno-economic quality created by the patent's underlying invention; and the legal quality created by the patent as an enforceable and reliable property right. In that context, the Delegation explained that the Romanian Patent Office performed, under two memorandums, two types of searches for the patent offices of Slovenia and the Former Yugoslav Republic of Macedonia, and also for third parties from those countries (both patent applicants and patent attorneys). The Delegation noted that under the first type of search, Special Search; OSIM prepared a search report containing the most relevant documents and a detailed written opinion regarding the patentability requirements in English, usually, using the Google Translate tool to translate the claims and abstracts into English. The Delegation further explained that the second type of search was the Standard Search where a search report was prepared without a written opinion.

71. The Delegation of the United Kingdom thanked the Secretariat for improving the web page on work sharing and collaborative activities and for the informative presentation on WIPO CASE. The Delegation also thanked the Delegation of Mexico for its presentation and expressed its appreciation to those Delegations who had taken the floor to share their experiences on work sharing. The Delegation stated that the experiences shared and the growing global membership of WIPO CASE demonstrated that work sharing could benefit offices of all sizes and from all regions. The Delegation expressed its support to further work in that area, such as the holding of annual conferences as proposed in document SCP/20/11Rev., and the studies proposed in document SCP/23/4. On the topic of quality, the Delegation expressed its agreement in the launching of a questionnaire as proposed in document SCP/18/9, which among other things, could help the Committee in reaching a common definition on quality.

72. The Delegation of the United States of America stated that improving the quality of issued patents had been one of the top priorities of USPTO leadership and that topic was also of great interest to many patent offices. The Delegation remarked that over the previous sessions of the SCP, many countries including Canada, Denmark, the Republic of Korea, the United Kingdom and the United States of America, had submitted proposals for work on patent quality, for example, in documents SCP/17/7, 8 and 10, SCP/19/4, SCP/20/11 Rev. and SCP/23/4. The Delegation encouraged the continued discussion by Member States on that important topic and maintained its view that granting high quality patents was fundamental to having a well-functioning patent system that promoted innovation, economic growth, employment and the general welfare. The Delegation recalled that during the 17<sup>th</sup> session of the SCP, it had provided a detailed explanation of quality management measures being implemented by the USPTO, and stated that the details could be found in document SCP/17/10. In view of recent developments in the United States of America, the Delegation gave an update on recent efforts at improving patent quality in the USPTO. The Delegation also encouraged the delegations of other Member States to reflect upon that topic and share their views on updating and improving their own quality management systems. The Delegation viewed high quality patents as instruments that facilitated certainty and clarity of rights, which in turn, helped to fuel innovation and reduce needless litigation. The Delegation explained that after the implementation of the America Invents Act, which was a sweeping patent reform legislation, the USPTO was able to better leverage its resources towards longer-term and more ambitious improvements to patent quality. The Delegation pointed out that, in January 2015, the USPTO had established the new senior level position

of deputy commissioner for patent quality, responsible for ensuring that the USPTO's patent examination processes and products maintained a high level of quality. The Delegation further pointed out that soon after, in February 2015, the USPTO had launched the Enhanced Patent Quality Initiative (EPQI). The Delegation explained that such initiative involved a comprehensive review and reformulation of the internal USPTO processes meant to enhance the quality of issued patents. The Delegation explained that several outreach programs had been carried out to gather the views and suggestions of stakeholders, which included a Patent Quality Summit held on March 25 and 26, 2015, a Patent Public Advisory Committee (PPAC) and Patent Examiner Joint Discussion held on May 4, 2016, and various other patent quality forums and other quality-related events. The Delegation remarked that many of the materials presented in those events were available online on the USPTO website. The Delegation explained that the EPQI focused on three pillars for enhancing patent quality and identified specific programs related to each pillar to increase patent quality. The Delegation specified that the three pillars were: Pillar No. 1 – excellence in work product, which was designed to provide the best work products and services at every stage of the patent process; Pillar No. 2 – excellence in measuring patent quality, designed to provide excellence in measuring patent quality ensuring appropriate quality metrics target examination issues requiring attention; and Pillar No. 3 – excellence in customer service, which was designed to improve the customer experience with emphasis on excellent customer service. The Delegation stated that those pillars served as guideposts for the USPTO as it undertook the necessary steps to ensure that examiners had the tools, resources and training required to perform their jobs optimally and to provide a superior work product. The Delegation pointed out that within the framework established by those three pillars, the USPTO had implemented eleven programs addressing different facets of patent quality. The Delegation explained that they had formulated those programs after conducting public consultations and outreach programs and receiving input from a diverse group of stakeholders throughout the country, ranging from large multi-nationals to independent inventors. The Delegation noted that trade groups, public interest groups, and bar associations had provided diverse views that had been integrated into the programs. The Delegation stated that those eleven EPQI programs could be categorized according to their designated pillar, for instance, to improve the quality of its work product (Pillar No. 1), the USPTO had instituted the following programs: (i) an Automated Pre-Examination Search Pilot to provide to the examiner relevant prior art through an automated pre-examination search, for review before the examiner began examination and conducted a manual search of the application; (ii) Scientific and Technical Information Center Awareness Campaign to highlight the USPTO's Scientific and Technical Information Center (STIC) search tools and resources; (iii) the clarity of record training – improving clarity and reasoning in office actions training which was meant to educate examiners on the latest legal developments and effective ways to convey their positions and reasons to applicants; (iv) Post Grant Outcomes Pilot to identify prior art raised in post grant proceedings that was relevant to related cases undergoing prosecution and to simplify access to such prior art for examiners in the related cases; and (v) topic submission for case studies, which was meant to use stakeholder suggestions to identify new topics for case studies. In that regard, the Delegation stated that six case studies had been already identified under that program. In addition, the Delegation referred to Pillar No. 2 (measuring patent quality) and explained that it had been instituting the following programs: (i) clarity and correctness data capture (using the Master Review Form), which was to develop and implement a new agency-wide consistent and transparent process and form to capture minable data on the correctness and clarity of examiners' work products; (ii) quality metrics to develop and implement new measures for understanding, evaluating, and reporting the correctness and clarity of examiners' work product. In this regard, the Delegation explained that the USPTO had developed the Quality Composite Metric in 2011 with the aim of identifying and correcting potential quality concerns that might arise during examination. Presently, the USPTO was receiving public input on how to fine-

tune the metrics in order to better measure the accuracy of examiner determinations and obtain data more representative of the effectiveness of examiner training. The USPTO intended to implement the new patent quality metrics in fiscal year 2017; and (iii) reevaluation of After Final Consideration Pilot 2.0, Pre-appeal, and Quick Path Information Disclosure Statement which was to evaluate improvements to existing after-final programs, to achieve compact prosecution and reduce the number of issues being appealed. Finally, the Delegation stated that with respect to Pillar No.3 (excellence in customer service), the following programs had aimed to improve the customer experience as a way of further increasing patent quality: (i) review of existing pre-appeal processes to better streamline examination; (ii) design patent publication quality, which was meant to improve the quality of images in published design patents; and (iii) interview specialist program, which was meant to provide a point of contact to facilitate applicant-examiner interviews and assisting examiners and applicants with interview logistics. The Delegation underlined that the USPTO's continued efforts at improving patent quality reflect the importance that the patent system played in a knowledge-based economy. The Delegation emphasized that in developing mechanisms to improve patent quality, the USPTO sought to take into account and understand the views of all stakeholders, and to explain to the public, in a transparent manner, the changes to be implemented in the quality management system. The Delegation expressed its interest in hearing the experiences and insight of other offices that had updated or refined over time their quality management systems. The Delegation invited interested offices to reflect on that issue and to share their views with the rest of the SCP membership.

73. The Delegation of Canada expressed its agreement with the statement made by the Delegation of the United Kingdom, and supported the proposal to revisit the questionnaire on patent quality in document SCP/18/9. The Delegation thanked the Delegation of the United Kingdom for its continued collaboration on that very important agenda item. The Delegation thanked the many delegations who had expressed their support for furthering work on that item or had contributed to the discussion. The Delegation stated that, together with the Delegation of the United Kingdom, they had proposed to the SCP a work program on the quality of patents that focused on technical infrastructure development, information exchange, and process improvement. The Delegation encouraged Member States to propose specific work projects that fell within the scope of those three elements. The Delegation stressed that their proposal was inclusive, covering a broad range of interest of Member States at different levels of development, and that it was consistent with the mandate and expertise of the SCP. The Delegation pointed out that the proposed work was aimed at providing benefits for patent offices and users of the patent system. The Delegation also pointed out that, taking into account the request of certain Member States, the revised proposal offered a very broad definition of quality that was not overly prescriptive and that encouraged a variety of aspects of a quality patent system, including legal, social and economic requirements. Noting that not all Member States had the same vision of what constituted patent quality, the Delegation, however, believed that there was commonality that enabled to commence and further develop the work in that area. The Delegation stated that the proposal responded directly to several recommendations of the Development Agenda, including but not limited to recommendations 10 and 11 contained in the cluster on technical assistance and capacity building. The Delegation reiterated that Canada and the United Kingdom had proposed moving forward on that agenda item by way of developing a questionnaire to facilitate the sharing of information between Member States and patent experts from national and regional intellectual property offices. The Delegation emphasized that the intention of the questionnaire was not to lead to a benchmarking exercise, but rather to advance knowledge and best practices. The Delegation recognized that quality of patents encompassed many different components, and it could have different meanings for different patent offices in different countries or for different stakeholders. The Delegation, therefore, supported the view that to prescribe a harmonized one-size-fits-all definition was not in the best interest of the Committee and Member States, and recommended that as part of the



proposed information gathering exercise, Member States would be asked to provide a definition of quality that was utilized in respective national or regional patent offices. The Delegation noted that some Member States had expressed that they had not been comfortable with the notion of quality and had been concerned that it might result in a ranking of the practices of patent offices based on some arbitrary quality ideal. The Delegation underlined that it was neither its goal nor intention. The Delegation believed that patent quality was an individual standard that reflected the objectives of the Member States' domestic patent policy. The Delegation stated that the objective of its proposal was to learn from other Member States and to obtain valuable information that would help them improve its own practices.

74. The Delegation of Australia thanked the Delegation of Canada for the information it provided on ways to gather information for improving office experiences and improving quality. The Delegation further thanked the Delegation from the United States of America for its statement on the progress of the Enhanced Patent Quality Initiative at the USPTO. The Delegation expressed its full support for the efforts to improve the quality of patents granted, which were an ongoing process. The Delegation stated that as an Office, it was always trying to do better by finding ways to improve its processes, products and ultimately the desirable outcomes for the users of the patent system in Australia, as an example, the Delegation drew the attention of the SCP to the Pre-Exam Processing Trial that IP Australia had been conducting during the first half of 2016. The Delegation explained that under that Trial, two months prior to examination commence, the applicant was given a notice to inform IP Australia of any known grounds of invalidity from other patent office's searches and examinations. The Delegation further explained that such notice was prepared by administrative staff and the applicant was encouraged to respond to those grounds either through a new submission or amendments prior to the commencement of examination. The Delegation underlined that the intention of such Pre-Examination Processing Trial was to help and encourage applicants to fix known issues before examination commences. In its view, that would work to raise the quality of the first report. The Delegation observed that as a result, it had also seen increased efficiencies in examination, and that it allowed its examiners to spend more time on tasks that added value for the users. The Delegation further stated that aside from such initiative, IP Australia was also continuing its efforts in other areas for the improvement of its quality system. The Delegation explained that, broadly speaking, IP Australia's quality system could be represented by three levels: (i) the Quality Management System which was governed by the ISO 9001:2008 Standard; (ii) the process layer which was defined by its various practices and procedures and was also subject to a continuous improvement program through internal audits and monthly updates; and (iii) the Quality Review System that was governed by the Product Quality Standards and was the subject of quality assessments. The Delegation stated that the quality assessments of its work products were undertaken through independent quality reviews. It specified that that was carried out by Quality Reviewers, all ex-examiners at IP Australia who had received a high level of training and remained able to exercise a delegated authority. The Delegation stated that IP Australia had begun conducting an internal review from February 2016, which was focused on how the Quality Review System within IP Australia was currently operating. The Delegation explained that such review sought to include recommendations and improvements from staff and external stakeholders that could be made in line with the Project's guiding objectives of maintaining high quality user outcomes. In its view, that reinforced IP Australia's commitment to continuous improvement and building a strong reputation for delivering high quality services to the users. The Delegation expressed its full support for further discussions and investigations to improve quality. The Delegation considered that it would be useful for Member States if the Secretariat would prepare a questionnaire or conduct a survey on Member States' experiences in seeking to improve the quality of patents within their offices.

75. The Delegation of Japan expressed its appreciation for the informative statements made by the Delegation of the United States of America. The Delegation stated that they had learned a lot from many offices about quality management systems. The Delegation expressed its support for the questionnaire and survey mentioned by the Delegations of Canada and Australia. The Delegation considered that, in order to enhance quality of patent rights, it was meaningful to share the experiences on quality management systems. The Delegation pointed out that the quality management system of the JPO had been improved on a regular basis, taking into account opinions of stakeholders. As the means of sharing the information, the Delegation believed that a questionnaire and a survey were convenient tools to collect comprehensive information.

76. The Delegation of Spain thanked the Secretariat for the presentations on WIPO CASE and on the work sharing web page. The Delegation also thanked the Delegation of Mexico for the complete presentation of its CADOPAT program. The Delegation drew the attention to the fact that the new web page on work sharing was only published in English. The Delegation asked whether there would be a translation in the future. With respect to its new proposal on additional studies on the assessment of inventive step, the Delegation recalled that the first proposal on the topic of quality of patents, including opposition systems had been presented by the Delegations of Canada and the United Kingdom (document SCP/16/5). The Delegation stated that its proposal contained in document SCP/19/5 had been a sub-item under the heading of “improving the knowledge of the inventive step requirement” in document SCP/16/5. Following the approval of that proposal, the Secretariat prepared a study (document SCP/22/3), which had focused on the definition of the person skilled in the art, methods used for the assessment of the inventive step and the concept of evidence. The Delegation recalled that during the 23<sup>rd</sup> session of the Committee, delegations from various states (Colombia, Spain, the United Kingdom and the United States of America) had made presentations on the assessment of inventive step in their respective patent offices, and other states such as Japan, Morocco, Romania and the Russian Federation had made statements on the assessment of inventive step in their countries. Noting that the Russian Federation had suggested the idea to add examples to document SCP/22/3, in the Delegation’s opinion, it would be highly useful for Member States if the Secretariat or some other recognized experts could carry out studies or a series of studies on the most difficult aspect on the assessment of inventive step. The Delegation considered that as happened in previous occasions, the information provided by Member States would be taken into account, and that the studies would tackle the definitions and the way it was addressed in different regions and/or the relevant patent offices, including examples and case law if possible. The Delegation noted that harmonization was totally ruled out, but what they were willing to achieve was collecting more information on how the assessment of the inventive step requirement took place in various regions, although every state was sovereign in deciding on substantive requirements and on its own definition of inventive step. The Delegation stated that in order for the patent system to achieve its social goal, which was to promote scientific and technological innovation, patents had to be granted only for deserving inventions, meaning inventions that complied with patentability requirements and the sufficiency of the disclosure requirement to enable a person skilled in the art to carry out the invention. The Delegation further stated that the better the knowledge of those substantive requirements and the various methods of assessment, the greater the probability that patents would be granted only to inventions that really deserved it. The Delegation drew the attention to the fact that for the above mentioned reasons, the studies regarding the assessment of patentability requirements, especially in connection with inventive step, were of the interest of all Member States, regardless of their level of development. For illustrative purposes, the Delegation highlighted some of the aspects that could be included in the studies: (i) general knowledge of the person skilled in the art: Definition and its combination with the state of the art; (ii) the combination of documents: juxtaposition and synergic effects; (iii) secondary indicia; (iv) danger of hindsight analysis; (v) selection inventions;

(vi) problem invention; (vii) the assessment of inventive step in the chemical sector; and (viii) the assessment of inventive step in other technological sectors presenting particular difficulties. The Delegation suggested that once the studies were completed, experts could exchange views and provide presentations at the Committee on some of those issues with examples that illustrated their examination practices. The Delegation recalled that the proposal was already included in the future work proposal that had been discussed at the previous session of the Committee. The Delegation stated that those studies and exchanges of experience on the assessment of inventive step would be of interest to all Member States, regardless of their level of development. The Delegation reiterated that the correct evaluation of that requirement would lead to patents granted for inventions that really deserved said protection, thus, benefiting the society. The Delegation requested the Committee's support for its proposal. In addition, the Delegation gave some additional arguments for its proposal taking into account some comments that had been made by other Delegations as follows: (i) since a lot of work had already been done on that subject, in its opinion, it would be a pity to leave it unfinished; (ii) the topic was clearly within the mandate of the Committee because it was a matter of substantive patent law; (iii) one of the arguments against the proposal had been traditionally the interference with national sovereignty. The Delegation considered that there was no such danger and that each patent office could draw up guidelines for examination including aspects that related to the examination of inventive step. (iv) some states would argue that no consensus had been reached on the quality of patents. The Delegation however believed that it was clear that a patent granted after examining its inventive step would be of high quality and more beneficial to society, than a patent granted without a corresponding assessment of the inventive step; and (v) in regard with frivolous patents, the problem would be solved with a correct assessment of inventive step. The Delegation finally expressed its hope that the Committee would support the proposal on performing additional studies for the assessment of the inventive step requirement.

77. The Delegation of Japan expressed its support to the proposal made by the Delegation of Spain. The Delegation believed that in order to grant a patent in a balanced manner, discussion on inventive step was useful for all Member States.

78. The Delegation of Portugal thanked the Secretariat for preparing the meeting and for the documents and presentations. The Delegation expressed its support for all proposals that would increase the quality system of each national office. The Delegation further expressed its support for the latest proposal of the Delegation of Spain contained in document SCP/24/3. In its opinion, those kind of studies were very important, as they allowed the sharing of information among Member States, and provided a strong knowledge and understanding of the inventive step requirement, which in the Delegation's opinion was a question of interest for everyone.

79. The Delegation of Mexico expressed its full support for all the arguments listed by the Delegation of Spain, in particular the assessment of inventive step as a very important requirement for the granting of valid patents. The Delegation considered that it did not interfere with the sovereignty of patent offices. Furthermore, the Delegation agreed to the proposed topics to be studied on the assessment of inventive step. The Delegation stated that it was prepared to participate in exchange of views in future sessions where experts from various groups could make presentations using specific examples of the assessment of inventive step in their respective offices.

80. The Delegation of the Republic of Korea expressed its appreciation to the Delegation of the United States of America and Australia for introducing the quality management system of their IP offices. The Delegation further expressed its interest in hearing the various efforts to enhance the quality. The Delegation noted that there were some good ideas which might be

applicable to improve the quality management system of KIPO. The Delegation believed that it would be beneficial to share information on the quality management system of Member States. The Delegation, therefore, expressed its support to conduct a survey and its wish to contribute to such activities. In addition, the Delegation thanked the Delegation of Spain for its interesting proposal. The Delegation stated that the assessment of patentability was an important issue since it potentially affected the quality of patents. The Delegation supported the proposal of the Delegation of Spain to conduct a study on the assessment of inventive step.

81. The Delegation of Argentina expressed its commitment in participating in a constructive and active way in the discussion to push forward the proposals presented by the Delegations of Denmark, the United Kingdom and Canada, as well as the proposal of Spain on inventive step. In its view, as patent quality had to be improved, and without such improvement, it would imply that the patent law had to be changed. In connection with the proposal of the United States of America and the Republic of Korea, the Delegation pointed out that Prosur, which was a union among various South American patent offices, signed a memorandum of understanding on May 6, 2016, to launch a pilot program for an accelerated patent examination program between the industrial property offices that were members of Prosur. The Delegation, therefore, expressed its support for the mentioned proposals and its commitment to actively participate in the discussion.

82. The Delegation of Turkey expressed its confidence in the Committee in reaching an agreement on its future work, reflecting desired results for the international patent system. The Delegation believed that the appropriate balance of interest between right holders and the public was necessary in order for the patent system to play an important role. The Delegation therefore stated that quality of patents was one of the important aspects of the patent system in order to maintain the economic and social objectives. The Delegation further stated that in order to be patentable, an invention must have the requirement of "inventive step" or must be non-obvious, so that patent protection should not be given to minor improvements which were simply obvious in relation to the existing prior art. The Delegation considered that inventive step played a very critical role separating the truly innovative inventions from the unpatentable minor improvements. The Delegation stated that the determination of inventive step was a kind of a tool or a process for the assessment of the quality of inventions. The Delegation therefore believed that inventive step was one of the most indispensable issues for the quality of patents. The Delegation pointed out that as a member of the European Patent Convention (EPC), the problem-and-solution approach of the EPO was predominantly accepted in Turkey in order to assess inventive step in an objective and predictable manner. The Delegation explained that the problem-and-solution approach had been applied by specialized IP courts throughout Turkey in many decisions, which had been approved by the Supreme Court. The Delegation thanked the Delegation of Spain for its informative presentation on the inventive step and for the preparation of a proposal in document SCP/24/3. The Delegation believed that it would be very useful to continue to study in greater depth the concept of inventive step.

83. The Delegation of India with respect to the proposal in document SCP/24/3 reiterated its stand that such study must not be construed as a tool for harmonization of concept of inventive step. The Delegation stated that the study should take into account the principles and objectives of the TRIPS Agreement, as well as the obligations of the Doha Declaration on the TRIPS and Public Health, and also the flexibilities in the TRIPS Agreement regarding the essential limitations of patentability as per the policy objectives of Members. The Delegation further stated that as long as that mandate of the TRIPS Agreement was maintained, it did not have any issues against the proposed study in document SCP/24/4. The Delegation expected the study to have the meaningful outcome as proposed and particularly, in the field of assessment of inventive step in the chemical sector (Markush

claims, enantiomers, etc.). In addition, the Delegation pointed out that in the area of chemicals and pharmaceuticals, the study should also look at the inventive step assessment in the context of polymorphs, salts, ethers, esters and isomers. The Delegation drew the attention of the Committee to take note of the proposal submitted by the Delegation of South Africa on behalf of African Group and DAG (SCP/16/7) and recalled one of its component, i.e., that the Committee would conduct a cost-benefit analysis of admissibility of Markush claims. The Delegation emphasized that Markush claims deserved special attention in the proposed study, as millions and millions of compounds were claimed and buried under the coverage of a single formula covering, even compounds, which were to be discovered in future. The Delegation further recalled that the study SCP/22/3, presented by the Secretariat in the 22<sup>nd</sup> session, had covered jurisprudence of different jurisdictions regarding various qualities of a skilled person. The Delegation noted that in almost all the cases, the skilled persons had ordinary or average skills in the art. The Delegation further noted that, however, in the past, on certain occasions and in certain areas of emerging technology, the courts conferred attributes of inventive ingenuity upon the skilled person. The Delegation pointed out that for instance, on the question whether the skilled addressee of inventive step should have inventive ability or not, Lord J Mustil, in *Genentech Inc v Wellcome Foundation's TPA* case, [Genentech's Patent [1989] RPC 147] had held that the hypothetical skilled man must be credited with a substantial degree of ability or ingenuity to solve the problems. The Delegation also pointed out that J. John Middleton, in his paper, "The Skilled Addressee", [Intellectual Property Society of Australia & New Zealand, 9 September 2012] had asked the question "Must the skilled addressee always be non-inventive?" and had explained that, based on the opinions in Genentech case and dissenting judgment in *Alphapharm* case [*Aktiebolaget Hässle v Alphapharm Pty Limited* (2002) HCA 59, 12 December 2002, S287/2001, HIGH COURT OF AUSTRALIA], the skilled addressee needed not always be non-inventive and determination of obviousness was not bound to be determined with reference to persons who were not particularly imaginative or inventive. The Delegation stated that although, as a tradition, the skilled person was presumed to be non-inventive, those case laws showed a different thinking (ingenuity in certain areas of technology) that the skilled person might have different attribute and might be considered as inventive or imaginative. The Delegation therefore proposed that the study might also include those elements, which might be useful in the context of the policy objectives. The Delegation further stated that in the same paper, J Middleton had raised another question, "whether the skilled person for inventive step and sufficiency must be the same entity?" and had explained that In *Schlumberger Holdings Ltd v Electromagnetic Geoservices AS* [2010] RPC 33, the UK Court had held that they needed not to be the same for both inventive step and sufficiency purposes. Hence, the Delegation stated that the study might further include the component of whether the persons skilled in the art were always same in different legal issues like inventive steps and sufficiency of disclosure. The Delegation emphasized that as those were important issues from the policy objectives, it looked forward to the meaningful study incorporating all those elements.

84. The Delegation of Brazil reiterated that patents of high quality were essential for the attainment of the goals of the patent system. The Delegation further stated that exploration of measures taken by the office for ensuring the overall quality of the examination procedure was a matter of great interest to Brazil. The Delegation underlined the effort of Brazil in hiring 70 new patent examiners with further 30 new examiners planned to be hired until the end of 2016. The Delegation explained that the medium term objective of Brazil's IP Office, INPI, was to completely eliminate all paperwork through the use of the e-patents, electronic patent system for processing of patents. The Delegation thanked the Delegation of Spain for the preparation of the proposal, and noted that taking into account the short time of circulation, it would make preliminary observations which might be complimented at a later stage. The Delegation stated that the discussion of the requirement of inventive step should be handled with great care, since the subject was directly related to the calibration of the

patent system. The Delegation further stated that it was the most important substantive criteria for examination of patent applications, and one that preserved the observability of Member States to calibrate their patent system. The Delegation stated that the Spanish proposal appeared to advance on aspects primarily related to substantive examination of inventions, including those in the chemical field with a high level of complexity that posed a number of questions. The Delegation requested more information for reasoning of the proposal in addition to what had already been presented and discussed during the 22<sup>nd</sup> session of the SCP. The Delegation expressed its interest in having a more comprehensive explanation of the topics listed in paragraph 8 of document SCP/24/3, and their relation to the criteria of inventive step. The Delegation expressed its view that a more precise and well defined objective of the proposal would be beneficial to the work of the Committee on the matter. The Delegation further expressed its readiness to discuss the details of the study with the Delegation of Spain and all other proponents. Pointing out that the TRIPS Agreement did not define inventive step or the person skilled in the art, among all the matters related to substantive criteria, the Delegation stated that the reasoning behind negotiators was to provide sufficient flexibility for Members to define those requirements, depending for instance on the technical development or the policy objectives of each country. The Delegation remarked that as stated earlier by the Delegation of the United States of America and Canada, one-size-fits-all was contrary to the spirit of the Development Agenda recommendations and not in the best interest of the members of the Committee. In its opinion, the discussions in WIPO confirmed that vision and that harmonized multilateral criteria for substantive patent examination were inadequate for efficient implementation of the patent law. The Delegation explained that different countries had different national high level goals, which were affected by many factors including national industry policies and the capacity of Member States to absorb technology. The Delegation expressed its opinion that a common definition of substantive patentability criteria would reduce policy space and thus would affect the capacity of Member States. The Delegation concluded that the protection of IP should be in a manner supportive of socio-economic development, economic growth, public health, food safety and education, and that it should be looked at within the framework of each country. The Delegation stated, that the SCP should maintain such view when considering the matter.

85. The Delegation of Australia thanked the Delegation of Spain for the proposal on conducting additional studies on assessment of inventive step. The Delegation considered that such information would be highly useful, and accordingly supported the proposal.

86. The Delegation of Switzerland thanked the Secretariat for preparing the Committee and the session. The Delegation expressed its support for the work on technical topics and proposals, as they were within the WIPO mandate. The Delegation thanked the Delegations of Mexico and the United States of America for their presentations on the work sharing initiatives. The Delegation also thanked all the delegates who had shared their work on quality management systems. The Delegation expressed its support to the quality management proposal made by the Delegation of the United States of America. The Delegation believed that it made sense to have more information on how other offices were dealing with those important questions. The Delegation also thanked the Delegation of Spain for its proposal, and considered it a very interesting and important proposal on inventive step, which was the core of the patent system and the patentability criteria. The Delegation, therefore, supported the proposal of Spain as it stood, and expressed its wish to have further discussions and exchanges on the assessment of inventive step. In order to assist the delegations in the room, the Delegation was of the view that it would be also useful to have a common understanding on the definition of patent quality. The Delegation, therefore, considered that the questionnaire proposed by the Delegations of the United Kingdom, Denmark and Canada would be helpful to reach such common understanding.

87. The Delegation of France thanked the Secretariat for preparing and making available the documents. The Delegation expressed its support for the proposal presented by the Delegation of Spain on inventive step, and expressed its commitment to participate in that study.

88. The Delegation of Romania thanked the Delegation of Spain for its proposal to conduct a study on the most difficult and complex tasks in patent practice. The Delegation expressed its support for the proposal, which would be extremely useful for the office's work. The Delegation stated that it was prepared to participate in sharing sessions with practical examples.

89. The Representative of Innovation Insight stated that quality of patents was a critical topic for all IP offices, IP holders, and anyone who would face the patents of others in the marketplace. The Representative further stated that poor quality patents created uncertainty, setting back efforts to invest in developing new solutions. The Representative remarked that innovators did not want poor quality patents. The Representative expressed its support for further work on inventive step and on quality management systems. In her opinion, those were precisely the types of technical exchanges the SCP was meant to host, so that offices could learn from each other and improve their own practices. The Representative concluded that to that end, it was interesting to hear about the different initiatives on the ground to improve quality, such as CADOPAT.

90. The Representative of ICC noted that the ICC membership included not only holders of intellectual property rights but also third parties affected by others' intellectual property rights. He remarked that such aspect was taken into account in ICC's positions and papers, also in the field of patents. The Representative expressed its support to a patent system that should ensure that society as a whole benefited from it. In regard to the topic of inventive step, the Representative pointed out that ICC had prepared a paper on "Inventive step criterion for patenting", copies of which were made available outside of the room, as well as on the ICC website. He explained that the study discussed among other things definitions of inventive step or non-obviousness, the principles for assessment of inventive step and provided a couple of case studies. The Representative drew the attention of the Committee to two aspects of the paper: (i) the principles of evaluation of inventive step should not depend on the subject matter involved and the same basic rules should be applied irrespective of the field of the invention; and (ii) neither the legal requirements for inventive step nor any other basic criteria made any distinction between different levels of invention, for example, between "incremental" and "radical" or "breakthrough" inventions. The Representative emphasized that any claim should be judged against the same basic principles of inventive step assessment.

91. The Representative of AIPPI noted that AIPPI was the world's leading International non-governmental Organization dedicated to the development and improvement of legal rights for protection of intellectual property. The Representative further explained that AIPPI had been created more than 100 years ago and that it had over 9,000 members in more than 100 countries around the world at present. The Representative remarked that the members of AIPPI came both from developing and developed countries and represented a broad spectrum of professionals interested in the field of intellectual property, including lawyers, patent attorneys, patent agents, trademark agents, judges, scientists, engineers, academics as well as corporations. The Representative pointed out that the substantive work of AIPPI was focused on the study of issues of topical concern in the IP world and adoption of resolutions by AIPPI by consensus. The Representative stated that to date, AIPPI had passed over 700 resolutions, many of them related to patents and directly relevant to the agenda of the Committee. The Representative further stated that resolutions in AIPPI were

developed based on extensive studies conducted at the national and regional levels by AIPPI members that were experts in the field in question. She underlined that the depth of the studies as well as the great diversity among the members and the countries represented in AIPPI enabled it to prepare resolutions with appropriate balance on the views of various stakeholders, including those in the developed as well as developing countries. The Representative pointed out that the reports of the national and regional studies as well as the final resolutions were available for public access at the AIPPI website at: [www.aippi.org](http://www.aippi.org). As to the substantive question on the agenda, the Representative expressed its support for the views presented by various delegations that the quality of patents was as an essential factor in the functioning of the intellectual property system. The Representative noted that AIPPI had considered that topic and had studied its various aspects relating to assessment of inventive step over the years. The Representative stated that among the most recent work by AIPPI in that area, there were studies on the criteria of non-obviousness, the use of the concept of the person skilled in the art in the context of inventive step requirement, as well as the inventive step requirement in relation to selection inventions. The Representative further stated that in the interest of time, she refrained from paraphrasing the above mentioned resolutions and instead, encouraged the members to explore the AIPPI resolutions and reports of the underlying studies. Finally, the Representative thanked the Committee, its members and the Secretariat on the continued efforts on the development of the regimes around the protection of intellectual property rights, and remarked that AIPPI stood ready and available to support the Committee in moving forward with its work.

92. The Delegation of Singapore thanked the Delegation of the United States of America for sharing information on initiatives within the office, and expressed the interest of its Office in ensuring that unmeritorious patents should not be allowed into the system. The Delegation believed that the validity of patents was the key aspect of patent quality. The Delegation noted that as part of its quality management framework, quality should be governed by the consistency of decisions issued by examiners as well as the timeliness of office actions. The Delegation, therefore, supported the proposal made by the Delegation of the United States of America, requesting the Secretariat to issue a survey or questionnaire to patent offices so that Member States could learn from each other's practices. The Delegation also expressed its support to the proposal made by the Delegation of Spain for conducting a study on the requirement of inventive step. In that regard, the Delegation agreed that such a study should not be a step towards the harmonization of patent laws, but a means to sharing Member States' practices within the Committee.

93. The Representative of APAA explained that APPA, a non-governmental organization dedicated to enhancing the intellectual property system, comprised patent professionals in 18 local recognized groups in Asia and the ASEAN region. The Representative stated that a study related to inventive step or non-obviousness determination, was conducted in 2012 and 2013. In that regard, the Representative explained that in the first year, it had provided a hypothetical case with two claims and had collected answers from APAA members on their assessment of the inventive step or non-obviousness regarding those claims. The Representative remarked that the answers had shown substantial differences in the outcomes and reasoning behind the various responses from the different jurisdictions. The Representative further explained that in the second year, in order to understand more about the differences among jurisdictions, it had distributed a questionnaire, including general questions on statistics of the inventive step or non-obviousness determinations and the specific questions on the practical evaluation of the inventive step or non-obviousness such as the level of a person skilled in art, combination of prior arts, teaching away, secondary indicia and hindsight approach. The Representative underlined that APAA had been able to improve understanding of different practices in evaluating inventive step in member countries and to expand the knowledge of the requirement of inventive step among its LDC members. APAA agreed that determination of inventive step was one of the most important factors to



enhance quality of patents, and therefore the Representative strongly supported the independent study on the concept of inventive step as proposed by the Delegation of Spain in order to improve the understanding of the different practices on inventive step assessment in different jurisdictions.

94. The Representative of TWN stated that it was very important to have a high level of patentability criteria which could reduce the burden of processing patent applications in many patent offices. The Representative further stated that at the same time, it was important that those studies should not lead to harmonization of patentability criteria. He remarked that a study should be factual, and at the same time it was important that the concept of inventive step did not exist in a vacuum, i.e. it should be informed by the socio-economic and development factors of various jurisdictions. The Representative stated that since there were different tests which were applied to assess the inventive steps and which were applicable to different technologies, it was important that the inventive step studies should focus on various technologies rather than to have a macro view on inventive step. In that regard, the Representative welcomed the proposal made by the Delegation of Spain, but added that a study on inventive step related to chemical inventions should cover polymorphs, metabolites, particle sizes, isomers and mixer of isomers and the last derivatives. The Representative concluded that the idea should be to perform a study very specific to some of those claims, so that Members are informed of what kind of practices existed, and that various patent offices could then pick and choose as per their development needs.

95. The Representative of JPAA stated that the discussion on inventive step was very useful and beneficial for the SCP. The Representative further stated that inventive step was the most important and complicated requirement of patentability. The Representative therefore, concluded that JPAA fully supported the proposal made by the Delegation of Spain.

#### AGENDA ITEM 7: PATENTS AND HEALTH

96. Discussions were based on documents SCP/16/7, SCP/16/7 Corr. and SCP/17/11.

97. The Secretariat listed the past activities performed on the issue of patent and health.

98. The Delegation of Greece, speaking on behalf of Group B, reiterated that both innovation and access were equally important in the relationship between patents and health, while patents were more strongly linked with innovation. The Delegation stated that in the whole picture of research and development in the field of pharmaceuticals, obviously, the incentive from patent protection was critical for research and development (R&D), but patent incentives were not the only factor to consider. The Delegation remarked that for example, a small market was disincentive for marketing products and R&D for pharmaceutical compounds having a very small market might require additional incentives. The Delegation believed that it was important to focus not only on a specific part but to keep in mind the whole context. In that regard, the Delegation stated that the whole context had to be kept in mind also for the future work of the Committee. The Delegation further stated that in the discussion of facilitating access to generic and patented medicines, Group B was interested in better understanding why unpatented medicines did not reach the intended patients. The Delegation considered that the availability of safe and effective medicines was a multi-faceted problem which impinged on many areas of law, national policy, physical infrastructure, social education and economic factors, to name only a few. The Delegation recalled that according to what was noted in the publication of the WHO, WTO, WIPO under the trilateral cooperation, "Public Health, Intellectual Property and Trade: Promoting Access to Medical Technologies and Innovation", the lack of access to medical technologies was

rarely due to a single isolated factor. The Delegation, therefore stated that Group B welcomed the seminar that has been held during the previous session under the agenda item on patents and health, during which the speakers had mentioned that patents had not been the only barrier. The Delegation stated that while the SCP would not be expected to take action on non-patent issues which were not within its mandate, it would benefit from an understanding of where its action fit within the broader range of factors influencing access to medicines. The Delegation explained that, as stated in the last session, work sharing could make more sense in that technical field because of more divergence of prior art and other information which perspective offices could access. The Delegation considered that a study by the Secretariat focusing on the differences of information available to the offices and how to overcome those differences in the field of medical technology through work sharing, was also a possible way forward under the agenda item, taking into account the expertise which the Committee should have. The Delegation further expressed its belief that the current international framework gave countries the policies space to impose new patentability criteria or require information beyond the current disclosure requirement that one of ordinary skill in the art could make and use the invention. The Delegation pointed out that as shown in document SCP/21/9, an INN was often only assigned years after a patent application was filed and sometimes granted, and thus in many instances, could not form part of the original disclosure of innovative drug applications. The Delegation stated that Group B welcomed the newly launched PATENTSCOPE project to improve the searchability of international published patent applications through nonproprietary names, and believed that investment in those technologies was the most efficient way forward. The Delegation finally stated that in that specific field, exploiting the expertise of the Committee could compliment the general discussion at the CDIP, avoiding duplication of work with other Committees.

99. The Delegation of the Netherlands, speaking on behalf of the European Union and its Member States, stated that the topic of patents and health was of great importance and interest to its group. Although it recognized and supported the numerous public health challenges faced by developing and least developed countries, such as those related to HIV/AIDS and malaria, the Delegation remarked that IPR flexibilities and widespread use of compulsory licensing were not the single solution for such problem. The Delegation considered that the lack of patent protection could, in fact, be one of the factors that prevented medicines reaching the neediest patients in developing countries. The Delegation pointed out that new drugs were more likely to be launched in a country where patent protection was strong. The Delegation also considered that many other factors besides patents directly affected the availability of medicines, as described in the trilateral study by the WTO, WHO and WIPO on access to medicines, published in 2012, "lack of access to medical technologies is rarely due entirely to a single determinant." In its view, there were many factors that affected access but were not related to intellectual property, such as lack of access to quality health care, poor infrastructure, lack of distribution in supply claims, lack of quality control, possible abuse in setting of prices, and the financial sustainability of national health systems. The Delegation expressed its hope that the outcome of the UN High Level Panel on Access to Medicine would contribute to clarify the barriers affecting access to essential medicines. The Delegation emphasized that any further work in the area of patents and health should reflect a balanced approach, taking into account the various interfaces and factors of relevance to patents and health, and drawing, for instance, inspiration from a proposal by the Delegation of the United States of America (document SCP/17/11).

100. The Delegation of Latvia, speaking on behalf of the CEBS group, recalled the importance given to the question by the members of its Group. The Delegation believed that the issue was a very complex one, and there was a need for a holistic approach in order to resolve the issues of access to medicines. The Delegation considered duplication with the work of the other international organizations on that topic should be avoided. The Delegation

expressed its belief that the proposal elaborated by the Delegation of the United States of America (document SCP/17/11) would be a way forward under the agenda item on patents and health.

101. The Delegation of Brazil stated that providing access to essential and lifesaving medicines at affordable prices was the goal of all countries and the necessary step for the achievement of the United Nations' Sustainable Development Goals. The Delegation pointed out that illustrative of that position was its Target 3.8, urging members to take measures that assured "access to affordable medicines and vaccines". The Delegation further noted that Target 3.8 requested the countries to provide access to affordable essential medicine and vaccines and to "use to the full provisions in the TRIPS Agreement regarding flexibilities to protect public health, and in particular provide access to medicines for all". The Delegation considered that WIPO, as a specialized agency of the United Nations, had much to contribute to that debate and should not evade itself from it. Furthermore, the Delegation stated that the discussion held in other Geneva fora, had pointed the fact that current mechanisms for pharmaceutical research were not aligning to the needs of many countries, particularly in developing countries that faced challenges, such as neglecting diseases. In its view, solid, creative and sound actions from policymakers were required in order to ensure the provision of adequate health care to the population. The Delegation stressed that almost 15 years after the Doha Declaration on the TRIPS Agreement and Public Health, it was for the SCP to further explore the issue in order to overcome the obstacles Members still faced. The Delegation considered that the relationship between the patent system and health brought a clear picture of inherent trade-off in intellectual property, namely, governments offered the incentive for innovation, while controlling eventual negative effects on competition and ensuring adequate balance between the rights granted and access to the products. In its opinion, it was a central issue to be discussed by Members considering the wide and complex issues that the governments had to guarantee its effectiveness. The Delegation considered that it was a matter of interest for countries from every region and every level of development. The Delegation stated that the subject could be better framed through the approval of the African Group and the DAG proposal as stated in document SCP/16/7, which, in its view contained a balanced work program that would enable exploration of such a complex subject. The Delegation recalled that as mentioned by Group B and the European Union and its Member States, patents were one of many barriers to access to medicines. The Delegation reiterated that it urged the adoption of the aforementioned proposal in order to expedite the work in that matter.

102. The Delegation of Pakistan stated that patents and health was a topic of great importance to all countries. The Delegation further stated that the Sustainable Development Goals had recognized and affirmed the importance of public health, enjoyment of which was a recognized basic human right. The Delegation pointed out that the UN Secretary-General's High Level Panel on Access to Medicines sought policy coherence and was an important step in the right direction. In its view the right to health was denied to large populations both in developed and developing countries, because of lack of affordable medicines. The Delegation considered that the SCP was the appropriate forum for sharing experiences on the use of health-related patent flexibilities and the challenges to their use. The Delegation stated that there was a need to analyze specific challenges to availability of medicines arising from the patent system in developing countries and LDCs. The Delegation questioned the impact, if any, of the patent systems as a facilitator of innovation on medicines for diseases spread predominately in developing countries, and whether the patent system had facilitated transfer of technology and local manufacturing of medicines in developing countries and LDCs. The Delegation looked forward to the revised African Group proposal and a work program that addressed that important issue.

103. The Delegation of Iran (Islamic Republic of) stated that the issue of patents and health

and having access to essential medicines with affordable price was an important issue for all Member States, in particular for developing countries. The Delegation further stated that there was a significant international focus on the role of patents in public health, specifically a persistent lack of access to health technologies, which included the lack of access to medicines in developing and least developed countries. The Delegation drew the attention of the Committee to the fact that the Resolution on Political Declaration on HIV and AIDS had been adopted by the UN General Assembly in June 2016. The Delegation remarked that the subject was also under discussion by the Human Rights Council, and two resolutions on promoting the right of everyone to enjoyment of highest attainable standard of physical and mental health, through enhancing capacity building in public health and access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health had been tabled for adoption. The Delegation, therefore, considered that the need to prioritize public health interest in pharmaceutical and health policies existed for all. In its opinion, the aim of the inclusion of that item in the work of the Committee was to recognize the practical ways to respond to the challenges caused as a result of the patent system in the field of health. The Delegation stated that the full use of flexibilities accorded under international agreements and ineffectiveness of such use, among other issues, should be addressed in the SCP. Therefore, the Delegation expressed its belief that any work program on health and patents should be balanced and based on a long-term approach. The Delegation considered that the work program of the SCP should provide the possibility of analyzing the potential impediments and obstacles created by the system in accessing medicines, such as the legal and structural impediments and capacity constraints that developing countries and LDCs had been facing in making full use of flexibilities and how those constraints could be removed. The Delegation expressed its support to the joint proposal of the African Group and the DAG contained in document SCP/16/7. The Delegation remarked that the proposal covered a work program which would seek to enhance the capacities of Member States, in particular in developing countries and LDCs, to adapt their patent regimes to make full use of flexibilities enabled in the international patent system in order to promote public policy priorities related to public health and to take full advantage of the international patent system to promote their policies on public health.

104. The Delegation of China noted the importance of the patent system and stated that while the patent system served to encourage innovation, it should also protect public interests. The Delegation remarked that it was necessary to craft a pragmatic and specific SCP work program so that discussions on patents and health could move forward. The Delegation considered that all parties and all stakeholders needed to understand better what was meant particularly with a reference to flexibility in relation to patents and health, and what kind of flexibilities could be afforded by the relevant treaties. The Delegation stated that, such approach would allow countries to improve their legislation and practices for public health and would also appropriately protect public interests when with respect to public health and access to medicines.

105. The Delegation of India stated that the public health was of paramount importance to developing countries and least developed countries. The Delegation expressed its concern about the issues relating to public health, and stated that any scientific and technological developments should reach all the mankind, irrespective of geographical boundaries. The Delegation further stated that at the same time, innovators also should be benefitted from the effective patent protection. The Delegation considered that necessary efforts should be taken for the availability and affordability of medicines to the neediest, but the patent system should not be a barrier for reaching medicines. The Delegation remarked that the system should strike a balance between the interest of innovators and public health interest. In its opinion, it was one of the foremost responsibilities of the patent system to ensure the accessibility of medicines to the public at affordable prices. The Delegation pointed out that,

even though many other factors affected the availability and affordability of medicines, patent protection was also directly affecting the developing countries and LDCs. The Delegation stated that it fully supported the proposal submitted by the Delegation of South Africa on behalf of the African Group and the DAG on patents and health to work out the balance between patent rights and caring for the public health by way of restricting patentee's rights so that their pharmaceutical products would be sold at an affordable price. The Delegation reiterated its stand on the inclusion of INN in a patent specification, which in its view, would facilitate grant of quality patents. The Delegation considered that while the term of patents according to the TRIPS Agreement was 20 years, in reality, by filing second level applications, the life of pharmaceutical ingredients in almost all cases was more than that term mandated in the TRIPS Agreement by filing second level applications. The Delegation, therefore, emphasized the importance of disclosing INN in patent applications. Noting that INN was a chemical name given by the WHO for a single, well-defined substance, but not for mixtures of substances, herbal substances or for homoeopathic products, the Delegation stated that during substantial examination, an examiner could easily access the details such as IUPAC name, structural formula, molecular formula, Chemical Abstract Service (CAS) number, therapeutic use and pharmacological action of the molecule, if INN was known. The Delegation pointed out that, as a result, granting a patent for the molecule with trivial modifications could be minimized to some extent. Therefore, the Delegation emphasized that the Secretariat should conduct a feasibility study for inclusion of INN in a patent specification, if the INN was known. In addition, the Delegation considered that the Markush type of claim was generally found in pharmaceutical and biotechnology-related inventions. In that regard, the Delegation stated that a group of several compounds was taking shelter under a single Markush claim, which would be later filed as a separate application so that the term of the patent was legitimately extended. In its view, even though the molecules were disclosed in the first application, it was still difficult for the examiners in the well-established patent offices to distinguish the molecules from Markush structure. As a result, the Delegation continued, the molecules disclosed in the Markush claim enjoyed the monopoly beyond the period specified in the TRIPS Agreement. The Delegation added that having a good number of examiners who were familiar with the respective IPC and with all necessary infrastructure would not eliminate the problem of conducting a search and examination of patent applications with broad or speculative Markush claims. Recalling the objective of the TRIPS Agreement in Article 8 and the Doha Declaration on the TRIPS Agreement and Public Health and their calls for empowering states to take appropriate measures to protect public health and nutrition, the Delegation of India reiterated its request for a study on cost and benefit of patenting overbroad Markush formulae. The Delegation considered that the study could be broadly divided into two areas: (i) issues of the patent law, for example, inventive step; and (ii) the relationship of overbroad Markush formulae with the sufficiency of disclosure. The Delegation noted that such study would fall under the scope of not only the quality of patents but also other areas which the Committee was presently pursuing, namely, patents and health and transfer of technology vis-a-vis sufficiency of disclosure.

106. The Delegation of South Africa, speaking on behalf of the African Group, stated that the subject of patents and health was indeed a priority area for both the African Group and South Africa. The Delegation further stated that the right to health was a fundamental part of the human rights and was relevant to Member States, developed and developing alike. The Delegation pointed out that the recent pandemic outbreaks of Ebola and Zika virus had showed that the disease did not respect geographical boundaries, did not distinguish between rich and poor and between developed and developing countries. The Delegation remarked that the global community had taken note of that, and had reaffirmed the importance of health when it had recognized access to public health as Goal 3 of the 2030 Agenda for Sustainable Development, which was particularly important because it recognized that there were unmet health needs present, both in developed and developing countries and significant health inequalities between and within regions themselves. The

Delegation, therefore, considered that all the UN organizations had the responsibility of working together to help the achievement of Goal 3. The Delegation stated that, since access to safe and affordable medicine remained a fundamental challenge for developing countries and LDCs, the Committee could play an instrumental role in the access to medicines and patents and health. The Delegation stated that as it did not deny the complex challenges the countries faced in providing health care, Members States should limit themselves to the impact of IPRs, which could limit or impact the availability of medicine. In its view, patents constituted an incentive to the pharmaceutical industry to undertake research, to find new cures for existing diseases, but the issue of patent protection in the health industry was becoming increasingly divisive, as health concerns escalated. The Delegation stated that in a recent submission to the UN High Level Panel, the WHO had noted that there were needs for more transparency about the patent status of essential medicines. In that regard, the Delegation endeavored to address the conflict between IPR and the right to public health, especially when market incentives did not always match public health priorities. In its opinion, governments had a constitutional and a social obligation to ensure access to medicines and the right to health care, and they should be encouraged to take proactive steps to ensure that IPRs did not prejudice or hinder the protection of public health. The Delegation remarked that developing countries should be capacitated to take maximum advantage of the flexibilities contained within the TRIPS Agreement and ensure that the TRIPS flexibility related to access and promotion of medicines was incorporated into their national laws. The Delegation concluded that the importance of public health was growing, and WIPO needed to take the lead and provide guidance on how to limit the negative impact of the IPR system on health and ultimately on sustainable development. The Delegation explained that the African Group had updated its proposal on patents and health and would make a formal presentation to the Committee at the later stage.

107. The Delegation of Nigeria, speaking on behalf of the African Group, recalled that at the fifteenth session of the SCP, the African Group had made a request for the Committee to take up a program of work in the area of patents and health, and at the sixteenth session, there had been a joint proposal by the African Group and the DAG, which had been included in documents SCP/16/17 and 7 Corr. The Delegation explained that the idea of that proposal had been to assist patent regimes in developing countries and LDCs and to make full use of flexibility in the patent system in order to address public health priorities. The African Group was of the view that fundamental public policy priority related to the promotion and protection of public health was the affordable access to healthcare and medicines internationally. The Delegation stated that the African Group had submitted a proposal the previous day, which updated the proposal made in 2011 as contained in document SCP/16/17. The Delegation stated that, for the African Group, the subject of patents and health was a priority and the call for a current policy on public health needs had been made at different international fora. The Delegation noted that the relationship between patents and public health was an issue of global concern among divergent countries, particularly in relation to the needs of developing and least developed countries. The Delegation recalled that while all types of technologies had been patentable since the conclusion of the TRIPS Agreement, prior to that Agreement, many countries had not offered patents for pharmaceutical products, which had been largely developed in the second half of the last century. The Delegation observed that the consequences and the problems had been quickly seen with respect to the HIV virus, almost immediately after the adoption of the TRIPS Agreement in 1994. The Delegation further recalled the threats that many developing countries had faced when they had tried to take necessary steps to respond to the public concerns, which had led to the modification of the TRIPS Agreement that had established a system for production and distribution of drugs in the global South. Also the Doha Declaration, the Delegation continued, allowed the enactment of limitations to patent rights for public health, as recognized by the flexibilities and use of compulsory licenses. In light of that history and the ongoing circumstances including the cost of medicines in developing and least developed countries, the Delegation

believed that the SCP, WIPO and its Member States could not afford to be silent on that very important issue. The Delegation explained that, in that regard, the African Group had made an updated proposal based on the three elements that had been contained in the previous proposal made by the African Group and the DAG. The three areas were: (i) the elaboration of studies to be commissioned by the WIPO Secretariat, following consultations with Member States at SCP, from renowned independent experts; (ii) information exchange among Member States and from leading experts in the field; and (iii) provision of technical assistance to Member States, and particularly developing countries and LDCs, in relevant areas, and building upon work undertaken in the first two elements of the work program. The Delegation stated that, while it did not wish to go into too much details of the context provided in the updated proposal, it would point out the ongoing work of the WHO and the WHO's Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG). The Delegation referred to the threat of Anti-Microbial Resistance (AMR), and noted that its updated proposal contained that issue in the first element of the studies. The Delegation specified that the first study put forward was an examination of regulatory and other incentives that could spur motivation without promoting overuse of antibiotics, including non-patent incentives to drive drug committees to invest in AMR research, including consideration of a "pay or play" levy on the pharmaceutical sector which would require companies to either pay the levy or invest in R&D that was deemed useful for AMR. The Delegation continued that the WHO and other international and government initiatives had joined their efforts to tackle that new area of AMR and to mitigate the threat that it posed to public health for patients all over the world, particularly in developing and least developed countries that were more vulnerable to accessing medicines, vulnerable to costs, funding, to innovate for themselves and vulnerable to receiving technology transfer to meet their health needs. The Delegation recalled the studies, reports and recommendations contained in the WHO CEWG the Global Action Plan on Anti-Microbial Resistance (GAP) as well as a recent review issued by the UK government led by Mr. O'Neal identifying that the AMR had been causing millions of deaths and despite efforts and investment in research funding, if new initiatives and policies were not developed, that would overtake the cost of debt by 2050. The Delegation was of the view that the Committee could share ideas on different initiatives and models in order to mitigate such concern and to respond to the needs of patients all over the world. The Delegation explained that it looked at the ideas such as tax credits and models that incentivized research and funding to provide more significant social support for diseases. The Delegation further noted that it also thought about the idea of research funding by costs of medicines, since investment in R&D was capital intensive in a scenario where a pharmaceutical company was aiming to recoup costs as well as profit margins through the high costs of medicines. The African Group considered that the Committee could discuss and look into those areas related to access to medicines for developing and least developed countries. The Delegation further explained that another study proposed was an assessment on possible adjustments to the patent system to encourage innovation in healthcare technologies related to reducing AMR, including improved diagnostics to better pinpoint infection and antibiotic treatment in humans, and to reduce antibiotic use in agriculture. The Delegation continued that such an exercise could include an assessment of the de-linkage principle related to research funding and drug price. The Delegation noted that one of the underlying causes of AMR was overuse of antibiotics and there had been worldwide calls to reduce its use for plants and animals. The Delegation stated that the fact that antibiotics were cheaper made it more accessible for patients who might not necessarily need them in developing and least developed countries. It also observed that there were reports that made a reference to the excessive use of antibiotics in the developed world, and that while it solved certain health concerns, it also had negative impacts on human beings. In addition, the Delegation stated that the African Group further made a proposal to study the relationship between patent systems and challenges related to the availability of medicines in developing and least-developed countries, including fostering of the requisite technology transfer to facilitate access to the affordable medicines in

developing and least developed countries. Furthermore, the Delegation explained that the African Group proposed that the SCP commission a study on the law and practices with regard to compulsory license and government use licenses in WIPO Member States, which would provide detailed information, for example, the Member States that had issued or that had attempted to issue compulsory and government use licenses, the details of the license used, the challenges faced and the impact on the public health. In its view, those studies would provide a good basis for continuing discussions in that field. The Delegation proposed that those studies lead to information exchanges and then to a follow-up technical assistance work program. The Delegation further stated that one of the points in the updated African Group proposal included “an analysis of the interface of competition law and patent rights in the context of pharmaceuticals in different countries, including a compilation of statutory and case law on anti-competition grounds for compulsory license on pharmaceuticals. Experiences from countries where the intersection of competition law and patent law had been used to facilitate access to medicines should be documented.” The Delegation further explained that the competition law prohibited the abuse of patent rights and regulated related issues, such as the overpricing of drugs, the manipulation and monopolization of the market by patent owners for their benefit without taking into consideration the social and health impact on the users or beneficiaries. In the view of the African Group, the competition law policed the use of patent rights. The Delegation recalled the South African experience when South Africa had faced outrage from developed countries when it had taken necessary steps to mitigate its exploding public health concerns. The Delegation further noted that the African Group's proposal included a study and evaluation of the law and practices of WIPO Member States with regard to voluntary licenses and the feasibility of a globally accessible license database for compulsory and voluntary licenses. In its view, those two proposals would promote transparency and disclosure in the system, and would facilitate access to data of companies that had issued licenses in order to get a sense of what licenses had been concluded, what were available and what would be the best model to use, especially for LDCs and developing countries. The Delegation moved on to the explanation of the second element of its proposal, which was on information exchange. The first proposal in the second element was to appoint a balanced Working Group or Task Force to study and synthesize the reports and recommendations from the United Nations High Level Panel on Access to Medicines and commitments in the WHO Global Action Plan on AMR in relation to the patent system and to consider how the SCP could contribute to advancing the innovation and health-related Sustainable Development Goals (SDGs), specifically goal three. The second proposal was a half-day information exchange session during SCP/26, where the invitation would be sent to the UN Special Rapporteur on the Right to Health to present the report of the Human Rights Council on IPRs and Access to Medicines. The African Group requested that the WHO be also invited in order to present the CEWG and GAP report as well as co-Chairs of the UN High Level Panel to share their views on the High Level Panel's objectives and findings. In addition, the African Group proposed that the SCP organize a technical workshop on state practice involving the compulsory and voluntary licensing of medical technologies, including the application of Articles 30, 31 and 44 of the TRIPS Agreement, and further proposed periodic information exchange on the margins of the SCP, involving leading experts, on identified development-oriented issues related to patents and health. Moreover, the African Group proposed that WIPO develop, in consultation with Member States and the support of the WHO, an International Patent Register for essential medicines to facilitate the determination of the patent status of a medicine internationally, including those for communicable and non-communicable diseases. The Delegation noted that since there was no efficient way to determine the patent status of medicines, including those on the WHO Model List of Essential Medicines, such lack of transparency in the patent status of essential medicines and other medicines negatively affected efforts of governments and procurement agencies to negotiate terms and conditions of access to medicines. In the opinion of the Delegation, that was one area that would facilitate the transparency, dissemination of information and knowledge and having access to knowledge on what was



available, where it was available, what it costed under what terms etc. The Delegation considered that it allowed the information seekers to make the best choice in their given circumstances, for instance, if a Health Minister wanted to buy drugs or sell drugs, it could provide useful information for his/her engagements. Finally, on elements related to information exchange, the African Group proposed development of an international license registry for licensed medicines to facilitate access to medicines internationally, which would provide abundance of information and transparency in the international patent system. In its view, it would be helpful to have a registry of licenses so that people knew about what drugs were licensed. The third element of the proposal put forward by the African Group was on technical assistance, which should have a synergy with the previous two elements, and would be flowing from the outcome of those two elements. In the third element, the first proposal of the African Group was to hold a series of workshops on negotiating and drafting license agreements for generic manufacturers, taking due cognizance of flexibilities in the international patent system. The second proposal was to have a development-oriented guide for the issuance of compulsory licenses on medical patents, based on successful case studies. Thirdly, periodic workshops to facilitate more rigorous interpretation and application of patentability criteria by patent examiners with regard to patent applications covering health technologies in developing countries and LDCs, was proposed. Finally, the fourth proposal was to develop a technical assistance module that would explicitly demonstrate the differences between compulsory licenses that were granted under Part II of the TRIPS Agreement concerning patent rights and those granted under Part III of the Agreement concerning the remedies for infringement of those rights. The Delegation noted that a module would explain both approaches, and focus on the flexibilities afforded to both systems, noting that under the structure of the TRIPS Agreement, Article 44 compulsory licenses were not subject to restrictions that existed for Articles 30 and 31 of the Agreement. The Delegation took note that its proposal had been communicated to Member States the day before, and there might have been not enough time to read through and make informed decisions or positions. The Delegation, however, welcomed Member States to reflect well on the proposal that had been put forward. As a backdrop, the Delegation highlighted the global health concerns and the rise of epidemics and pandemics, such as the Ebola that had ravaged West Africa, and more recently the Zika virus causing a level of mayhem in the Americas and Caribbean and the increasing threat of AMR on global health. In examining the African Group proposal, the Delegation also urged other Member States to consider the SDGs, which was a commitment by all countries in the world under the UN system to provide access to health, medicines and medical technologies, especially in developing and least developed countries.

108. The Delegation of the Russian Federation thanked the Delegation of Nigeria on behalf of the African Group for the presentation of its proposal, and stated that it would express its views on the proposal in the subsequent session. Noting the high level of interest in the topic of patents and health expressed by many delegations which had made many interesting proposals, the Delegation stated that the problem of access to health and medicines was a burning issue for many Member States, which was of vital importance of each Member State. The Delegation pointed out that the problem was multifaceted, because patent protection was closely linked to exceptions, such as compulsory licenses, and related to substantive issues of public law. The Delegation stressed the importance of the studies prepared by the Secretariat, namely, documents SCP/21/4 and SCP/21/9. The Delegation was of the view that the Committee should continue studying and exchanging views and experiences on those issues. The Delegation considered that a questionnaire on the feasibility of disclosure of INN might assist discussing the issues in more details and preparing recommendations for Member States. The Delegation further noted that patent search and examination in the field of pharmaceuticals were very complex and time consuming, both during the substantive examination stage and the opposition stage, with respect to the assessment of patentability, for example, inventive step, sufficiency of disclosure, industrial applicability etc. The

Delegation therefore was of the opinion that studies on the assessment of patentability of inventions in the area of pharmaceuticals, particularly those characterized by Markush claims and selection inventions be continued. The Delegation expressed its interest in exchanging experiences of patent offices and sharing examination practices in that area, so that in the future, the Committee could prepare recommendations. In its view, it would be wise to prepare a compilation of recommendations based on the experiences of Member States in compulsory licensing, providing actual examples and jurisprudence as well as obstacles met by Member States in applying such exceptions and limitations.

109. The Delegation of Brazil thanked the Delegation of Nigeria on behalf of the African Group for their efforts in developing the new proposal. The Delegation observed that the topic patents and health was a very important one, therefore it had continuously been debated in the SCP and elsewhere in Geneva. As the subject was linked to exceptions and limitations, quality of patents and transfer of technology, the Delegation was of the view that the African Group proposal deserved the consideration of Member States. Noting that the new proposal contained many elements of the previous proposal found in document SCP/16/7, the Delegation expressed its belief that the proposed studies would shed light on the subject in the work carried out by the SCP, and would bring important elements of discussion, taking into account the recent developments in the area, such as the landmark decision of the United Nations on the SDGs and the debates being held in conjunction with the UN Secretary General's High Level Panel on Access to Medicines. The Delegation observed that the patent system was about stimulating innovation, and that the society depended on the continuous development of new medicines, as pointed out in the debates held in conjunction with AMR, where experts had alluded to the fact that microbes were developing a resistance to drugs and there was a lack of a new substance in the pipeline of research and innovation. That was also a concern that had been encountered by states in recent outbreaks of the Ebola and the Zika virus. The Delegation was of the view that the patent system needed to be an adequate instrument that ensured research and development of medicines and access to such medicines for raising living standards, which was a basic human right. The Delegation further observed that a solid grasp of the public space allowed by the patent system was vital in order to enable members to understand and adapt the national system according to their needs. In that light, the Delegation urged members to continue to work in the area of patents and health, and to develop new studies, taking into account the initiative of the African Group and other points raised by other delegations in the Committee.

110. The Delegation of South Africa expressed its support for the statement made by the Delegation of Nigeria on behalf of the African Group. The Delegation stated that the right to health was a fundamental part of human rights, which were relevant to all Member States, developed and developing countries alike. In that regard, the Delegation was of the view that all countries had a shared responsibility to lessen the impact of the health burden and improve the quality of life and livelihood of people. The Delegation stated that the African Group proposal on patents and health was very useful, as it provided a meaningful insight onto how the Member States of WIPO could assist in that critical task. The Delegation explained that the proposal provided a comprehensive overview of developments in the health field leading up to the recent establishment of the UN High Level Panel on Access to Medicines, and highlighted the critical need for the global community to address challenges in the wake of the devastating impact of the Ebola and Zika virus. The Delegation reiterated that, since public health was a shared concern, all Member States had the responsibility to address those challenges and to ensure that IPRs did not prejudice or hinder the protection of public health. The Delegation stated that, since developing countries suffered the bulk of the disease burden, they should be able to take advantage of the TRIPS flexibilities to address the health concerns. In its opinion, the proposal contained a wealth of suggestions which WIPO was most competent to address, for example, commissioning a study to

examine the challenges and opportunities faced by developing countries in using licenses for healthcare technologies: this could include the interface between competition law and patent rights in the context of pharmaceuticals in different countries. The Delegation considered that it would provide South Africa the opportunity to share its experiences, since South Africa viewed competition law as a useful tool to improve innovation, reduce prices, increase access and protect consumer welfare. The Delegation noted that, in addition, obtaining relevant and up-to-date information from experts in the field and the provision of targeted technical assistance based on the outcome of the aforementioned activities would be also envisaged in the proposal. The Delegation invited Member States to examine the proposal with the attention that it deserved so that the Committee could operationalize the elements in the proposal, taking into account the human right factor of the topic.

111. The Delegation of Algeria aligned itself with the statement made by the Delegation of Nigeria on behalf of the African Group. The Delegation considered that the subject of patents and health within the SCP was critical for the development and balanced use of the international patent system. The Delegation, therefore, supported the updated proposal by the African Group and substantive discussions on patents and public health within the SCP in order to assist countries to make full use of the patent flexibilities in compliance with the international obligations and to adapt their patent laws in accordance with their public health needs. In its view, it was an important principle that international commitments should not hinder the use of the flexibilities and safeguards provided in the international patent system.

112. The Delegation of India, speaking in its national capacity, expressed its support for the updated proposal by the African Group, composed of three interlinked items, namely studies, information exchange and technical assistance. The Delegation observed that the proposal appeared to be a balanced one that addressed the concerns of developing countries and public policy priorities related to public health. In its opinion, the proposal would enhance the capacity of developing countries and LDCs to adapt patent regimes and make use of flexibilities related to public health. The Delegation expressed its wish that other delegates would also support the proposal wholeheartedly so that the Committee would have a consensus on the issue.

113. The Delegation of the United States of America thanked the Delegation of Nigeria on behalf of the African Group for its updated proposal. The Delegation, however, clarified that since it had not been able to study the proposal, its statement was not directed to that proposal. With respect to the earlier proposal submitted by the Delegation of South Africa on behalf of the African Group and the DAG, the Delegation reiterated its strong support for the Doha Declaration on the TRIPS Agreement and Public Health as a firm declaration, and stated that it respected Member States' rights to protect public health, in particular to promote access to medicines for all. In support of the vital role of the patent system in promoting development and creation of new and innovating life-saving medicines, the Delegation was of the view that a robust patent system did not prevent countries from taking measures to protect public health. The Delegation, however, considered that the premise of the proposal in document SCP/16/7, which implied that simply making full use of patent flexibilities available under the international agreements would significantly improve the access to medicines in developing countries and LDCs, was not correct. The Delegation expressed its disagreement with such a view, which overly simplified complex issues on patent rights, as if the flexibility were the only obstacle to drug availability. In its opinion, the issue was multifaceted, and the proposal left out manufacturers, which were fundamental in addressing the problem of access, from the picture. The Delegation stated that the patent protection system provided the incentives to pharmaceutical industries around the world to develop treatments and new medicines, to make them available in developing countries and to carry out transfer of technology that would ultimately benefit all countries. In its view, without patent protection, there would be fewer new medicines, including generic medicines,

treatments and diagnostic tools. A WIPO/WHO/WTO joint study “Promoting Access to Medical Technologies and Innovation” (Trilateral Study), published in 2012, supported the view that many factors beside the patent system contributed to the availability, or lack of availability, of medicines. The Delegation considered that an important conclusion of that study was that the mere existence of IP rights on a product was neither a barrier to, nor the absence of IP rights guarantee of, access to that product. Regarding the first element of the proposal in document SCP16/7, the Delegation noted that, since much work on that element had already been carried out, additional studies would duplicate the work that had already been done in the Committee and by the WHO and WTO. For example, document SCP/18/5 listed work done by WIPO, the WHO and the WTO related to patents and health, including studies, reports, comments, articles, technical assistance, conferences etc. and provided links to the various relevant documents. The Delegation pointed out that compulsory licenses and exhaustion of rights had been extensively and thoroughly studied at WIPO and other UN organizations. Furthermore, the SCP had had a thorough discussion on compulsory licenses, including country-specific experiences and practices. The Delegation considered that further addressing those issues would likely be duplicative. Regarding a study on Markush claims, the Delegation expressed its concern about the cost and benefit analysis of the admissibility of those claims. In its opinion, such an analysis would require the Secretariat to determine and agree to the definitions of what are the benefits and what are the costs in that context. The Delegation further noted that, even assuming that such determination was possible, it would be difficult to consider the interest of all parties while balancing the two. Therefore, at that point, the Delegation could not support the proposed cost/benefit analysis proposed in document SCP/16/7.

114. The Delegation of Nigeria, speaking in its national capacity, aligned itself with the statement made by its Delegation on behalf of the African Group and the updated proposal on patents and health by the African Group. The Delegation noted that the proposal contained practical and actionable steps, which would enable the SCP to contribute to enumerating the barriers posed by the patent system to enhancing public health. The Delegation expressed its commitment to working with Member States and all relevant stakeholders in order to advance the work of WIPO in the vital field of patents and health.

115. The Delegation of Japan expressed its support for the statement made by the Delegation of the United States of America. Noting that the Delegation needed more time to consider the new proposal, it made a general statement under the agenda item, patents and health. The Delegation expressed its hope that many new medicines would be further developed, as there were many diseases all over the world for which no effective treatment existed. It noted that since developing new medicines required a large amount of time and resources, certain incentives to develop new medicines through a patent system were necessary. In its view, ignoring the contributions of the patent system in terms of how it enhanced public health would prevent medicines from being developed in the future. The Delegation stated that the existing patent system was not a barrier to access to medicines but was a well-balanced one, and that any work should not shift that balance with greater flexibilities.

116. The Representative of KEI stated that since the African Group and the DAG had tabled their proposal on patents and health in May 2011, much had happened: the Ebola and Zika had made a resurgence, and governments and health systems all over the world were struggling to cope with the high cost of medicines for cancer, hepatitis C, HIV and rare diseases, as well as the challenge of growing antimicrobial resistance. For example, on October 1, 2015, the Coalition for Affordable T-DM1, a group of cancer patients, doctors, and access to medicines advocates, had sent a letter to the Secretary of State for Health of the United Kingdom requesting the government to authorize the manufacture or importation of generic versions of the expensive breast cancer treatment T-DM1. The Representative

explained that T-DM1 was used to treat late-stage breast cancer patients who were tested positive for a protein that caused an aggressive form of breast cancer. The Representative noted that Roche held the patents on T-DM1, and charged extraordinarily high prices: a year of treatment for the average patient cost £102,405, roughly 3.9 times the UK's income per capita in 2014. The Representative further noted that, on August 8, 2014, the National Institute for Health and Care Excellence (NICE) had decided that T-DM1 should not be made available on the National Health Service (NHS), citing its extraordinarily high cost. The Representative explained that while NHS patients in England continued to get access to T-DM1 through the Cancer Drug Fund (CDF), it did not extend to patients living in Northern Ireland, Scotland and Wales, demonstrating the disparity in access to high-cost medicines that existed even within one nation. Turning to Colombia, the Representative noted that in November 2014, civil society groups in Colombia had petitioned the Colombian government to issue a compulsory license on the expensive anti-leukemia medicine, Imatinib. While the process for issuing a compulsory license was specified in the Colombian law, and the right was preserved through numerous well-known international trade agreements, including the TRIPS Agreement, the Doha Declaration on the TRIPS Agreement and Public Health, and the US-Colombia Free Trade Agreement, the Representative stated that there had been well-documented pressure on the Colombian government not to use the TRIPS flexibilities by the Swiss government, the pharmaceutical industry, the United States Trade Representative (USTR), the United States Senate Finance Committee and the United States Chamber of Commerce. The Representative noted that the Minister of Health recently had taken the commendable step of issuing a public interest declaration, which was a prerequisite under the Colombian law before issuance of a compulsory license. In terms of the Committee's work program on patents and health, the Representative urged the SCP to commission a framework study by leading independent experts to examine the implications of international trade agreements on access to medicines, including norms on the evergreening of patents, mandatory patent extension, *sui generis* exclusivity, damages and the investor state dispute system (ISDS). In his opinion, the study should examine the impact of patent monopolies on the prices of, *inter alia*, hepatitis C medicines and cancer medicines, and should also examine limitations and exceptions to remedies for infringement contained in Part III of the TRIPS Agreement, which was the area that was facing new challenges from the new norms on remedies for infringement included in the Trans-Pacific Partnership (TPP). The Representative considered that if the patent system was going to survive and thrive, it would have to be seen as an instrument to benefit society, and not as a weapon of mass destruction. In his view, reforms that moderated the abuses of the patent system would protect the patent system's legitimacy and its role in promoting social welfare.

117. The Representative of TWN expressed his concern about the access to patented medicines in developing and developed countries, since lack of access to patented medicines resulted in the delay of treatments to millions of people in developed and developing countries. The Representative noted that the report of the 2015 Social Forum of the Human Rights Council documented that there were two billion women, men and children who did not have access to even essential medicines. A recent study published by a WHO staff had reviewed prices, costs and affordability of new medicines for hepatitis C in 30 countries and had analyzed the prices of a drug Sofosbuvir obtained from 26 developed countries and Brazil, India, Egypt and Mongolia. The Representative noted that according to the prices available in 21 countries, the total cost of treating all patients with hepatitis C would be equal to at least a tenth of the current annual cost for all medicines in all of the countries studied, and that the total cost of treating all infected patients would be more than the cost of all other medicines put together. According to the study, the Representative continued, patients in Poland had paid the highest price and those in India had paid the lowest price. According to a health advocate, to pay the current price of the hepatitis C medicine, if an average Polish citizen saved every penny of income every day, the savings could fully discount the treatment that would begin in 2021. In the opinion of the

Representative, such situation called for an urgent action from Member States and the Secretariat. The Representative considered that since the lack of access to patented medicines was due to the cost of the highest prices of medicines emanating from the patent monopoly, non-action to curb that by Member States violated the international human rights obligations, such as right to health and right to science. In its view, as a UN specialized agency, WIPO could not run away from its responsibility: WIPO had an obligation to assist Member States in providing effective means to implement the SDGs. The Representative noted that the Goal Three meant the TRIPS flexibilities, and that the first step was the recognition of the problem – the Secretariat needed to recognize that there were negative issues related to medicines. The Representative was of the view that access to medicine should not be predicated upon the pharmaceutical companies, private initiatives or patent pools, but that actions ought to be taken by governments to ensure access to medicines, which was part of the international obligation. The Representative reiterated that it was time for WIPO to take up elements suggested in the SCP/16/7 and 7 Corr., which included an independent experts study in consultation with SCP members on challenges and constraints faced by developing countries and LDCs in making full use of the public health related patent flexibilities in the post-grant stage. The Representative noted that the updated proposal also contained the same proposal along with a few more proposals to address the issues regarding patents on medicines. The Representative encouraged all Member States to approve the remaining elements of the proposed work program in light of the latest proposal.

118. The Representative of JIPA noted that its statement was made in conjunction with the Japan Pharmaceutical Manufacturers Association (JPMA) comprising 72 research-oriented pharmaceutical companies. The Representative was of the view that while the discussion on INN continued in the SCP, before discussing the feasibility of disclosure of INN in a patent specification, the Committee needed to discuss why laborious and costly disclosure of INN in the specification was useful for public health. The Representative was not convinced why the disclosure of INN, instead of chemical names or CAS Registry Numbers, in the specification, was useful for public health. As to the suggestion that INN be disclosed in the specification if it was known to the applicant at the time of filing, the Representative noted that it needed to be carefully examined whether imposing such an obligation on the applicants of pharmaceutical patent applications alone violated Article 27.1 of the TRIPS Agreement or not. In his view, since INN was information which was not necessary for the description of the invention and the determination of the patentability of the invention, a new obligation to disclose INN in the specification should not be imposed on the applicants and applicants should be allowed to disclose chemical names, chemical structures, CAS Registry Numbers or INN in the specification at their discretion. Regarding the patent system and access to medicine, the Representative stated that it was important for the SCP to agree that provision of excellent medicines to many patients in the world was a mission of the governments and companies in both developed and developing countries. The Representative considered that, based on that agreement, the Committee should discuss the methods and means for accomplishing the mission after a long and careful analysis of causes of existing problems and the like. In his opinion, as reported in “Medicines in Development”, PhRMA, 2015, the role of IP as an incentive for innovation and long-term access was well versed. The Representative pointed out that pharmaceutical industry’s R&D had contributed to nearly every important medicine over the past century, including antibiotics, vaccines, HIV and HCV treatments, cancer and cardiovascular medicines, and that the industry had developed over 550 medicines in the last 15 years for the world’s emerging health needs, including oncology, cardiovascular disease, and diabetes. In his opinion, the industry continued to be instrumental in exploratory research, as well as in translating research into patient-ready treatments, with more than 7000 medicines in development across all therapeutic fields. The Representative stated that launching a new medicine into a country had significant costs for originator companies – to be successfully distributed to patients in a new country, companies must first bear the cost of 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. He pointed out that IP rights could provide a company financing the launch of a new medicine in a market with the opportunity to recoup those costs before a generic competitor could free-ride on them. The Representative noted that as reported in *Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry* (2005), a number of studies confirmed the importance of IP in accelerating the global diffusion of new medicines. According to the Representative, that study covering a large number of developed and developing countries had found that stronger patent protection increased the speed of new drug launches in those countries. The Representative further noted that, *Patents and the Global Diffusion of New Drugs* (2014), which had reviewed drug launch data comprising over 600 drugs in almost 80 countries from 1983-2002, had shown that robust patent protection accelerated new product launches in higher and lower income countries alike. In that study, strong patent protection was defined as providing for product patents (as opposed to only providing for only process patents) and the duration of patent terms. The Representative, therefore, was convinced that the patent system was a vehicle for commercialization of new technologies, and that fair patent protection of pharmaceutical technology would allow pharmaceutical companies to continuously carry out R&D activity of new drugs for patients in developing countries. The Representative further noted that pharmaceutical companies in the world had been seriously working on the issue of access to medicines in the LDCs. According to the *Access to Medicine Index 2014* report, some pharmaceutical companies committed not to file or enforce patents in LDCs, or if they filed patent applications in LDCs, they applied licensing and/or pricing strategies. The Representative explained that, for example, since a Japanese pharmaceutical company, Eisai had been committed to improving the affordability of its products, it had introduced the *Strategies for Affordable Pricing* for selected products in countries outside of those defined as high-income countries as well as the *Tiered Pricing Model* that involved establishing multiple price burden levels from full payment by the patient to free of charge in order to enable patients who needed the medicines to receive treatment regardless of their income level. The Representative further noted that Astellas Pharma's basic position was not to file or enforce patents in selected countries with significant economic challenges, considering the importance of improving access to health. The Representative thus concluded that Japanese pharmaceutical companies, which strongly requested the operation of a proper patent system for protecting pharmaceutical technology in developed and developing countries, were currently working on the issues of access to medicines. The Representative expressed his belief that the price of the medicines which were affordable to the patients was greatly affected by the country-specific drug price system and the medical insurance system of each country and the subscription rate thereof. He, therefore, hoped that the medical insurance system would be improved in developing countries. The Representative also noted that according to the UN and the WHO, global health and medical issues included research and development, human resource development, training support, education for prevention and emergency support. The Representative then introduced efforts made by the Japanese pharmaceutical companies to provide new drugs for patients in developing countries: six Japanese pharmaceutical companies, Astellas, Chugai, Daiichi Sankyo, Eisai, Shonogi and Takeda, participated in the *Global Healthcare Innovative Technology Fund (GHIT)*, established by the Japanese pharmaceutical companies, the Japanese government and Bill & Melinda Gates Foundation in order to promote development of pharmaceuticals via global cooperation; Takeda officially joined the *WIPO Re:Search* consortium on September 25, 2015; Bill & Melinda Gates Foundation had awarded a \$38 million grant to Takeda to support polio eradication in over 70 developing countries in May 2016. Takeda would use those funds to develop and manufacture a Sabin-strain Inactivated Poliovirus Vaccine (sIPV), and make at least 50 million doses per year available to Gavi-supported countries at an affordable price; Astellas Pharma, which established a consortium together

with other pharmaceutical companies, academia, and global non-profit organizations, engaged in the development of a pediatric formulation of praziquantel for the treatment of schistosomiasis, one of the most prevalent parasitic diseases worldwide. Astellas also conducted collaborative research with the National Institute of Advanced Industrial Science and Technology (AIST) to discover Anti-protozoan parasite drugs for the treatment of Chagas disease, one of the neglected tropical diseases; Daiichi Sankyo's subsidiary Kitasato Daiichi Sankyo Vaccine and the Japan International Cooperation Agency (JICA) had begun technical cooperation to produce the first measles-rubella combined vaccine (MR vaccine) in Vietnam in May 2013. From the above, the Representative was of the opinion that in order to improve access to medicines in developing countries, it was necessary to promote research and development of medicines centering on patent systems, and to strengthen medical insurance systems and human resource development. The Representative stated that Japanese pharmaceutical companies were honestly working on those issues, and were convinced that the patent system promoted public health in both developed and developing countries.

119. The Delegation of the Netherlands, speaking on behalf of the European Union and its Member States, took note of the proposal on patents and health made by the African Group. The Delegation noted that it had not been in a position to analyze the proposal in detail and proposed to come back to it during the next SCP session as part of a balanced agenda. As a general remark, the Delegation stated that it would continue to consider those proposals that fell within the WIPO mandate and within the agreed scope of the Committee in a constructive spirit.

120. The Delegation of Greece, speaking on behalf of Group B, stated that while it took note of the updated African Group proposal, Group B had not had time to thoroughly consider the proposal. The Delegation therefore reserved its right to make an intervention at a later stage.

121. The Representative of MPP, referring to the statements of some delegations regarding the need of transparency and more information about patent status, stated that since 2011, MPP had been working with patent offices and other stakeholders to enhance the transparency of the patent status of HIV medicines in developing countries. The Representative noted that the database had been launched in April 2011 with contributions from over 40 regional and national patent offices including data from the PATENTSCOPE and the WIPO Patent Register portal. The Representative explained that it included information on 24 HIV medicines in 88 countries and had become a reference tool for patent status information on HIV medicines for public health organizations, pharmaceutical manufacturers, policymakers and civil society organizations. According to the Representative, MPP was in the process of revamping its patent database to extend its scope, and would launch the new expanded database at a side event during the next WIPO General Assembly. The new database, the Representative continued, would include patent status information of medicines for hepatitis C and tuberculosis in addition to HIV, more detailed patent data from over 90 developing countries, licensing data per country based agreements with the MPP or between patent holders and generic manufacturers, increased reliability of the data through automatic updates, possibility to download search results and improved capabilities.



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

122. The Delegation of Greece, speaking on behalf of Group B, observed that the importance of protecting communication between patent advisors and their clients had been extensively discussed at the SCP. The Delegation noted that users had expressed the need of addressing that issue at the international level. In its view, Committee should take a step forward towards a solution at the international level, such as a soft law on the patent advisor client privilege. The Delegation was of the opinion that a sharing session among the Member States concerning the confidentiality applied to different types of patent professionals and to national and foreign patent advisors, such as the one which had taken place during the previous session of the SCP, could contribute to the discussion. The Delegation stated that since the different opinions around that issue had been known, the Delegation suggested looking at actual problems and/or difficulties in a more objective and precise manner. To reach that purpose, the Delegation was of the opinion that two studies could be considered by the Committee. The first one was a study based on a questionnaire/survey to Member States, including elements such as (i) obstacles to expand the types of professionals covered by client-attorney privilege; (ii) differences in the treatment between national and foreign patent advisors including the client-attorney privilege; and (iii) obstacles, if any, to the elimination of such differences. The Delegation specified that the second study should deal with court decisions on that subject matter in Member States. The Delegation considered that a collection of court cases and their analysis could give more visibility to the issues on that subject matter, and how those could be addressed. The Delegation believed that a cross-border solution to that issue was critically important for practitioners and their clients. The Delegation expressed its wish that the Committee could respond to the voices of business community and contribute to the enabling business environment essential for innovation.

123. The Delegation of Latvia, speaking on behalf of the CEBS Group, attached great importance to the continuation of work under agenda item 8. The Delegation believed that that issue was relevant to the work of the Committee, as it had a cross-border dimension. The Delegation was of the opinion that working on a non-legally binding instrument would be beneficial for all Member States. In more concrete terms, the Delegation reiterated its proposal made during the previous session of the SCP, and requested the Secretariat to conduct a study that would describe and assess various types of soft law approaches that could be effectively applied in that area.

124. The Delegation of the Netherlands, speaking on behalf of the European Union and its Member States, believed that the time was ripe to consider a concrete mechanism to adjust the recognition of foreign patent advisor privilege. The Delegation suggested considering a soft law approach aiming at conferring in WIPO Member States the same protection to communication between clients and their foreign patent advisors as the one applicable under the national law between a client and a national patent advisor. The Delegation specified that such an approach should be taken without prejudice to the existing national legislation. The Delegation was of the opinion that the convergence of existing diverse systems in the area of confidentiality of communications between clients and patent advisors among WIPO Member States would be beneficial for the users of the patent system, irrespective of the level of development of each Member State.

125. The Delegation of Iran (Islamic Republic of) was of the opinion that the confidentiality of communication between clients and their patent advisors was falling outside the scope of the patent law. The Delegation specified that the topic had not been treated similarly by the domestic law of Member States. The Delegation considered that it was a matter falling within the purview of private law and the regulation of professional services, and hence outside of

the mandate of WIPO and the SCP. The Delegation stated that it did not support any suggestion concerning norm-setting, such as soft law, and any substantive work on that topic.

126. The Delegation of the United States of America provided an update to the Member States on that topic. The Delegation stated that since it had last reported in the 23<sup>rd</sup> session of the SCP, attorney-client privilege in the United States of America had been clarified as applying to patent agents or non-attorney practitioners in its country. The Delegation explained that such a solution had resolved at least some of the inconsistencies in its system. The Delegation informed the Committee about some of the major activities that the USPTO had conducted over the last two years. For example, the USPTO had hosted a roundtable discussion in February 2015, with panelists representing a broad cross-section of IP interests. The Delegation noted that it had reported the results to Group B + and also published a report on the USPTO website summarizing the feedback received from their stakeholders. The Delegation noted that the USPTO had also drafted a model legislative language that could address the US domestic situation with an accompanying description of the policy issues involved. The Delegation stated that it had shared that language with its stakeholders to determine where consensus existed in the US. The Delegation specified that it had also solicited public comments on promulgating a privilege rule in its administrative IP court, the USPTO's Patent Trial and Appeals Board, (PTAB) that would grant privilege to communications with foreign patent practitioners in the PTAB proceedings, and had held public meetings regarding a notice of proposed rulemaking issued by the USPTO. The Delegation stated that it planned to work with Group B + on that matter and to provide policy guidance to stakeholders and to the US Congress as needed on the topic of possible federal legislation in the area. The Delegation noted that progress on a more comprehensive solution was dependent on the actions of groups outside of the USPTO's control. The Delegation therefore stated that while it continued to work with relevant parties, the USPTO was limited in what it could accomplish without additional support from those groups, for example, further progress in that area could require action by stakeholders and Congress. The Delegation highlighted that once it developed a potential domestic solution to attorney-client privilege issues, it would be ready to explore possible international approaches. The Delegation stated that it would keep the international community apprised of domestic changes in that area of law.

127. The Delegation of Japan supported the statement made by the Delegation of Greece on behalf of Group B, requesting the two studies. The Delegation believed that the issue of client-attorney privilege was not limited to domestic issues. The Delegation therefore considered that it was necessary to discuss the issue in terms of cross-border cases as well. The Delegation specified that communication between patent attorneys and their clients included information that their clients absolutely felt a need to be treated as strictly confidential, for example, legal opinions on the validity of the patent rights, the scope of the rights, and the existence or not of any infringements of patent rights. The Delegation was of the opinion that it was important to keep such information as confidential as possible, even for cross-border cases. The Delegation noted that the patent attorney-client privilege should also involve cross-border communications. The Delegation observed that due to the increased globalized economic activities, clients needed to communicate with their IP advisors before launching business activities in several countries. Therefore, the Delegation continued that there was need to conduct searches to check for the so-called "patent clearance" and that cross-border activities could be conducted smoothly only when confidential communication was protected from being disclosed, not only in home countries but also overseas.

128. The Delegation of Canada stated that as of June 24, 2016, Canada's law amending privilege had been in force. The Delegation specified that Canada recognized

communications between patent advisors and their clients as privileged confidential communication. The Delegation stressed that the new patent law also recognized communications between the client and patent advisors from another country as privileged, provided the law of the other country also recognized those communications as privileged.

129. The Delegation of India reiterated its stand on the issue of client-attorney privilege as it had taken in the previous SCP meetings. The Delegation also recalled that neither the Paris Convention nor the TRIPS Agreement provided any provision concerning privilege. The Delegation believed that since such issue was of a substantive nature and could be governed by the applicable national laws, it should be discontinued from the work of the SCP. Moreover, the Delegation was of the opinion that there was nothing left to discuss on that issue in the SCP. The Delegation stated there was no provision on the client-attorney privilege in the Indian Patents Act. The Delegation explained that, in India, patent agents did not need to be lawyers or advocates and persons who had a degree in science or engineering could also practice before the patent office as patent agents after qualifying patent agent examination. The Delegation pointed out that the Indian Evidence Act only provided protection for lawyers or advocates from discovery proceedings, and patent agents, being persons of scientific or technical background, did not fall under such protection. The Delegation expressed its view that such privilege might be detrimental to the patent system, since such disclosure might be helpful for the final determination of substantive issues of patent laws in court proceedings. Hence, from the Indian perspective, it was not compatible in the SCP to have any attempts for cross-border harmonization of the issue. The Delegation reminded the Committee that they had opposed and continued to oppose. Referring to the sharing sessions and discussions on the issue in the previous SCP sessions, the Delegation expressed its concern over the manner in which the issue was progressing towards a soft law approach in order to harmonize the issue in the SCP.

130. The Delegation of China noted that the confidentiality of communications between clients and their patent advisors had a certain value in ensuring the quality of legal services and protecting public interests. The Delegation, on the other hand, recognized that countries had different legal systems. The Delegation observed that such agenda item was closely linked to the fundamental litigation mechanisms chosen by different countries. The Delegation specified that in many countries' legal systems, especially when it came to patent law, there were no specific provisions for such mechanism. Therefore, the Delegation believed that it was necessary to respect the various legal traditions of different countries and to continue to discuss whether the countries should freely and independently use that mechanism.

131. The Representative of TWN noted that one of the most important justifications for patent monopoly was the disclosure of the invention. The Representative observed that almost all patent laws requested the full disclosure of the invention and the non-full-disclosure of the invention constituted a ground for refusal or revocation of a patent. The Representative pointed out that in many WIPO Member States, non-disclosure, partial disclosure, or wrong disclosure constituted a ground for pre- and post-grant opposition. The Representative was of the opinion that the extension of the plain attorney privilege to patent advisors went against the fundamentals of patent law. The Representative further believed that, considering the emerging public policy concerns about patent law, it was important to maintain absolute transparency around the patent grant procedure and patent litigation. Since a patent specification was a public document, the Representative believed that any related records used for the preparation of the patent specification should also be available to the public scrutiny. The Representative was of the opinion that such transparency would help authorities and courts verify the validity of the claims in the specification. The Representative further noted that since the 16<sup>th</sup> session of the Committee, the demanders of the patent attorney-client privilege had failed to provide a convincing answer to the concerns

and doubts on the implication of such a privilege on the patent system. In the light of those concerns, the Delegation requested to suspend that agenda item and to move forward to issues that were considered more relevant.

132. The Delegation of Switzerland noted that in a world with increasing international trade and related IP issues, patents mattered. The Delegation was of the opinion that the question of professional secrecy and the importance of protecting communication between patent advisors and their clients in cross-border situations had been extensively discussed in the Committee. The Delegation observed that the topic of confidentiality of communications between patent advisors and their clients was a long-standing one. The Delegation pointed out that the Committee had discussed national practices regarding the cross-border aspects, had conducted a study on confidentiality question and a compilation of law, practices and other information, and had held a seminar on the practical experiences of practitioners. The Delegation further noted that the users of the patent system from various regions had stressed the need to approach that topic at the international level in order to address the problems practitioners were facing in cross-border activities and to find solutions to improve the situation in cross-border court proceedings. Noting the statement made by the Representative of TWN about disclosure, the Delegation stressed that the disclosure of an invention in a patent application needed to be distinguished from the disclosure of confidential information between patent advisors and their clients within a discovery procedure. The Delegation observed that national patent laws required that an applicant describe his or her invention in a clear and complete manner so that a person skilled in the art would be able to carry out the claimed invention. In consequence, the Delegation noted that the applicant was obliged to disclose all information necessary to fulfill the enabling requirement. The Delegation clarified that such condition was not compromised by professional secrecy, and that the disclosure requirement continued to apply, even if what had been discussed between the patent advisor and the client during the preparation of the patent application could be kept confidential. The Delegation further observed that the Secretariat's study on sufficiency of disclosure (document SCP/22/4) revealed that patent laws of Member States varied on the details of the enablement requirement, but that was unrelated to the confidentiality of communication between patent advisors and their clients. The Delegation believed that the SCP should take a step forward in the form of a non-binding instrument on the patent advisor-client privilege. The Delegation reiterated its proposal made during the 21<sup>st</sup> session of the Committee on the work of non-binding soft law as a solution to the cross-border aspects of the patent advisor-client privilege. The Delegation considered that such non-binding framework could serve as a template for national laws. The Delegation was of the opinion that such solution would allow individual Member States to adapt their national legislation according to their domestic legal backgrounds and needs. The Delegation suggested that such instrument included definitions of key terms, such as patent advisors, or further minimum standards of the patent advisors privilege. As a concrete step forward, the Delegation encouraged all Member States to enter into discussions on the content of a non-binding framework which could also serve to address the concerns expressed by some of them. The Delegation invited Member States to provide possible topics that could be included in a non-binding framework. The Delegation invited the Secretariat to compile such contributions and to present them during the following SCP sessions for future Member States' discussion.

133. The Delegation of Indonesia was of the view that some elements of the issues related to confidentiality of communications between clients and patent attorneys should be further discussed. The Delegation endorsed the statements made by the Delegations of Iran and India. Taking note of the statement made by the Representative of TWN regarding confidentiality and the disclosure requirement, and of the following explanation by the Delegation of Switzerland, the Delegation was of the opinion that there were still many other elements of the disclosure requirement, including the disclosure of source and origin of

genetic resources, which had still to be discussed and which had not been clearly defined and solved within the Committee. The Delegation further specified that a solution about that topic still had to be found in the Indonesian national law. The Delegation pointed out that there were so many elements to be discussed at the national level because of the interrelationship between such IP subject-matter with other public policies, such as the one on public health and customer protection. The Delegation considered that efficiency and transparency were very important in many areas of discussion in WIPO and were key issues to be solved. The Delegation expressed its wish to have more studies and samples regarding that issue. The Delegation thanked the Delegate of Canada for the explanation on the Canadian national law. The Delegation, despite its wish to further engage in that topic, regretted not being able to agree on the soft law proposal. The Delegation reiterated that the Committee needed to further study that issue.

134. The Representative of JPAA believed that the situation around the confidentiality of communication between patent attorneys and their clients had improved in the framework of the SCP. The Representative strongly hoped that the issue would be approached from the point of view of the users (clients), not of the representatives (patent advisors). The Representative fully supported the statement made by the Delegation of Japan on that issue. In his opinion, a soft law approach would be an appropriate one.

135. The Representative of APAA explained that APAA comprised professionals from 18 countries such as Australia, India, Indonesia, Japan, the Republic of Korea, Myanmar, New Zealand, Philippines, Singapore, Thailand and Vietnam, including both developed and developing countries, and was dedicated to promoting and enhancing intellectual property protection. The Representative stated that during its Council Meeting in 2008, APAA had adopted unanimously a resolution on patent attorney-client privilege, supporting and urging international consensus on setting minimum standards or other remedies against the forced disclosure of confidential communication between codified IP professionals and their clients. The Representative observed that IP had become internationalized and therefore the number of cross-border IP disputes had increased. In such scenario, APAA strongly supported the proposal of studying the feasibility of setting minimum international standards for mutual recognition of client-patent advisor privilege. The Representative considered that those measures were necessary to protect clients from exposure to a high risk of forced disclosure that could potentially undermine clients' ability to obtain suitable legal advice on IP related matters. In her opinion, that could be achieved only through protecting full and frank communications between clients and their patent advisors.

136. The Representative of FICPI stated that FICPI was an international association of free practicing intellectual property attorneys and had members all over the world. Noting that a lot of focus had been put on the issue of disclosure, the Representative considered there was not a unanimous understanding about the meaning of such concept. The Representative also pointed out that, in his view, there was a problem of discrimination among users of the patent system, since users in some countries might enjoy the client-patent attorney privilege, while in other jurisdictions that would not be possible. The Representative, therefore, observed that the discussion on confidentiality of communication between patent attorneys and their clients was also about discrimination, or avoiding discrimination, between users in different countries and in cross-border situations.

137. The Representative of TWN noted that one of the reasons given to support the confidentiality of communication between patent attorneys and their clients was the need to allow a frank interaction between the clients and their advisors in relation to patent protection and enforcement. The Representative considered that, on the other hand, it might be possible that the client could use the loopholes in the patent law and compromise the disclosure requirement. The Representative requested some concrete examples on how the

absence of such patent attorney-client privilege could affect the frank discussion between IP advisors and their clients.

138. The Delegation of Guatemala thanked the Secretariat and the Chair for their work carried out in the framework of the Committee. The Delegation noted that, in Guatemala, the law regulated the patent attorney-client privilege considered the matter as an ethical issue, since keeping professional secret constituted the duty and right for both a client and an attorney. The Delegation explained that such duty had to last even beyond the service and had to include all the issues related to the topic.

139. The Delegation of Switzerland, in responding to the question raised by the Representative of TWN, stated that patent attorneys and advisors needed to know all relevant facts to provide their clients appropriate legal advice, which would encourage the clients to form an informed decision and to conform his behavior to the law. The Delegation considered that the privilege promoted broader public interest in the observance of law and administration of justice. In its opinion, a patent attorney or counsel played an important role through the entire patent process, and that a counsel, an attorney and a client must work together in an open and trustful environment to prepare and file an accurate application in order to comply with the requirements for patent grant, and also to avoid malfeasance and prosecution that might result in penalties to both parties.

140. The Representative of JPAA, in response of the question raised by the Representative of TWN, provided information on the examples on the necessity for discussing the cross-border aspect of confidentiality of communication between clients and patent advisors. He explained that if a Japanese company did its business in a foreign country and when a patent dispute occurred in the foreign country, it was quite common that the company would ask advice from a Japanese patent attorney whether it infringed the patent under dispute in the foreign country or not. In another case, before filing a patent application in a foreign country, a Japanese company might seek advice from a Japanese patent attorney on the patentability of the claimed invention in the foreign country. The Representative noted that, in those cases, if the communication between the Japanese patent attorney and the Japanese company were not protected in the foreign country based on the so-called client-attorney privilege, it would be necessary for the Japanese company to submit and disclose every related document in the discovery procedure when a law suit, for example, a patent infringement law suit, occurred. He explained that, as a result, the interest of the Japanese company would not be protected in the foreign country. The Representative supposed that those kinds of situation would occur in every country, and concluded that it was necessary to have the discussion in the SCP on the confidentiality of communication between clients and patent advisors to be protected in foreign countries, which was the cross border aspect of the client-patent advisor privilege issues.

141. The Representative of AIPPI noted that AIPPI had studied the question of attorney-client privilege in detail in the past, and those studies disclosed the many challenges that arose from the lack and limitations of the current attorney-client privilege frameworks in various countries and the impact of the challenges on the quality of the patent work. The results of those studies had been presented to and discussed also in the Committee during the previous sessions. Without repeating in detail the results of the AIPPI studies, the Representative stated that, in summary, AIPPI continued to support the view that the protections and obligations of the attorney-client privilege should apply with the same force and effect to confidential communications between patent (as well as trademark) attorneys, whether or not qualified as attorneys at law, and their clients regardless of whether the substance of the communication might involve legal or technical subject matter. The Representative noted that, in terms of patents, that view was founded among others on the understanding that communications between attorneys and clients regarding technical

matters were as deserving of protection as were communications involving purely legal matters, due to the fact that technical and legal matters were closely inter-related in patent matters. Noting that due to the multifaceted nature of patent law, and IP law in more general, people frequently relied on patent and other IP advisors for advice in their IP matters, the Representative considered that at the core of that guidance was the information shared between the client and their advisors. The Representative pointed out that as in any other fields, in patent advisory, incomplete information led to incomplete advice and, consequently, to a lack of quality in patent work. Therefore, the Representative was of the view that sharing technical as well as legal information fully, freely, and frankly between clients and their advisors was essential in guaranteeing the high quality of patent work, which applied to patentees and other parties alike. The Representative noted that such free information sharing would, however, only take place if confidentiality of communications between patent advisors and their clients was ensured and, consequently, if the clients could be certain that communication which was intended to be confidential would stay confidential and would not be subject to measures in court or other proceedings where the content of the communication would have to be disclosed to third parties. As highlighted by a number of delegations, the Representative stated that, in the global context, the practical challenges relating to the uncertainties and limitations of attorney-client privilege between patent advisors and their clients arose in particular in cross-border litigations and, for example, in relation to certain types of discovery and disclosure proceedings available in some jurisdictions around the world. The Representative explained that, in practice, in such scenarios, absent appropriate privilege rules, information that the client shared in confidence with their patent advisors could be disclosed to third parties. Thus, in the opinion of the Representative, given the current differences in approach to privilege around the world, ensuring that attorney-client privilege was appropriately applied to confidential communications between patent attorneys and their clients as well as to attorneys at laws and their clients alike would also contribute to the certainty, predictability, and quality of the patent framework equally for all stakeholders involved. Finally, the Representative stated that, with the permission of the Chair, AIPPI would provide specific references to previous work and submissions by AIPPI on the topic through the Secretariat to be transmitted to the delegations and could provide further concrete updates and studies on the topic during the forthcoming sessions of the Committee.

142. The Representative of FICPI supported the statement made by the Representative of JPAA and the initiative of AIPPI.

143. The Delegation of Japan expressed its appreciation for the concrete examples, and noted that it had also made a presentation that had included similar examples during the 23<sup>rd</sup> session of the SCP. The Delegation considered that the Secretariat should research the issue further in order to share and elaborate on the current and possible future issues, in order for the Committee to have a better understanding of the topic.

144. The Representative of TWM noted that, as he understood, discovery of documents took place at patent offices and in courts, and the confidentiality of information was most important in the cases of making inquiries on patentability and infringement. The Representative however considered that no patent office had a discovery process to which confidential information to determine the patentability was relevant. In the case of infringement, the Representative said that cases, where discovery led to an extra determination of infringement based on the private communication between a patent advisor and his client, were the kind of examples he sought. The Representative stated that if there were such concrete examples and empirical evidence, they would be helpful for moving the debate further on the agenda item.

## AGENDA ITEM 9: TRANSFER OF TECHNOLOGY

145. The Delegation of India stated that the promotion of transfer of technology was one of the most important steps towards attaining the objectives of its recently announced national IP policy. The Delegation recalled that, according to the objective of the TRIPS Agreement, the protection and enforcement of intellectual property rights should contribute to the transfer and dissemination of technology in a manner conducive to social and economic welfare and to a balance of rights and obligations. The Delegation also recalled the principle of the TRIPS Agreement that appropriate measures were needed to prevent abuse of international intellectual property rights by right holders or the resort to practices which adversely affected the international transfer of technology. The Delegation further made reference to paragraphs 48 and 49 of document SCP/14/4, and reaffirmed that the knowledge contained in patent specifications served as an extremely important tool for the transfer of technology. The Delegation believed that the sufficiency of disclosure was at the heart of the matter of patent law and provided the *quid pro quo* of the patent system. Regarding the transfer of technology and sufficiency of disclosure, the Delegation noted that document SCP/22/4 had revealed that, under ideal conditions, patent specifications should divulge the technology in an enabling manner. The Delegation referred to Article 29 of the TRIPS Agreement, which stipulated that an applicant for a patent should disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. However, the Delegation was of the opinion that in many instances, especially in the healthcare sector, a product could not be produced due to insufficient disclosure in patent specifications. The Delegation therefore wondered to what extent the patent system could contribute to transfer of technology as a stand-alone system without the aid of accompanying trade secrets. The Delegation believed that if the technology transfer without the accompanying trade secrets was not possible, the basic purpose of the patent system was forfeited, and such inability of transforming inventions into commercial reality posed a serious threat and challenge to the very purpose of the patent system. Having that in mind, the Delegation reiterated its proposal that the role of the patent system in the context of transfer of technology should be carefully studied in the background of sufficiency of disclosure. In its opinion, the SCP was required continuing the study on document SCP/22/4 concerning sufficiency of disclosure under the agenda item of transfer of technology. The Delegation also proposed that a sharing session on the sufficiency of disclosure be considered under the agenda item of quality of patents, because the Delegation considered that the logic of having a sharing session on inventive step during the previous session of the SCP should also apply to the sufficiency of disclosure.

146. The Delegation of South Africa, speaking on behalf of the African Group, supported the statement made by the Delegation of India. The Delegation reiterated that, although the SCP had agreed to undertake a discussion on technology transfer, particularly as it related to sufficiency of disclosure based on document SCP/22/4, such document did not succinctly describe how the sufficiency of disclosure could facilitate transfer of technology. The Delegation stated that sufficiency of disclosure was an important flexibility provided by the TRIPS Agreement and had the potential to play a key role in national, regional, and international innovation systems. The Delegation believed that disclosure was the bedrock of the patent system, and therefore discussions should continue at WIPO on how it was applied by different countries and whether there were any problems in it. The Delegation considered it also important that the protected inventions were sufficiently described to enable the transfer of technology in view of IP for development. The Delegation was of the opinion that such discussions could lead to initiatives that would encourage full disclosure of inventions built on the existing base of knowledge, while still maintaining the system's integrity, ensure knowledge dissemination and avoid duplicative R&D efforts with human and financial implications, thereby allowing quality patents, which build on the existing base of knowledge. The Delegation noted that the study contained in document SCP/22/4 had



revealed that, in general, the relevant provisions in most of the laws were largely similar, and reflected Article 29.1 of the TRIPS Agreement according to which members should require an applicant for a patent should disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. Bearing in mind the vast number of issues that led to the sufficiency of disclosure, the Delegation suggested some activities that could assist the Committee to move forward on that topic. Firstly, the Delegation requested a study to be prepared by the Secretariat on which components of the sufficiency of disclosure could limit the transfer of technology in developing countries. The Delegation suggested that the focus be, for instance, on dependent technologies. Secondly, the Delegation proposed that the Secretariat explore patent-related policies and initiatives necessary to promote the transfer and dissemination of technology to the benefit of all, in particular, developing countries and least developed countries. To conclude, the Delegation requested that advice on how to implement rights and obligations contained in international treaties, and on the use of the TRIPS flexibilities in relation to sufficiency of disclosure, be provided to developing countries.

147. The Delegation of the Netherlands, speaking on behalf of the European Union and its Member States, noted that during the 23<sup>rd</sup> session of the SCP, the Committee had discussed document SCP/22/4, which contained a study on sufficiency of disclosure. The Delegation supported the statement contained in the study, that it was through the disclosure requirement that the patent system facilitated the dissemination of information and access to technological knowledge contained in patent applications, which resulted in the expansion of public stocks of technology knowledge and increase in the overall social benefits, for example, technology transfer and avoiding duplicative R&D. The Delegation observed that during the 17<sup>th</sup> session of the Committee on Development and Intellectual Property (CDIP) which had taken place from April 11 to 15, 2016, Member States had discussed the “Evaluation Report on the Project on Intellectual Property and Technology Transfer: Common Challenges - Building Solutions”. The Delegation also took note of document CDIP/17/9 entitled Mapping of Activities Related to Technology Transfer. The Delegation considered that such mapping document was highly useful, as it allowed for a deeper understanding of how WIPO activities were relevant to promoting technology transfer. The Delegation was of the opinion that the CDIP had produced an excellent overview of work that WIPO had performed in that area. The Delegation believed that the SCP should avoid duplicating the efforts of the CDIP in that respect. As a way forward, the Delegation was committed to consider proposals to deepen the Committee’s understanding of the impact of patent disclosure on transfer of technology, and as a concrete step, the Delegation suggested, as it had also done in the 17<sup>th</sup> session of the CDIP, updating the existing WIPO web page on technology transfer.

148. The Delegation of China attached great importance to the agenda item on technology transfer. The Delegation was of the view that discussions under agenda item played an important and positive role in recognizing and understanding the opportunities and challenges facing technology transfer, promoting effective free flow of technology and promoting innovation in all countries. The Delegation hoped that the SCP could further study the relationship between the patent system and technology transfer with a focus on the difficulties faced by developing countries and possible solutions. The Delegation was of the opinion that Member States should share experiences in promoting technology transfer and patents, and study all appropriate rules enabling technology transfer. In its view sufficient disclosure of inventions in patent applications contributed to the dissemination of patented technology, thus avoiding duplication of research and enhancing overall social benefits. The Delegation therefore proposed that the SCP further assess evidence in order to find out the role of patent disclosure in promoting technology transfer.

149. The Delegation of Brazil noted that discussions on providing adequate encouragement to transfer of technology had a long history in the multilateral fora. The Delegation was of the opinion that bringing challenges and opportunities to the transfer of technology to light was beneficial to Member States, especially developing countries. The Delegation considered that it was a necessary step in order to tackle multilateral issues. The Delegation observed that, because of its importance, that subject matter was in the agenda of the United Nations Framework Convention on Climate Change (UNFCCC) and in the Development Agenda's Recommendations 22, 23, 25, 28, 29, 31 and 45. The Delegation further pointed out that technology transfer was also found in the TRIPS Agreement, especially in Article 8, constituting the basic principle of the Agreement. The Delegation mentioned that recently, the United Nations Sustainable Development Goals touched upon a number of subjects that demanded the attention of Member States in order to ensure the technology transfer. Therefore, the Delegation was of the view that continued work on the subject in the SCP would bring benefits to all Member States. The Delegation considered that the Committee could further elaborate the topic of disclosure on the basis of document SCP/22/4. The Delegation believed that the full disclosure of inventions, including the most relevant prior art, was one of the most relevant factors for the transfer of technology and constituted the basic tenant of the patent system, since it allowed the correct examination of patent applications by the patent offices and ensured dissemination of the precise content of the invention to third parties. The Delegation stressed the importance of the full disclosure, because it avoided the granting of frivolous patents which had a negative effect on innovation and facilitated the transfer of technology by the adequate description of the invention. The Delegation suggested that the SCP consider working on the subject on the basis of the proposals made during the plenary session.

150. The Delegation of Latvia, speaking on behalf of the CEBS Group, believed that transfer of technology was an important factor in fostering development. In that regard, the Delegation observed that the CDIP had completed a Project on Intellectual Property and Technology Transfer: Common Challenges - Building Solutions. The Delegation further noted that the CDIP had also finalized a mapping exercise demonstrating the role of WIPO in that area. The Delegation pointed out that any activities under that agenda item should take into consideration the work carried out by the CDIP in order to avoid any duplication. On the question of the impact of the patent disclosure on the transfer of technology, the Delegation supported discussions in sharing sessions and the elaboration of case studies.

151. The Delegation of the United States of America noted that WIPO was actively involved in a wide range of technology transfer-related activities within the framework of WIPO's CDIP, which benefitted least developed, and developing countries as well as countries with economies in transition. The Delegation observed that, as emphasized by the European Union and its Member States and the CEBS group, document CDIP/17/9 contained information on existing technology transfer-related services and activities undertaken by WIPO during the 2014/2015 biennium. The Delegation mentioned that during the 17<sup>th</sup> session of the CDIP, the Chair had suggested that interested Member States should submit proposals to the Secretariat for consideration at the 18<sup>th</sup> session of the CDIP, regarding both general and concrete issues relating to a way forward for addressing next steps and the role of WIPO in technology transfer. The Delegation pointed out that such work would be built on the Project on Intellectual Property and Technology Transfer: Common Challenges - Building Solution, which was an important element of WIPO's technology transfer strategy. Since such work was still ongoing in the CDIP, the Delegation believed that any further work on technology transfer in the SCP should await the results of that Project to avoid duplication of work and to benefit from the deliberations of the Member States within the CDIP. The Delegation also added that the disclosure provided by the applicant was a fundamental part of the public's and patent holder's bargain struck by the patent system, which required a full enabling disclosure of the claimed technology in

exchange for the patentee receiving the exclusive rights conferred by a patent. The Delegation believed that disclosure allowed the public to learn about the most recent technical developments and to freely use the technical teachings after the expiration of the patent. The Delegation stressed that if an invention was not sufficiently disclosed, the patent might not be able to derive the benefits derived by the patent system. From the patent examination point of view, the Delegation explained that if an invention was not sufficiently disclosed, under the US law, a patent would not be granted. Noting that the disclosure requirement had been recently studied in the SCP resulting in document SCP/22/4, the Delegation agreed with the statement contained in paragraph 14 of that study, according to which it was neither necessary nor desirable that the description provided the details of well-known ancillary features, instead the description must only describe any feature essential for carrying out the claimed invention in such sufficient detail so that the skilled person would be able to put the invention into practice without undue burden or experimentation and without needing inventive skill. The Delegation also agreed with the content of paragraph 23 of that document which stated that the audience of the description was the person of ordinary skill in the art. The Delegation considered that it allowed for a simplified description to be provided by the applicant, since it could be assumed that the reader would be an informed reader, having the background knowledge which made it unnecessary to describe every basic detail of the invention. The Delegation opposed additional studies on the disclosure requirement, and supported the proposal made by the Delegation of the Netherlands on behalf of the European Union and its Member States, to update the WIPO technology transfer web page.

152. The Delegation of India recalled the statement made by the Delegation of Nigeria on behalf of the African Group during the previous session of the SCP, expressing the view that the work of the CDIP should be independent of the work of the SCP, since the CDIP's activities on technology transfer covered different areas. The Delegation of India further recalled that the Delegation of Nigeria had expressed its interest in continuing the discussion on that agenda item as a part of the future work in the Committee. The Delegation reaffirmed its support to the statement of the Delegation of Nigeria on behalf of the African Group during the previous SCP session.

153. The Representative of TWN reminded Member States that one of the core-mandates of WIPO was to facilitate technology transfer. The Representative observed that the "Declaration on Patents Protection: Regulatory Sovereignty under TRIPS" drafted by 40 international patent scholars under the auspices of the Max Plank Institute for Innovation and Competition in Munich, Germany, had highlighted the historically unprecedented number of patent filings and grants and had noted that, besides creating backlogs at patent offices, such phenomenon had led to legal interdependencies, patent thickets, market-entry barriers, royalty stalking and increased litigation: all which generated impediments to research and commercial applications. The Representative commented that such result was confirmed by another academic study entitled "Do Patent Licensing Demands Mean Innovation?" by Robin Feldman and Mark A. Lemley. The Representative quoted a part of the study according to which very few patent license demands actually led to new innovation, while most demands simply involved payment for the freedom to keep doing what the licensee was already doing. The Representative mentioned that that study found such result was true not only in case of non-practicing entities (NPE) licenses but even in case of licenses from product-producing companies and universities. The Representative believed that the results of those studies casted significant doubt on one common justification for the patent system. The Representative therefore concluded that it was important to understand the implications of patents on technology transfer, since he believed that the mere presence of patents increased the bargaining power of the technology holder, and put the technology buyer not on an equal footing. The Representative also believed that a large number of the patents created barriers to technology transfer. The Representative encouraged WIPO and its Member States to start a work program on technology transfer and patents with a focus on

the issue of patents as a barrier to technology transfer. The Representative was of the opinion that the CDIP work on technology transfer did not discuss the topic of patent barriers to technology transfer. The Representative further considered that the High Level Forum on Technology Transfer failed to take note of those concerns and even recommended accession to WIPO's treaties such as the Patent Cooperation Treaty (PCT) as a way to promote technology transfer. The Representative was of the view that such recommendations had been adopted because the experts, being mainly executives from private firms, had supported in a partisan manner technology licensing and had never had any kind of exposure on development and technology transfer issues. The Representative further noted that the WIPO initiative on technology transfer was a technology-match-making platform and was not addressing the issue of patents as a barrier to technology transfer. The Representative recommended that the SCP discuss the issue, being the only forum in WIPO where the issue of technology transfer was discussed in a focused manner.

154. The Representative of Innovation Insight stated that the technology diffusion and the commercialization of new solutions were to a large extent related to handover: handover from research institutes to private sector partners who could take the technology forward; handover from SMEs to larger companies or vice versa; or other forms of handover of research or technology among partners. The Representative believed that patent tools were used to underpin those forms of engagement, through which research and early stage technology could be refined and transformed into actual offerings that could touch people's lives. The Representative stated that the SCP could help to shed light on how IPRs were used to facilitate technology transfer and deployment of technology to the business of developing countries. The Representative encouraged initiatives aimed at talking about concrete cases providing specific information about how technology handover and diffusion occurred by using patent tools. The Representative stated that Innovation Insight was agnostic about the forum where that would be discussed: in particular, the Representative noted that both the SCP and the CDIP were valid fora and considered such choice should be left to Member States.

155. The Delegation of Greece, speaking on behalf of Group B, reiterated the importance it attached to WIPO's work in facilitating transfer of technology. The Delegation observed that transfer of technology was a very complex subject matter consisting of various different aspects, and that during the previous CDIP session, the Committee had discussed a comprehensive mapping document on the WIPO activities related to transfer of technology conducted in the 2014 to 2015 biennium, which was part of the Project on Intellectual Property and Technology Transfer: Common Challenges – Building Solutions. The Delegation noted that according to the CDIP document, WIPO had been actively involved in a wide range of technology transfer-related activities to benefit developing countries, LDCs and countries with economies in transition. Therefore, in its view, the CDIP was the appropriate forum to discuss the general aspects of technology transfer. Until that Project was completed at the CDIP, the Delegation was of the opinion that the SCP should place on hold its discussions on transfer of technology. The Delegation stated that the Secretariat should review and update the existing WIPO technology transfer web page by incorporating links to additional materials, documents and activities contained in the CDIP document, Mapping of Activities related to Technology Transfer, for example, the links to the WIPO Green, guides on licensing and IP asset development and management and various studies commissioned by WIPO.

156. The Delegation of Iran (Islamic Republic of) stated that transfer of technology was a significant subject in the agenda of the SCP. It considered that the SCP should play an important role in understanding the opportunities and challenges faced by technology transfer, enhancing free and efficient flow of technologies and promoting science and technology innovation by holding discussions and sharing information. Supporting the

statement made by the Delegation of India as well as the statement made by the Delegation of Nigeria on behalf of the African Group during the previous session, the Delegation also considered that the work in the CIDP was independent of the work in the SCP, since their activities on technology transfer covered different areas. The Delegation stated that the work on transfer of technology should be continued in the SCP, and suggested that the Committee prepare a study on inter-relationship between patent systems and transfer of technology. In its view, that could contribute to identifying possible difficulties faced by developing countries on the promotion of technology transfer. In addition, the Delegation noted that the requirement of sufficiency of disclosure had a potential to play a key role in national innovation systems and it was a crucial component of transfer of technology and proper functioning of the patent systems.

157. The Delegation of Indonesia, noting the statements of some delegations regarding the competency of the SCP on the issues of transfer of technology, stated that the issue of fora should be discussed on the basis of the substance of discussion under each forum. In its view, while the CDIP discussed transfer of technology, the issues of patents and transfer of technology should be discussed in the SCP, and there was no conflict of authority to discuss transfer of technology in the SCP. The Delegation considered that issues relating to transfer of technology should be mainstreamed and discussed in all relevant bodies, including the CDIP and SCP. The Delegation further stated its support to the statements made by the Delegations of Iran, India, Nigeria on behalf of the African Group and South Africa regarding sufficiency of disclosure. The Delegation stressed the importance of discussions on the sufficiency of disclosure, and noted that there were very important elements in the discussions. In its view, those discussions in the Committee on transfer of technology in relation to the sufficient disclosure could lead to the enhancement of transparency in a patent system, which would support dissemination of technology, innovation and R&D. The Delegation further observed that health and climate change issues, for instance, were global issues that the delegates had been facing, and expressed its hope that WIPO could also contribute to those discussions. In conclusion, the Delegation stated that while it acknowledged the different positions and a huge gap between the positions of the delegations, concrete discussions especially about sufficiency of disclosure, health and climate change in relation to the transfer of patented technology should be carried out in the SCP.

158. The Delegation of Nigeria, speaking on behalf of the African Group, reiterated its position, and stated that the discussions in the SCP on transfer of technology were different from those in the CDIP, which were general discussions on transfer of technology. In its opinion, the agenda item on transfer of technology should be kept, and the Committee should engage in concrete work towards facilitating transfer of technology via the patent system so that it would serve a technological teaching purpose through sufficiency of disclosure.

#### AGENDA ITEM 10: OTHER ISSUES: PROPOSAL OF THE GROUP OF COUNTRIES OF LATIN AMERICA AND THE CARIBBEAN (GRULAC) ON THE REVISION OF THE 1979 WIPO MODEL LAW FOR DEVELOPING COUNTRIES ON INVENTIONS

159. Discussions were based on document SCP/22/5.

160. The Delegation of the Bahamas, speaking on behalf of GRULAC, expressed its wish to address the Committee on its proposal on the revision of the 1979 WIPO Model Law on Inventions for Developing Countries. The Delegation stated that it was a very important topic for GRULAC, as well as for other developing and least developed countries Member States of WIPO. Noting that the Bahamas, a country in the process of acceding to the WTO, was in

the process of updating and upgrading its IP legislation, the Delegation was of the opinion that an update of the Model Law under discussion would be very beneficial for the Bahamas' relevant agencies that should ensure that the Bahamas would be completely compliant with the international requirements related to IP law. The Delegation recalled that the starting point of the development of the Model Law had been in 1965, when the United International Bureau for the Protection of Intellectual Property (BIRPI), the predecessor of WIPO, had published a Model Law for Developing Countries on Inventions. The Delegation pointed out that in 1974, that Model Law had been revised and resulted in the publishing of the current Model Law in 1979. The Delegation reminded that during the 22<sup>nd</sup> session of the Committee, with the intention of providing the Secretariat with a useful tool for capacity building activities, GRULAC had proposed the commencement of discussion on the revision of the 1979 Model Law for Developing Countries on Inventions, with its main objective as the development of the patent regimes of those countries in order to promote innovation, creativity, competition and foreign investment. The Delegation noted that its proposal, as articulated in document SCP/22/5, took into consideration the following elements: the availability of funds and the budget of the Program to carry out progress in the revision of the Model Law for the developing countries and least developed countries; the consideration of the relevance of the main factors related to patent law in a comprehensive and holistic manner; the need to respond to the increasing demand for Member States for legislative and policy assistance in line with the Development Agenda recommendations 13 and 14; the opportunity to update a document from the 1970s to reflect changes that had occurred after that period in the patent law area, in particular, the entry into force of the TRIPS Agreement in 1995 and its implementation in national legislation; the usefulness of a revised document that would be the basis for consideration for Member States when updating or reviewing their patent legislation. The Delegation observed that in previous sessions of the Committee, GRULAC proposal had received support from many regional groups and various delegations and that such support had been reiterated during the current session of the SCP. The Delegation stressed that there were many Member States that viewed the WIPO Model Law as being outdated and in need of revision. However, the Delegation highlighted that the exercise was not intended to lead to harmonization. The Delegation suggested that the Secretariat prepare a proposal for WIPO Member States' consideration on the terms of reference and modalities that such a revision could follow. The Delegation pointed out that Member States would be able to intervene and participate in that process as usual, and that the final product would not constitute a binding document. The Delegation suggested that the parameters of the Committee's discussion on that topic be: the usefulness of the Model Law for the work of the Secretariat; the situation of the Model Law in relation to the international patent system; information exchanged with regard to what Member States would expect in the Model Law from a UN agency such as WIPO. The Delegation hoped that Member States would agree to engage in constructive discussions on such an important issue for the developing and least developed countries.

161. The Delegation of Iran (Islamic Republic of) believed that it was time to revise the WIPO Model Law for Developing Countries on Inventions of 1979. The Delegation was of the opinion that revision should be development-oriented and in line with the Development Agenda recommendations. The Delegation further observed that the Model Law should provide legislative and policy options for developing countries to utilize the flexibilities contained in the TRIPS Agreement. The Delegation supported the proposal submitted by GRULAC on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions.

162. The Delegation of Paraguay supported the statements made by the Delegation of the Bahamas on behalf of GRULAC with regard to GRULAC proposal contained in document SCP/22/5, on the revision of the WIPO Model Law for developing countries on inventions of 1979. The Delegation was of the opinion, that updating that Model Law, which was 40 years

old, was a valid and necessary task, in particular, if the SCP treated current topics from the real world perspective. In its view, that exercise was even more important in the area of patents, where major progress had been seen since 1979, like the entry into force of the TRIPS Agreement, the implementation of the Development Agenda, and the increasing number of patent applications at the international level. The Delegation reiterated that such updating was not a piece of work the intention of which was to harmonize the laws of Member States. The Delegation considered that an updated Model Law would reflect progresses made since 1979 and provide guidance and illustrate the available flexibilities so that those members who would amend their respective legislation might find that reference document useful and beneficial. With regard to the argument that such proposal might affect the balance of the work of the SCP, the Delegation noted that since in the previous sessions, the Committee had completed discussions on agenda items in an increasingly rapid and efficient manner, the proposal from GRULAC or any other proposal on that matter would not have implications in terms of use of available time. On the contrary, the Delegation was of the view that the Model Law would contribute in a positive manner to the quality of patents, promote transfer technology and provide the necessary flexibility so that those Member States who wished to use it could take decisions in line with their respective realities. The Delegation requested that the Secretariat brief the Committee about the use that the Model Law of 1979 had had. The Delegation further expressed its wish to know whether an updated Model Law might be used as a reference tool by the Secretariat when carrying out activities of technical assistance and legislative support.

163. The Delegation of Indonesia thanked GRULAC for its proposal on the revision of 1979 WIPO Model Law and supported it. The Delegation further expressed its wish to have more guidance on how to promote research and development and innovation. The Delegation was of the view that the SCP should have focused not only on patent protection, but also on ways to promote research and development and inventions. The Delegation endorsed the statements made by the Delegations of Iran and Paraguay regarding the TRIPS flexibilities. The Delegation believed that for substantive harmonization law the work of the Committee should take into account different levels of development, within or among the developing countries.

164. The Delegation of Brazil aligned itself with the statement made by the Delegation of the Bahamas on behalf of GRULAC. The Delegation deemed important to continue the discussion on the revision of the WIPO Model Law for Developing Countries on Inventions. The Delegation believed that an adequate Model Law should take into account the current multilateral legal framework, offering legislative and policy options for Member States while taking into account their different stages of development. The Delegation considered the revision relevant, considering the extension of the transition period for least developed countries as agreed by the TRIPS Council in its decision of November 2015. The Delegation was of the opinion that an updated Model Law would provide valuable input for those countries in the process of considering the available options for implementing their international obligations. The Delegation was of the view that future WTO and WIPO members could also benefit from the revised Model Law in adapting their national laws to the multilateral requirements. The Delegation finally observed that a revised Model Law would become a more relevant document in the framework of technical and legislative assistance activities undertaken by WIPO.

165. The Delegation of India reaffirmed its support to the proposal made by GRULAC in document SCP/22/5. The Delegation also reiterated that the revisions of the 1979 WIPO Model Law should fully and adequately reflect the recent developments, as well as the TRIPS flexibilities in respect of the legislative and policy options for the developing countries. However, the Delegation believed that the proposal should not be construed to mean any harmonization of patent laws.

166. The Delegation of the Netherlands, speaking on behalf of the European Union and its Member States, noted that at the 22<sup>nd</sup> session of the SCP, the proposal by GRULAC to revise the 1979 WIPO Model Law for Developing Countries on Inventions included in SCP/22/5 was introduced. Although the background information was interesting, the Delegation considered that it was still unclear as to the reason and background why that revision was sought, and believed that more appropriate means were already available. In that regard, the Delegation stressed the importance of tailor-made and demand-driven technical assistance by the WIPO Secretariat that was being provided along the lines of the Development Agenda recommendations, including technical assistance on legal matters concerning the area of patents. The Delegation specified that technical assistance took into account specific country needs and situations, in a way that was much more wide ranging than a simple application of the Model Law. The Delegation stated that it had not yet heard any convincing arguments about the need to revise the Model Law in order to further consider the proposal. The Delegation believed that, if taken forward, a revision would lead to substantive harmonization of patent laws. The Delegation observed that, in such a case, the Committee could use the opportunity and start with harmonization of other aspects of patent law, which could be beneficial to all. The Delegation further emphasized that WIPO should not touch upon interpretation of the provisions of the TRIPS Agreement.

167. The Delegation of China supported the proposal on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions, since it would provide policy and legislative assistance to developing countries. The Delegation considered that such revision belonged to the terms of reference and mandate of the SCP, and it would be a good trial to promote the work of the Committee. The Delegation proposed that the Secretariat fully listen to the needs of developing countries for the Model Law in order to collect relevant information and draft a report to be used as a basis of future discussion.

168. The Delegation of South Africa reiterated its support for the GRULAC proposal on updating the 1979 WIPO Model Law for Developing Countries on Inventions. In its opinion, it was important that such a revision took into account developments relating to the IPR system since 1979, such as the reflection of the TRIPS flexibilities, which were critical for countries seeking to preserve their policy space and address developmental objectives. The Delegation believed that it would serve as a useful tool for Member States when updating or reviewing their patent legislation or drafting IP policies. The Delegation recalled that South Africa was currently engaged in a similar process. The Delegation did not agree with the assumption that such exercise amounted to harmonization. The Delegation further stated that any legislative assistance rendered by WIPO should have been development-orientated and demand-driven, and should take into account the special needs of developing countries.

169. The Delegation of India, speaking on behalf of the Asia and Pacific Group, supported the proposal of GRULAC on the revision of 1979 WIPO Model Law for Developing Countries on Inventions, contained in document SCP/22/5. The Delegation believed that the revision of such Model Law should emphasize legislative and policy options for Member States. In its view, that agenda item was by no mean of lesser priority. Therefore, the Delegation considered that the revision should be given as equal importance as the substantive agenda items of the Committee.

170. The Representative of TWN noted that the proposed revision of the WIPO Model Law for Developing Countries on Inventions would make it a reference guide to many Member States in the process of revising their patent law or planning such process. The Representative considered that it was important to implement that proposal, since such Model Law dated 1979, when the TRIPS Agreement had not yet been signed. The Representative further observed that the Secretariat was carrying out technical and



legislative assistance in various member countries. The Representative stressed that during that process, WIPO had advised many Member States on how to put in line their patent law with the TRIPS Agreement. The Representative stated that he had come across with some recommendations which were not illustrating the optimal use of flexibilities: for instance, the Representative stated that in a certain number of proposals from the Secretariat, not all grounds of compulsory licenses were indicated. The Representative considered it important that the Secretariat's technical assistance be transparent, accountable and consistent. The Delegation believed that the revision of that Model Law would serve that purpose. The Delegation was also of the opinion that the Secretariat could save millions of francs by simply revising the Model Law, since Member States could refer to such document as a guide and they would not need to request the assistance of the Secretariat each time when they wanted to comply with the TRIPS Agreement and use its flexibilities.

171. The Representative of KEI welcomed the GRULAC proposal, which sought to reflect changes that had occurred in the patent law area after the adoption of the Model Law, particularly the entry into the force of the TRIPS Agreement in 1995. The Representative noted that, for the preparation of the initial Model Law WIPO, after consultation with interested governments, had appointed experts who acted in their personal capacity to serve on the Working Group that had drafted the 1979 Model Law. The Representative specified that such experts had come from governments, intergovernmental organizations, and nongovernmental organizations. The Representative asked the Committee if the same process could be followed in the case of revision of that Model Law.

172. The Delegation of Greece, speaking on behalf of Group B, took note of the fact that the GRULAC proposal on the revision of the Model Law had been discussed under agenda item 10, which referred to other issues. At the same time, the Delegation noted that the topic was not part of the five subjects forming the substantive body of the agenda, and Group B could not accept a significant imbalance in the SCP discussions created by its continued discussion. The Delegation stressed the importance of the legislative assistance provided by the Secretariat to developing countries in the field of patents for the purpose of establishing or improving patent systems in those countries. It considered that WIPO's assistance was very important in order to have a patent system function as a driving force in innovation. In its opinion, WIPO had proven to deliver useful and effective technical assistance on legislative drafting on a bilateral basis, and WIPO's website contained an impressive collection of laws that could be used as a model. As a result, the Delegation questioned whether an update to the Model Law was necessary. Noting the confirmation by the Secretariat, that a Model Law was a normative exercise, the Delegation pointed out that the Committee had agreed that the work of the SCP would not be normative. In that context, the Delegation stated that while Group B was prepared to revert to the normative mandate of the SCP and to continue that normative work, other groups did not share that interest. In its opinion, if the Committee could agree to resume normative work, the nature of the work should not be prejudiced - while a model law could be one outcome, a substantive patent law treaty could be another outcome. The Delegation reiterated that the patent law harmonization was clearly in line with the mandate of the SCP, and stated that Group B would find the discussion useful and worthy of further consideration only if the resumption of normative work addressed the harmonization of all elements of patent law, including harmonization of substantive aspects, such as examination of the applications and rights conferred by patents, without prejudging the resulting instrument so as to potentially result in a new substantive patent law treaty.

173. The Delegation of Latvia, speaking on behalf of the CEBS Group, thanked GRULAC for its proposal to review the Model Law. The Delegation was of the opinion that that proposal might shift the balance of the work program of the SCP, as the five agenda items represented a delicate balance of interests of Member States, and adding a new item would

need an in-depth discussion on the ways to regain the equilibrium. In its view, one piece of text could not reflect the various needs of countries that were supposed to benefit from it. Furthermore, the Delegation noted that it was not under the impression that the Committee had decided to take the path towards harmonization of the substantive patent law. For those reasons, the CEBS Group was not convinced of the need to engage in the discussion on the Model Law revision.

174. The Delegation of the Bahamas, speaking on behalf of GRULAC, reiterated that its proposal for the revision of the Model Law was viewed by GRULAC and by various delegations in other regions as an important exercise, since the Model Law was outdated and in need of revision. The Delegation highlighted that that exercise was not intended to lead to harmonization, and reiterated that its proposal was that the Secretariat should prepare a proposal for consideration by WIPO Member States on terms of reference and modalities that such a revision could follow. It explained that Member States would be able to intervene and participate in that process, as was the usual practice in WIPO. Since the final product would not be a binding document, the Delegation expressed its belief that its proposal did not create an imbalance in the normative work of the Committee and that it should remain on the agenda.

175. The Delegation of the United States of America supported the statements made by the Delegations of Greece on behalf of Group B and the Netherlands on behalf of the European Union and its Member States. While it had listened closely to the statements of support for the GRULAC proposal, the Delegation stated that it was not convinced that the undertaking of the revision of the Model Law was necessary. In its view, the proposal contained in document SCP/22/5 did not provide detailed reasons and data, explaining why a revision was necessary nor why the current WIPO technical assistance mechanisms were insufficient. While recognizing that the Model Law included a number of patent law elements, the Delegation was of the opinion that there was very little need for a model patent law, since most of the developing and least developed countries already had patent laws. As those patent laws were available on the WIPO website, the Delegation noted that they would serve as a valuable resource for those jurisdictions considering new or revised patent laws. In addition, the Delegation observed that the modern approach for assistance by WIPO was to provide legislative or technical assistance to Member States that requested it. The delegation pointed out that such a flexible approach was enshrined in the Development Agenda recommendations, which had been unanimously approved by all Member States and which were being mainstreamed in WIPO's substantive technical assistance activities. The Delegation noted that Recommendation 1 provided that WIPO technical assistance should be *inter alia*, development-oriented, demand-driven and transparent, taking into account the priorities and special needs of developing countries, especially LDCs, as well as the different levels of development of the Member States. As it had been noted previously by the Delegation and had been re-emphasized by the Delegation of Brazil with respect to the proposal from Spain on inventive step, the Delegation highlighted that a one-size-fits-all was contrary to the spirit of the Development Agenda and not in the best interest of the members of the Committee. The Delegation further stated that the Delegation of Brazil had gone on to point out that the discussions in WIPO should confirm such a vision that harmonized multilateral criteria for substantive patent examination were inadequate for efficient implementation of patent law. The Delegation was of the opinion that the individualized approach provided by WIPO working directly with requesting Member States was important and effective. It expressed its belief that the technical assistance provided by WIPO should continue to be demand-driven, country-need specific and should take into account the different levels of development from the individual Member States. The Delegation emphasized that the Committee saw no evidence that WIPO had been unable to meet the current demand for Member States with its existing technical assistance programs. Finally, in spite of the assertions from the regional coordinator of GRULAC, the Delegation was of

the view that a revision of the Model Law would necessitate substantive patent law harmonization as confirmed by the Secretariat during the 22<sup>nd</sup> session of the SCP. The Delegation observed that such discussion would necessarily have to include harmonization of all aspects of substantive patent law and of patent procedures, and noted that a number of delegations who had supported the proposal also had stated that they opposed any work that would lead to harmonization. The Delegation therefore stated that it failed to understand how the two positions could be reconciled. Noting that the current understanding under which the SCP had been operating was that its work should not lead to substantive patent law harmonization, the Delegation stated that in order to continue to discuss a possible revision of a Model Law, that understanding must be changed to allow for work in the SCP towards substantive patent law harmonization. The Delegation further observed that any work on harmonization could neither be limited to only certain patent law topics to the exclusion of others nor should it be limited by prejudging the nature of the results. In view of those concerns, the Delegation did not support work at WIPO or further discussions in the SCP on developing new Model Laws or on revising the existing Model Patent Law. The Delegation expressed its belief that resources would be better used if specific needs and circumstances of the individual Member States were addressed.

176. The Delegation of Brazil expressed its appreciation to the Delegation of the United States of America for referring to the Development Agenda recommendations which were useful in conducting the work on the matter. The Delegation stated that it was positive to see the development of the use of the Development Agenda by all delegations from all regions. The Delegation reiterated its vision and stated that it did not understand that the revision of the Model Law would amount to harmonization. In its opinion, it would rather provide important elements for consideration by the Member States that were interested in the matter. The Delegation considered that, since the current Model Law was from 1979, it was outdated and in need of revision.

#### AGENDA ITEM 11: FUTURE WORK

177. The Delegation of the Bahamas, speaking on behalf of GRULAC, stated that its Group would like to see a well-balanced agenda that would deal with all of the issues, and that the interest of all delegations should be taken into account. The Delegation noted that the Committee should agree upon future work, because it wanted to avoid a reduction in the number of days or meetings of the Committee to which its region attached great importance. The Delegation reiterated its proposal that future work contain analysis by the Secretariat of those exceptions and limitations that had proven effective to address development concerns, and as a second step, based on such analysis, development of a non-exhaustive manual on that topic for Member States of WIPO. In relation to exceptions and limitations, the Delegation invited other stakeholders to send comments on their experience and how those limitations and exceptions were used in their jurisdictions. The Delegation also stated that it would appreciate a collection or compilation of case law by the Secretariat on limitations and exceptions in various jurisdictions. Further, thanking the African Group for their updated patents and health proposal, the Delegation expressed its hope that it would be able to discuss that proposal at the next session as well as on matters relating to transfer of technology. With regard to the 1979 WIPO Model Law, the Delegation took note that there was certain support within the Committee that the outdated WIPO Model Law should be revised and should be brought up to standard. The Delegation reiterated the importance of the revision of the Model Law for GRULAC, especially for small island developing states. The Delegation clarified that there was no intention for harmonization. The Delegation therefore stated that GRULAC sought at least having a follow-up and continuation of discussion on that issue in the next session, and exploring ways to move forward. Although GRULAC did not understand why there were other delegations that had other views in

relation to the 1979 WIPO Model Law, the Delegation stated that the Committee should continue the discussion under the relevant agenda item. The Delegation noted that GRULAC was ready to constructively engage in finding a future work program related to a revision of the Model Law.

178. The Delegation of Latvia, speaking on behalf of the CEBS Group, noted that during the previous SCP sessions, tremendous amount of efforts and time had been dedicated to discuss the future work program of the Committee. In its view, the five agenda items accommodated the interests of all Member States in a delicate balance. As the interest of each individual Member State lay within those items, the CEBS Group encouraged other Groups to bear that in mind when engaging in discussions on the future work. The areas of interest of the CEBS Group lay in the quality of patents and on confidentiality of communications between clients and their patent advisors. The Delegation expressed its belief that it was crucial to continue the work on improving the quality of patents, and in that regard, the Delegation supported the proposals to launch a questionnaire and to study the inventive step contained in document SCP/24/3. In the area of confidentiality of communications between clients and their patent advisors, the CEBS Group supported work on a soft law approach.

179. The Delegation of Nigeria, speaking on behalf of the African Group, stated that it also supported the balanced work program. Noting its updated proposal on patents and health, the Delegation expressed its wish to have ambitious future work in the area of patents and health, which was a priority for the African Group. While the Delegation took note that many Member States might not have read the proposal very well, the Delegation emphasized that, in the area of patents and health, the African Group proposed preparation of a study by independent experts in consultation with the Secretariat of the WHO and WTO, examining the constraints to full use of patent flexibilities and impact on access to affordable medicines for public health purposes in developing countries and LDCs as one of the elements under the study. For information exchange, the African Group expressed its wish to hold a half-day information exchange that would include an invitation to the Special Rapporteur on Right to Health to present his report to the Human Rights Council, and the information exchange among the members of the SCP relating to the use of health-related flexibilities for promoting public health objectives or the challenges thereof with a view to explore issues to be examined in a future study. On transfer of technology, the African Group reiterated the three proposals that had been put forward earlier: one was on a detailed study by independent experts on the relationship between patent systems and the transfer of technology, the second one was on an updated study by the Secretariat regarding the components of sufficiency of disclosure that could limit the transfer of technology to developing countries, and the third proposal was a presentation by the Secretariat on patent-related policies and initiatives to promote the transfer and dissemination of technology for the benefit of developing and least developed countries, including the implementation of rights and obligations and understanding the use of flexibilities contained in the TRIPS Agreement. On limitations and exceptions, the African Group supported the proposal that was put forward by the Delegation of Brazil that had two elements: (i) invitation of submission by stakeholders other than Member States about their practical experiences, including obstacles and opportunities faced in using limitations and exceptions to patent rights; and (ii) compilation of court cases that involved use of limitations and exceptions to patent rights.

180. The Delegation of Ukraine, speaking on behalf of the Central Asian, Caucasus and Eastern European Countries (CACEEC), expressed its appreciation to the Chair and the Secretariat for their efforts made in seeking to move forward with the work of the Committee. The Delegation reiterated that the countries of the CACEEC Group stood ready to work on the five topics that were before the SCP for consideration: patent quality, limitations and exceptions to patent rights, patents and health, confidentiality of communications between

patent advisors and their clients and transfer of technology. Noting an important interlinkage between all of those issues, the Delegation stressed the importance of working on all of them in order to assure balanced patent system and to achieve the goals of sustainable development of the system. As regards limitations and exceptions to patent rights, the Delegation observed that the Secretariat had already prepared voluminous documentation, and the Committee already had had fruitful discussions on that topic. In its view, it was time to move forward to a new stage to look at practice that was applicable through various national mechanisms. The Delegation expressed its particular interest in the issue of compulsory licensing, and suggested that the Committee continue studying that matter, in particular looking at difficulties that might arise and barriers that might have been encountered by stakeholders and governments in trying to apply such a system. In addition, the Delegation stated that it would be very important for all Member States to have a compilation document setting out all of the limitations and exceptions to patent rights that existed throughout the world so that Member States could have a full picture of the situation. Concerning quality of patents, the Delegation was of the view that the Committee should look at the experience of different patent offices which had sought to improve the quality of their patents as well as the assessment of inventive step as suggested by the Delegation of Spain. On the topic of patents and health, the Delegation invited the Secretariat to undertake a study of practice in that area, in particular looking at Markush applications and the way they could be used. In its opinion, it was also important to look at the IP infrastructure. As regards the confidentiality between clients and their patent advisors, the Delegation considered that it was important to focus on the cross-border aspect, and to identify challenges that might be posed to the patent system in that area. On transfer of technology, the Delegation emphasized that the Committee should give more attention to the sufficiency of disclosure.

181. The Delegation of Greece, speaking on behalf of Group B, reiterated its position that future work had to be undertaken only under the five agreed agenda items of the Committee. On the issue of quality of patents, the Delegation reiterated the proposals made by members of its Group (documents SCP/18/9, SCP/19/4, SCP/20/11 Rev., SCP/23/4 and SCP/24/3). In addition, the Delegation stated that it also supported the proposal made by the Delegation of Australia on how various offices could update their quality management systems. Furthermore, the Delegation supported a sharing session on work sharing and more detailed discussions on the Global Dossier. On the issue of patents and health, Group B supported proposals in document SCP/17/11. With regard to the confidentiality of communications, the Delegation reiterated the two studies as a possible approach: (i) a study, based on a questionnaire to Member States, addressing obstacles to expand the types of professionals covered by attorney-client privilege and differences of the treatment between foreign and local attorneys, and the elimination of any such differences; (ii) a study regarding court decisions on the subject in Member States. Regarding transfer of technology, the Delegation proposed that the Secretariat review and update the existing WIPO web page by incorporating links to additional materials, documents and activities contained in the CDIP mapping document, for example, WIPO Green, WIPO Research as well as the guides relating to commercialization, evaluation and licenses. Lastly, the Delegation invited the Secretariat to make a presentation on PATENTSCOPE.

182. The Delegation of the Netherlands, speaking on behalf of the European Union and its Member States, was of the opinion that during previous SCP sessions, the Committee had spent a disproportionate amount of time on the deliberations of the future work program. With regard to the discussions on the future work of the Committee, the Delegation stressed the importance of retaining the delicate balance in the current work program. In its view, that balance was captured through the agreed scope of the five agenda items which reflected different priorities. The Delegation reiterated that inclusion of discussions on the 1979 Model Law took the Committee further away from such a balance. The Delegation was convinced

that a number of proposals on the table could be beneficial to all WIPO members, as they would enhance international cooperation and improve the knowledge on patentability requirements, thus assuring a more efficient, effective and higher patent quality system to all. In its opinion, that was the case for quality of patents where several constructive proposals had been made, such as assessment of inventive step and improvement of search and examination. The Delegation reiterated its support for the proposals of the Delegation of the United States of America on the study of work sharing, the proposal made by the Republic of Korea, the United Kingdom, and the United States of America during SCP 20, the Spanish proposal regarding studies on inventive step during SCP 19, and earlier proposals made on improving the efficiency of patent offices by Denmark and other Member States. On attorney-client privilege, the Delegation noted that the compilation of court cases with respect to client-advisor privilege would be useful to all users of the patent system. On limitations and exceptions, the Delegation considered that a sharing session between Member States on case studies would be useful. The Delegation stated that future work on patents and health should reflect a balanced approach and could, for instance, draw inspiration from a proposal made by the Delegation of the United States of America (document SCP/17/11). On confidentiality of communications between clients and their patent advisors, the Delegation was of the view that time was ripe to consider a concrete mechanism to address the recognition of foreign patent advisor privilege through a soft law approach. Finally, on transfer of technology, the Delegation remained committed to consider proposals to deepen its understanding of the impact of patent disclosure on transfer of technology and supported the update of the existing WIPO web page on technology transfer.

183. The Delegation of India, speaking in its national capacity, stated that while it understood the challenge of maintaining the delicate balance, it would ideally like to have the following proposals to be part of the future work. One, a sharing session on experience of experts from the different regions on sufficiency of disclosure assessment in examination, opposition and revocation procedures should be considered under the quality of patents, in a similar manner as the sharing session on inventive step in the previous SCP session. The Delegation stated that since those two studies had been agreed in the 20<sup>th</sup> session and presented in the 22<sup>nd</sup> session under the quality of patents, the same logic for having a sharing session on inventive step in the previous SCP session should apply to the sufficiency of disclosure. Two, the Delegation wanted to continue studying the feasibility of disclosure of INN in patent applications if the applicants knew the INN, as it had concerns on certain elements in the study. Three, the Delegation wanted a study on Markush claim formula, which should focus on the cost and benefits of patenting Markush formula claims and the huge impediments created by them towards access to the WHO essential medicines in developing countries and least developed countries, adversely affecting the access to the public healthcare system. In elaborating on that particular topic, the Delegation noted that the study on cost and benefit of patenting inventions in the Markush claim format could broadly be divided into, for example, the two issues: one was the question of inventive step, sufficiency of disclosure and industrial applicability, and the other was the scope of such claims in the context of generic/specific disclosure and the contribution of such claims to the development of essential medicines. Four, the Delegation wanted to have a study to correlate the relationship between enabling disclosure and the transfer of technology, which should include the question as to what extent the patent system was a stand-alone system that could contribute to transfer of technology without the accompanying trade secrets. The Delegation added that the role of patent systems in the context of transfer of technology should be carefully studied in connection with the sufficiency of disclosure. Five, the Delegation supported the proposal by the Delegation of Brazil, contained in documents SCP/14/7 and SCP/19/6, and suggested that the Secretariat continue developing working documents on the potential flexibilities and exceptions and limitations to patent rights which would be useful for developing consensus. The Delegation further stated that it supported the three elements in the revised proposal by the African Group on patents and health in

document SCP/24/4. Moreover, the Delegation supported the proposal by GRULAC on the revision of the Model Law, reiterating however that the proposal should not be construed to mean any harmonization of patent laws. Finally, the Delegation stated that it would like to discontinue the issue of client-attorney privilege, since that issue was of a substantive nature and could be applied by national law.

184. The Delegation of Pakistan stated that it attached great importance to the work of the SCP, and expressed its hope to see a balanced work program. The Delegation stressed that limitations and exceptions to patent rights and patents and health were its priorities. It therefore supported the proposal by the African Group regarding a study on constraints to affordability of medicines and an information exchange session. The Delegation also supported the GRULAC proposal regarding exceptions and limitations and revision of the Model Law.

185. The Delegation of Brazil aligned itself with the statement made by the Delegation of the Bahamas on behalf of GRULAC. It stressed the importance of expediting the work as described by the Delegation of the Bahamas. The Delegation explained that the proposed work was divided into two elements: (i) to invite inputs from stakeholders about the obstacles and opportunities encountered by them for the implementation of exceptions and limitations to patent rights; and (ii) to ask the Secretariat to compile a list of court decisions in relations to exceptions and limitations. In its view, those would provide Member States with analyses of exceptions and limitations that had proven to be effective to address development concerns. The Delegation noted that, on the basis of those analyses, expert studies and discussions, the Committee would be able to develop a non-exhaustive manual on that topic, which would serve as reference to the Member States of WIPO. Further, the Delegation expressed its support for the statement made by the Delegation of Nigeria on behalf of the African Group regarding future work on patents and health, including the studies by the Secretariat and a half-day information exchange. While the Delegation observed the differing views on the subject of patents, it expressed its belief that the differences were positive, since they showed various contributions from Member States, addressing the complex matter in its entirety. The Delegation shared the view that the patent system should respond to the needs of the evolving world not only for right holders but also for universities, research institutions and other stakeholders. Accordingly, the Delegation was of the opinion that governments should act accordingly to address the demands and challenges. In its opinion, harmonized patentability criteria would not be beneficial to Member States, and the SCP should refrain from advancing work to that direction. The Delegation looked forward to having all Member States showing flexibility in the future work discussions.

186. The Delegation of Iran (Islamic Republic of) stated that work program should be balanced, and expressed its hope that the voices of all sides be respected and each position be considered. Noting that patents and health was its priority, the Delegation supported the proposal made by the Delegation of Nigeria on behalf of the African Group, *inter alia*, a study by independent experts in consultation with the Secretariat, WHO and WTO to examine the constraints to and full use of patent flexibilities and impact on access to affordable medicines for public health purposes etc. having information exchange with the participation of the WHO and Co-chairs of the UN High Level Panel on Access to Medicines, and to exchange national experience regarding use of flexibilities on public health. On limitations and exceptions to patent rights, the Delegation supported the proposal made by the Delegation of Brazil on that item. As regards quality of patents, the Delegation seconded the India's proposal which was made on that item. On transfer of technology, the Delegation proposed that the Secretariat continue analyzing the relationship between sufficient disclosure and technology transfer, and prepare a study on the relationship between the patent system and international technology transfer to identify possible difficulties faced by developing countries on the promotion of technology transfer. Concerning item 10, the proposal of GRULAC, the

Delegation strongly supported that proposal, and expressed its hope that the Committee could reach consensus to have the revision of the Model Law.

187. The Delegation of China stated that it would actively participate in a future work discussion, in particular with respect to limitations and exceptions to patent rights, patents and health, and transfer of technology as well as the revision of the Model Law. As for the quality of patents and confidentiality of communications between clients and their patent advisors, the Delegation stressed that it would continue to participate in the discussions on those topics. The Delegation hoped the healthy development of the SCP.

188. The Delegation of Mexico stated that among the five topics on the SCP agenda, it was interested considerably in the work carried out on quality of patents. In particular, the Delegation supported the proposal made by the Delegation of Spain for additional studies to be carried out on the assessment of inventive step. The Delegation clarified that it did not mean that the Delegation opposed to the development of the other topics, and expressed its readiness to deal with a balanced agenda, showing its constructive attitude. As regards the limitations and exceptions to patent rights, the Delegation considered that, in general, the Committee should have exchange of experiences, which would enable Member States to understand more in depth the technical aspects involved in the topic.

189. The Delegation of the Republic of Korea supported a balanced approach, reflecting the different interests of Member States. The Delegation emphasized that it was flexible and open to discussions on various issues in the SCP that was the only international forum in the field of patents. In that context, the Delegation supported further discussion on the five standing topics. In addition, the Delegation stated that it would like to further discuss the necessity of the revision and nature of the Model Law under the category of "other issues". Among the five topics, The Delegation noted that the key interest of the Republic of Korea was further work on quality of patents. Particularly, the Delegation expressed its belief that annual conferences and a study on work sharing would be beneficial for all Member States. The Delegation therefore strongly supported the proposals on work sharing contained in documents SCP/18/9, SCP/20/11 Rev. and SCP/23/4. Furthermore, the Delegation supported the proposal by Spain in document SCP/24/3 as well as conducting a survey on quality management systems of Member States by the Secretariat.

190. After some consultations conducted by the Chair, the Committee decided 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:

(a) Exceptions and Limitations to Patent Rights

(i) The Secretariat will prepare a document, compiling information to be submitted by members and observers of the SCP, regarding their practical experiences on the effectiveness of, and challenges associated to, exceptions and limitations, in particular in addressing development issues.

(ii) A sharing session among Member States on case studies, including court cases, on those exceptions and limitations that have proven effective to address development issues and/or economic strengthening.



(b) Quality of Patents, including Opposition Systems

(i) The Secretariat will circulate a draft Questionnaire prior to SCP/25 for comments from Member States and regional patent offices, which will contain the following elements:

- how each Member State understands “quality of patents”; and
- implementation of cooperation and collaboration between patent offices in search and examination of patent applications, including experiences, their impacts, exchanging search strategies, tools to share information and capacity building needs in the area of such cooperation and collaboration.

(ii) Based on the responses to the Questionnaire, a compilation of information by the Secretariat will be submitted to SCP/26.

(iii) Based on input received from Member States and regional patent offices, the Secretariat will update the information contained in document SCP/18/4 (Opposition Systems and other Administrative Revocation and Invalidation Mechanisms), and publish the information on the SCP electronic forum website in more accessible and user-friendly format.

(iv) Continuation of a sharing session on examples and cases relating to assessment of inventive step, including, but not limited to, the topics suggested in document SCP/24/3, paragraph 8.

(c) Patents and Health

(i) A sharing session among Member States on national experiences relating to use of health-related patent flexibilities for promoting public health objectives or the challenges thereof with a view to explore the issues to be examined in a study to be submitted to SCP/26.

(ii) The study to be submitted to SCP/26 will be prepared by the Secretariat, consulting with independent experts, the WHO and the WTO, and will examine the constraints faced by developing countries and LDCs in making full use of patent flexibilities and their impacts on the access to affordable especially essential medicines for public health purposes in developing countries and least developed countries (LDCs).

(iii) Further discussion on the feasibility study on the disclosure of International Nonproprietary Names (INN) in patent applications and patents (document SCP/21/9), specifically where the INN is known to applicants at the time of filing. Members and regional patent offices are invited to make presentations in order to clarify the issues and their concerns. The Secretariat is invited to make a presentation on the PATENTSCOPE Chemsearch which facilitates patent search using the INN.

(d) Confidentiality of Communications between Clients and Their Patent Advisors

Based on the information received from members and observers of the SCP, the Secretariat will prepare a compilation of court cases with respect to aspects of client-patent advisor privilege including limitations or difficulties encountered.

(e) Transfer of Technology

- (i) A sharing session on the relationship between patent systems and transfer of technology as well as examples and cases presented by experts from different regions with a view to deepening the understanding of the impact of sufficiency of disclosure on transfer of technology.
- (ii) The Secretariat will update the WIPO web page on transfer of technology.

AGENDA ITEM 12: SUMMARY BY THE CHAIR

191. The Chair introduced the Summary by the Chair (document SCP/24/5).

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

193. 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 by the SCP at its fourth session (see document SCP/4/6, paragraph 11), which provided for the members of the SCP to comment on the draft report made available on the SCP Electronic Forum. The Committee would then be invited to adopt the draft report, including the comments received, at its following session.

AGENDA ITEM 13: CLOSING OF THE SESSION

194. The Delegation of India, speaking on behalf of the Asia and Pacific Group, expressed its delight that all the regional groups had been able to build consensus and agree on the future work. The Delegation stated that the future work that had emerged after a series of negotiations looked balanced and contained the issues which were very important for most of the members of the Committee. Recalling the long evening during the previous session where the Committee had not been able to reach a consensus, the Delegation noted that the effort made at that time had had a compounding effect on the positive outcome of SCP/24. The Delegation further expressed its special gratitude to the Chair for guiding the Committee through the process of negotiations and creating positive vibrations in the informal regional group meetings. The Delegation also expressed appreciation to be put on record for various sincere hard work by the Secretariat and the interpreters, and above all congratulated all the delegates. The Delegation concluded by stating that the spirit of multilateralism had prevailed and created a positive spirit. The Delegation was hopeful that this would have a spillover effect in the forthcoming meetings of other sessions of other Committees.

195. The Delegation of the Bahamas, speaking on behalf of GRULAC, thanked the Chair, the Secretariat, the interpreters, the regional group coordinators and all the delegates for the excellent result. The Delegation expressed its appreciation to all, since it was its last day as a GRULAC coordinator, which had been an enriching, challenging and rewarding experience.

196. The Delegation of Latvia, speaking on behalf of CEBS thanked the Chair for skillful guidance through the work of the Committee, and expressed its appreciation to all regional groups for their openness and flexibility, which had led the Committee to find an agreement on the future work.

197. The Delegation of Nigeria, speaking on behalf of the African Group, thanked the Chair and the Secretariat, all Member States and all stakeholders who played a role in ensuring that the Committee adopted a future work program for the SCP. The Delegation expressed its belief that that was a splendid result for the Committee, and leadership of the Chair in that discussion had been instrumental. While welcoming the work program that had been adopted, the Delegation also encouraged that the next work program of the Committee should be more ambitious in promoting disclosure and transparency in the patent system, promoting technology transfer, concretely tackling the question of patents and health as it was critical to human life and development, and designing a path forward for the question on exceptions and limitations in a way that Member States would be able to use the benefits of those systems and flexibilities.

198. The Delegation of Greece, speaking on behalf of Group B stated that the Committee had a good outcome, while it had spent a disproportionate amount of time on future work deliberations. In its view there was a delicate balance in the future work program.

199. The Delegation of the Netherlands, speaking on behalf of the European Union and its Member States thanked the Chair for her guidance and efforts in identifying a compromised solution in order to achieve consensus on future work, as well as the Secretariat for the support that it had provided during the week, as well as the interpreters for their hard work. The Delegation of the European Union and its Member States welcomed the agreement on future work and expressed the opinion that it represented a reflection of regional interest and the spirit of compromise that should be the hallmark of the Committee's work. The Delegation noted that, in that spirit, it was looking forward to the following sessions of the Committee. The Delegate also informed the Committee that that was the last meeting where the Delegation was representing the Presidency of the Council of the European Union and that it would be an honor and pleasure to hand over the baton to the Delegation of the Slovak Republic.

200. The Delegation of China thanked the Chair and the Secretariat, and acknowledged that thanks to her guidance and help, the Committee had been able to strengthen mutual understanding and managed to achieve very good results during the session.

201. The Delegation of Iran (Islamic Republic of) thanked the Chair and the Secretariat for the hard work and efforts, as well as all delegations for their flexibilities and constructive spirit during the meeting. The Delegation expressed its satisfaction to the future work, which was balanced and a good basis for upcoming session of the SCP.

202. The Delegation of Brazil thanked the Chair for hard work and firm leadership that led the Committee to reach agreement on the work program on the SCP. The Delegation also thanked the Secretariat and interpreters. The Delegation observed that it was a very balanced work program, and that all delegations had shown a lot of flexibility in agreeing to it. The Delegation was looking forward to continuing work on exceptions and limitations with respect to which Brazil had suggested two items for further discussion.

203. The Delegation of Indonesia thanked the Chair for her leadership and guidance in the meeting, especially during the informal meeting. The Delegation acknowledged that although it was a very difficult session, the Committee could find a balance and flexibility from many delegations. The Delegation also thanked the Secretariat, as well as the interpreters. The Delegation welcomed the future work and expressed its belief that there were many issues the Committee should work hand in hand together, through which the Committee could find many solutions to many pending issues. The Delegation further highlighted the importance of the exceptions and limitations, the disclosure and transparency

to increase the quality of patents, patents and health especially in the implementation of the SDGs and the transfer of technology.

204. The Delegation of India understood the challenges of maintaining a delicate balance, addressing all the concerns of member countries and arriving at a balance for the work of the next session SCP. The Delegation expressed its appreciation for the spirit of flexibility demonstrated by all the regional coordinators and Member States towards arriving at a concrete work for the next session.

205. The Deputy Director General, speaking on behalf of the Director General and all of the members of the Secretariat, expressed his genuine delight by the success of the meeting, and stated that the Secretariat would carry out the program of work that the Committee had laid out for the Secretariat. The Deputy Director General on behalf of the Director General and the Secretariat expressed their sincere appreciation to the Chair, who had led the Committee through three sessions.

206. The Delegation of Mexico thanked the Chair for her efforts, work and leadership, which had led to the agreement on the future work. It also thanked the Secretariat for their work. The Delegation stated that the agenda of the SCP addressed cross-cutting issues in the patent system in general, and expressed its interest in participating in the subsequent session by presenting concrete examples and cases related to the inventive step and on the topic of patents and health related to the INN.

207. The Delegation of Pakistan thanked everybody for a productive outcome, and expressed its belief that that was a success of multilateralism. The Delegation hoped to see such constructive experience continue.

208. The Chair reiterated that it was the spirit of multilateralism that had prevailed and that the Committee had shown much flexibility and maturity. The Chair hoped that the subsequent SCP session would be fruitful, and encouraged the delegations to come with input in sharing sessions and to show the country's experiences and case law. The Chair closed the session.

*209. The Committee is invited to adopt this Draft Report.*

[Annex follows]

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