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Standing Committee on the Law of Patents

Twenty-Third Session
Geneva, November 30 to December 4, 2015

DRAFT REPORT

prepared by the Secretariat

INTRODUCTION

1. The Standing Committee on the Law of Patents ("the Committee" or "the SCP") held its twenty-third session in Geneva from November 30 to December 4, 2015.

2. The following States members of WIPO and/or the Paris Union were represented: Afghanistan, Algeria, Argentina, Australia, Austria, Bahamas, Brazil, Cameroon, Chile, China, Colombia, Costa Rica, Côte d'Ivoire, Croatia, Czech Republic, Democratic Republic of the Congo, Denmark, Dominican Republic, El Salvador, Estonia, Finland, France, Georgia, Germany, Ghana, Greece, Holy See, Honduras, Hungary, India, Iran (Islamic Republic of), Ireland, Italy, Japan, Kenya, Lebanon, Libya, Lithuania, Luxembourg, Malaysia, Morocco, Mexico, Monaco, Montenegro, Mozambique, Myanmar, Nepal, Nicaragua, Nigeria, Norway, Pakistan, Paraguay, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Saudi Arabia, Senegal, Singapore, South Africa, Spain, Sri Lanka, Sudan, Sweden, Switzerland, Tajikistan, Thailand, Trinidad and Tobago, Turkey, Ukraine, United Kingdom, United States of America, Viet Nam (77).

3. The Representative of Palestine took part in the meeting in an observer capacity.

4. Representatives of the following intergovernmental organizations took part in the meeting in an observer capacity: the African Regional Intellectual Property Organization (ARIPO), the African Union (AU), the Eurasian Patent Organization (EAPO), the European Union (EU), the Patent Office of the Cooperation Council for the Arab States of the Gulf

(GCC Patent Office), the South Centre (SC), United Nations (UN), and the World Trade Organization (WTO) (10).

5. Representatives of the following non-governmental organizations took part in the meeting in an observer capacity: Asian Patent Attorneys Association (APAA), European Law Students' Association (ELSA International), International Association for the Protection of Intellectual Property (AIPPI), Centre for International Intellectual Property Studies (CEIPI), International Center for Trade and Sustainable Development (ICTSD), International Chamber of Commerce (ICC), Chartered Institute of Patent Attorneys (CIPA), Actors, Interpreting Artists Committee (CSAI), CropLife International (CROPLIFE), International Federation of Intellectual Property Attorneys (FICPI), International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Innovation Insights, Institute of Professional Representatives Before the European Patent Office (EPI), Knowledge Ecology International, Inc. (KEI), Médecins Sans Frontières (MSF), Medicines Patent Pool Foundation (MPP), and Third World Network Berhad (TWN). (17).

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

7. The following documents prepared by the Secretariat had been submitted to the SCP prior to the session: “Draft Report” (SCP/22/7 Prov. 2); “Seminar on the Relationship between Patent Systems and the Availability of Medicines in Developing Countries and Least Developed Countries” (SCP/23/INF/2 Rev.); “Draft Agenda” (SCP/23/1 Prov.); “Report on The International Patent System: Certain Aspects of National/Regional Patent Laws” (SCP/23/2); “Member States’ Experiences and Case Studies on the Effectiveness of Exceptions and Limitations” (SCP/23/3); and “Proposal by the Delegation of the United States of America on the Study of Worksharing” (SCP/23/4)

8. 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.); “Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents” (SCP/21/9); “Study on the Sufficiency of Disclosure” (SCP/22/4); and “Proposal by the Group of Latin American and Caribbean Countries (GRULAC)” (SCP/22/5); “Seminar on the Relationship between Patent Systems and the Availability of Medicines in Developing Countries and Least Developed Countries” (SCP/23/INF/2 Rev.).

9. 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

10. The twenty-third session of the Standing Committee on the Law of Patents (SCP) was opened by the Deputy Director General, Mr. John Sandage, who welcomed the participants. The session was chaired by Mrs. Bucura Ionescu (Romania). Mr. Marco Aleman (WIPO) acted as Secretary.

AGENDA ITEM 2: ADOPTION OF THE AGENDA

11. The SCP adopted the draft agenda (document SCP/23/1 Prov.) with a modification to the document number under agenda item 3 and inclusion of two new documents under agenda items 6 and 7.

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

12. The Committee adopted the draft report of its twenty-second session (document SCP/22/7/Prov.) as proposed.

GENERAL DECLARATIONS

13. The Delegation of Greece, speaking on behalf of Group B, strongly believed that the SCP, as a multilateral forum in the field of patents, had a responsibility to provide a venue for technical discussion and issues of substantive patent law in a manner responding to the evolving real world. In that context, the Delegation was pleased to see sharing sessions on experiences of experts from different regions on inventive step assessment in examination, opposition and revocation procedures, under the agenda item on quality of patents. The Delegation considered that in order to properly understand what a patent was and how patents might have been granted, it was critical to have a correct and deep understanding of those core patentability requirements. The Delegation noted that the studies prepared by the Secretariat and presented during the last session of the Committee were a very good basis for the discussion to deepen the SCP understanding in that regard. The Delegation considered important to continue that kind of substantive and technical work in order to let the SCP continue to be a central multilateral forum where experts gathered and contributed to the development of the patent system. The Delegation further believed that useful information could be obtained by the Seminar on the relationship between patent system and, *inter alia*, the challenges related to the availability of medicines in Developing Countries and Least Developed Countries, including on the promotion of innovation and fostering of the requisite technology transfer to facilitate access to generic and patented medicines in developing and least developed countries. In that regard, the Delegation commended the Secretariat for its efforts to select panelists covering all viewpoints. Finally, the Delegation welcomed the sharing session among Member States concerning confidentiality protection applied to different types of patent professionals, international and foreign patent advisors. Group B underlined the importance of cross-border aspects on that issue and considered that predictability in that context was one of the important elements of enabling business environment. The Delegation was looking forward to discussion on how the Committee could respond to such demand from the business world. The Delegation further expressed

its wish to welcome presentations by members of its Group under the respective agenda items. The Delegation stated that it was regrettable that there were only those possibilities of experience sharing and not any more items for substantive discussion at the twenty-third session because of the general and long disagreement on the future work of the Committee. Group B declared itself ready to engage constructively in the discussion on the future work. With respect to quality of patents, including opposition systems, Group B expected that the Committee could further work on the basis of what would be established during the session in the light of substantial contribution to the real world of patents. The Delegation believed, as it had previously been underlined by Group B, that international work sharing and collaboration was one of the critical issues. The Delegation noted that it was expected that the Committee would agree to concrete work for the future, which could substantively contribute to that perspective. Referring to the Chair's opening remark stating that the program of the Committee mirrored the efforts of the last session to find a balance of different regional interests, the Delegation expressed its regret that current discussions did not reflect that balance. The Delegation stated that Group B stood ready to engage in discussions on other topics of the Committee from the perspective of future work with a constructive and forward looking spirit.

14. The Delegation of Romania, speaking on behalf of the Central European and Baltic States (CEBS), expressed its full support and cooperation in the advancement of the work of the SCP. The Delegation thanked the Secretariat for its contribution to the organization of the session and welcomed events to be organized during that session in the format of a seminar and sharing sessions. The Delegation considered that those events provided the delegates with the opportunities to discuss both core patent issues and patent related issues. The Delegation hoped that further discussions would facilitate the Committee decisions on the focus of its work and would allow it to prepare the ground for the harmonization of substantive patent laws. The CEBS Group attached great importance to the topic of quality of patents, including opposition systems, as a core topic for consideration at the SCP. The Delegation noted that the very objectives of the patent system of stimulating innovation and dissemination of its results could be undermined by low quality patents. The Delegation hoped to see progress on that subject, and reiterated its support for the proposal to launch a questionnaire on quality as presented in concrete terms by the Delegations of Canada, the United Kingdom, Denmark and the United States of America. The Delegation also expressed its interest in the topic of confidentiality of communication between clients and their patent advisors. The Delegation believed that addressing challenges faced by users of the patent system at the international level should be part of the Committee's tasks. The Delegation considered that a soft law approach in that area would benefit both holders and users of IP rights. With regard to exceptions and limitations, the Delegation thanked the Secretariat for the compilation prepared on Member States' experiences and case studies on the effectiveness of exceptions and limitations, in particular, in addressing development issues. The Delegation further underlined that a deeper understanding of those issues and their application was only possible if they were addressed in conjunction with the topic of patentable invention. The Delegation was looking forward to discussing other topics such as patents and health, transfer of technology and the proposal by GRULAC to revise the 1979 WIPO Model Law for Developing Countries on Inventions. The Delegation expressed its wish to reiterate the commitment of the CEBS Group to engage constructively in the SCP debates in order to have a productive session.

15. The Delegation of Nigeria, speaking on behalf of the African Group, took the opportunity to underscore the instrumental role of the patent system in facilitating knowledge and fostering innovation for the broader human and societal development. The Delegation believed that, in order to meet that objective, it was important that the work of the SCP, balanced the needs and interests of diverse stakeholders in the international patent landscape, including developing and least developed countries, in a manner that aligned

with the Development Agenda recommendations. The Delegation noted that the agenda before the Committee held the promise towards providing more insight and resourceful information on the five, non-exhaustive, list of issues under the SCP's consideration. The Delegation placed particular emphasis on the crucial topic of patents and health. The Delegation looked forward to the half-day seminar that would discuss, *inter alia*, the challenges encountered by developing and least developed countries in accessing affordable medicines, innovation and technology transfer in the area of patents and health. The Delegation hoped that the seminar would shed light on resourceful and functional ways forward in that sphere and that the SCP could advance towards undertaking a study dedicated to assessing the benefits of mandatory disclosure of International Nonproprietary Names (INN) in patent applications. The African Group thanked the Secretariat for having engaged the time and services of four professional and renowned panelists in the field of patents and health in relation to the seminar. The Delegation expressed its confidence in their expertise and had no doubt about their knowledge that would be brought to the seminar. The African Group, however, underscored the need for balance in the representation of future panelists. The African Group was of the opinion that, being the theme of the seminar principally focused on challenges of developing and least developed countries in accessing medicines, innovation and technology transfer, amongst others, it would have been more instructive to have included, amongst the panelists, representatives from developing and least developed countries to share their perspectives from their home advantage. Nevertheless, the Delegation looked forward to the seminar. The Delegation thanked the Secretariat for the preparation of the compilation contained in document SCP/23/3, which provided Member States' experiences and case studies on the effectiveness of exceptions and limitations. The Delegation hoped that the Committee could advance its work in that field in a more robust manner. The Delegation further thanked the Secretariat for providing an updated report on the international patent system. The Delegation considered that disclosure was the bedrock of the patent system. In its view, those practices within the patent system that enabled avoidance of full disclosure of all necessary information to ensure integrity, high quality patents and full dissemination of knowledge in exchange of exclusive patent rights, were the departure from the intentional *quid pro quo* nature of the patent system and the international IP structure. The Delegation observed that being the transfer of technology possible on lying gaps in the international patent system that permitted the lack of disclosure in such a manner that impeded access to the teaching function which the international IP system was designed to serve. The Delegation further hoped that the twenty-third session of the SCP could discuss more concrete ways to address adherence to such *quid pro quo* nature of the international IP system, which was enjoyment of exclusive rights in exchange for fostering knowledge, innovation and creativity. The African Group looked forward to constructive discussions on quality of patents, including opposition systems and confidentiality of communication between clients and their patent advisors. The Delegation had no doubt that the sharing sessions on both agenda items would provide helpful information that would aid discussions on both issues. However, with a view to a balanced and comparative analysis, the Delegation believed that the Secretariat should undertake studies on opposition systems as regards the criterion of inventive step and insufficiency of disclosure as useful information to guide the Committee's work in that area. The African Group took note of the proposal of the United States of America on work-sharing and expressed its wish to provide further comment after the presentation of that proposal. The African Group viewed positively the proposal by GRULAC on the revision of the WIPO Model Law for Developing Countries on Inventions, and hoped that the SCP could hold and enhance discussion on that proposal.

16. The Delegation of Brazil, speaking on behalf of the Group of Latin American and Caribbean Countries (GRULAC), observed that the agenda was interesting and that, in particular, under agenda item 5, exceptions and limitations to patent rights, a report on the compilation of Member States' experiences and case studies on the effectiveness of

exceptions and limitations would be presented. The Delegation recalled that, as a result of the discussions held since SCP/14, it had requested that the Secretariat prepare an analysis of those exceptions and limitations that had proven effective to address development concerns. Similarly, based on that analysis, the Delegation had proposed the development of a non-exhaustive manual on that topic as a reference to Member States of WIPO. Further, the Delegation stated that under agenda item 7, the GRULAC was interested in discussions on patents and health and in particular in the half-day seminar on the relationship between patent systems and, *inter alia*, challenges related to availability of medicines in developing countries and least developed countries, including on the promotion of innovation and fostering of the requisite technology transfer to facilitate access to generic and patented medicines in those countries. The Delegation looked forward to listening to the experts' views on that matter, but believed that a more representative list of panelists, with at least one expert from a developing country, would have been more conducive to a balanced result in the seminar. The Delegation expressed its hope that the panelists would reflect the realities of developing countries. The Delegation further noted that the GRULAC was also interested in new joint efforts related to agenda item 9, on the discussion of the topic of technology transfer. Regarding the agenda item 10, the GRULAC recalled its statements made during the previous three SCP meetings on the need for a complete revision of the 1979 WIPO Model Law for Developing Countries on Inventions. The Delegation expressed its wish to continue the discussion on the revision of the WIPO Model Law. In its opinion, such a document should take into account international legal frameworks, such as the WTO Agreements, and the WIPO Development Agenda recommendations. The Delegation urged all delegates to go through the document a few days before the start of the discussion on that topic and recognize that it was outdated and did not serve the intended purpose. The Delegation considered that such an academic exercise could have shed light into the way WIPO implemented legislative technical assistance.

17. The Delegation of India, speaking on behalf of the Asia and Pacific Group, expressed its appreciation for the hard work of the Secretariat in preparation of the meeting, including organizing informal consultations among regional coordinators. The Delegation believed that the work of the Committee was critical in creating equilibrium between the rights of patent owners and the larger public interest, particularly in the area of public health, transfer of technology and patent related flexibilities. The Delegation considered that those flexibilities could be critical for policymakers to craft and amend domestic patent laws in accordance with national development priorities and socio-economic realities. The Asia and Pacific Group looked forward to listening to the views of the experts at the seminar on patent systems and their relationship with the availability of medicines in developing countries and least developed countries. The Delegation observed that an optimal balance between patent rights and the right to health was essential and that the different level of social, economic and technological development among Member States could not be ignored. The Delegation believed that the TRIPS flexibilities took into consideration those differences and played an important role in achieving the requisite balance, since they allowed governments, especially in countries with limited resources, the necessary policy space to meet the health needs and at the same time foster innovation. The Delegation expressed its eagerness to participate and contribute towards a productive discussion on that important developmental issue. The Delegation hoped that exchange of Member States' experiences and case studies on the effectiveness of exceptions and limitations in the twenty-third session of the Committee would provide guidance to improve and further enhance the efficiency of the current patent system in a manner sensitive to the diverse needs. The Delegation requested the Secretariat to continue updating the study and also invited 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 exceptions and limitations to patent rights under their relevant national legislations. The Asia and Pacific Group further requested the Secretariat to revise the feasibility study and address the

questions about feasibility of disclosure of INNs in patent applications, specifically where the INN was known to the applicant. The Delegation supported the proposal of GRULAC on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions. The Delegation stated that the revision of the aforementioned Model Law should emphasize legislative and policy options for Member States. The Delegation believed that that agenda item by no means was at a lesser level of priority even when it was described as "Other Items" and that it had should be given equal importance as the other substantive agenda items. The Delegation specified that members of the Group would intervene in their national capacity on specific agenda items. The Delegation looked forward to a productive session under the Chair's able guidance.

18. The Delegation of China believed that SCP was an important platform for discussing the international patent system. It expressed its hope that all Member States would make joint effort 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 expressed its appreciation for the efforts made by different parties to continuously ensure the steady and sustainable development of the SCP. The Delegation considered that Member States were able to better understand and learn from one another by extensive and in-depth information sharing and experience exchange at that stage. Further, the Delegation stated that the fact that each Member State had different national conditions, priorities and agenda and was going through various stages of development called for all Member States to work together with greater flexibility and to the greatest extent accommodate different interests so as to move the work of SCP forward. The Delegation expressed its hope that the SCP could help patent offices improve their capacity building in order to provide better services to patent users in different regions, and expressed its commitment to constructively engage in discussions as before.

19. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States, was pleased to see two sharing sessions on the program: the first on experience of experts from different regions on inventive step assessment in examination, opposition and revocation procedures, and the second on confidentiality protection applied to different types of patent professionals and to national and foreign patent advisors. The Delegation was confident that those sharing sessions would provide useful insights and a valuable basis for further progress in that area. In that respect, the Delegation welcomed the contributions that the Delegations of Spain and the United Kingdom would make at the sharing session. The Delegation noted that in relation to the topic 'quality of patents', it was agreed at the twenty-second session of the SCP that the Secretariat would have improved the webpage on work sharing and collaborative activities. The Delegation expressed its gratitude if the Secretariat could provide the Committee with a presentation during its twenty-third session on the improved features of the website. The Delegation was also looking forward to the seminar on patents and health. The Delegation hoped that the seminar would have provided useful information in relation to challenges and opportunities faced. With regard to discussions on the future work of the Committee, the Delegation believed that it was important to retain the delicate balance of different regional priorities in the current work program. The Delegation believed that, in that light, the inclusion of discussions on the 1979 Model Law would have taken the SCP further away from a balanced work program. The Delegation underscored the areas of interest of the European Union and its Member States. First, on the topic of quality of patents, the Delegation observed that several proposals had been made by the Delegations of Canada and the United Kingdom, Denmark, the United States of America, and by the Delegation of Spain, as endorsed by all other Member States of the European Union. The Delegation remained in favor of launching a questionnaire containing the elements of all the proposals by the Delegations of Canada and the United Kingdom, Denmark and the United States of America, as contained in document SCP/18/9. The Delegation believed that work in that area could

be beneficial to all WIPO members, as it could enhance international cooperation, and ensure a more efficient, effective, and higher quality patent system to all. Second, in relation to the client-patent attorney privilege, the Delegation hoped that the sharing session would provide valuable input in taking that work forward, as convergence of differing provisions would be of benefit to users of the patent system. The European Union and its Member States remained committed to discussing key aspects of substantive patent law, with the aim of international patent law harmonization. Finally, the Delegation stated that the European Union under its enhanced cooperation procedure had made significant advances on the European Patent with unitary effect. The Delegation explained that the unitary patent provided for a simple and affordable patent protection and that it would help to attract and retain innovation, talent and investment. The Delegation specified that the unitary patent would come into effect once the necessary ratifications had taken place. The European Union and its Member States reiterated their dedication to the work of the Committee and looked forward to a constructive session.

20. The Delegation of the Republic of Korea supported the statement made by the Delegation of India on behalf of the Asia and Pacific Group and emphasized the importance of the work of the SCP as the only multilateral forum in the field of patents. The Delegation considered that the Committee should provide substantive and technical discussions to improve patent systems. The Delegation firmly believed that enhancing quality of patents was very important to improve the patent systems, and was the core topic of the SCP. The Delegation observed that high quality of patents was essential to avoid unnecessary socio-economic costs and to achieve the goal of patent systems in promoting innovation and economic development. The Delegation reiterated its position that the Committee should study and exchange the views of Member States on work-sharing, since the Delegation believed it was one of the most effective solutions to achieve tangible outputs in enhancing the quality of patents. The Delegation also attached great importance on other issues, such as the client-patent advisor privilege, transfer of technology and a revision of the WIPO Model Law. The Delegation expressed its eagerness to participate and contribute towards a productive discussion on those important issues and expected fruitful results from the session. The Delegation further expressed its wish to participate in a constructive way to the discussion on all items under the agenda.

21. The Delegation of Iran (Islamic Republic of) endorsed 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 Member States. The Delegation considered that the new 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 provided the opportunity for fruitful exchange of views on a wide range of topics related to patents. The Delegation observed that all agenda items before the SCP should be treated on an equal footing. It noted that the issue of patents and health, including access to essential medicines with affordable price, was an important issue for developing countries. The Delegation expected that the Committee would recognize the

practical ways to respond to the challenges caused by patent systems in the field of health. The Delegation noted that the full use of flexibilities accorded under international agreements was another issue which should be addressed in the SCP. The Delegation expressed its support for the proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group in respect of a work program on patents and health, contained in document SCP/16/7. The Delegation stated that it was eager to listen to the views of the experts at the seminar on patent systems and its relationship with the availability of medicines in developing countries and LDCs. Regarding the topic of quality of patents, the Delegation reiterated that a precise definition of the concept of patent quality was highly necessary for further discussions in the SCP on that issue. The Delegation considered that, in the absence of common understanding on the meaning of that concept, it would be difficult to fully comprehend the proposals on that topic. The Delegation also supported further discussions on opposition systems and the preparation of a compilation of models on opposition and administrative revocation systems. The Delegation further sought a study on different thresholds in national patent legislations for sufficiency of disclosure as a problem linked to patent quality. The Delegation pointed out, that the issue of client-attorney privilege was a matter of procedure that fell outside the scope of the application of patent law. The Delegation believed that, as a matter of fact, it fell within the purview of private law and the regulation of professional services, and hence fell outside of the mandate of the SCP and WIPO. Starting from that assumption, the Delegation did not support any suggestion for norm-setting or further substantive work on that issue. The Delegation finally believed that it was time to revise the 1979 WIPO Model Law for Developing Countries on Inventions and stated that such revision should be development-oriented, be in line with the Development Agenda recommendations and provide legislative and policy options for developing countries to utilize the flexibilities envisaged in the TRIPS Agreement. The Delegation therefore supported the proposal submitted by the GRULAC on the revision of the Model Law.

22. The Delegation of Pakistan stated that the work of the Committee was critical in balancing the rights of patent owners and public interest, particularly in the area of public health, technology transfer and patent related flexibilities. The Delegation considered that it was essential to find the right balance between patent rights and public welfare, taking into account the differences in the social, economic and technological development of Member States as well as the TRIPS flexibilities, respect for intellectual property laws and the needs of all Member States. The Delegation noted the compilation of Member States' experiences and case studies on the effectiveness of exceptions and limitations, particularly in addressing development issues, contained in document SCP/23/3. The Delegation noted that the small sample of case studies highlighted the limited practical experience of using the statutory exceptions or limitations in advancing specific policy objectives. The Delegation requested the Secretariat to update the study and also invite submissions from civil society organizations, research institutions and local industries in developing countries about their practical experiences on that matter. The Delegation pointed out that the global public health scenario had become increasingly complex with the emergence of new diseases and epidemics and, as an example, observed that the recent Ebola outbreak and current Hepatitis C situation had posed grave challenges to both developed and developing countries. The Delegation stated that the revised WHO model list of essential medicines included new medicines for treating Hepatitis C, cancer and drug resistant tuberculosis, most of which were unaffordable, especially to populations in developing countries. The Delegation believed that the right to health was a universally recognized basic human right; however, it was of the opinion that practical enjoyment of that right was increasingly impeded by a large number of people in countries all around the world due to lack of affordable medicines. The Delegation considered that sharing national experiences on the use of health-related patent flexibilities and the challenges to their use was of crucial significance to allow WIPO to better assist Member States to adapt their national laws by optimally utilizing

patent flexibilities in accordance with the public health needs and in compliance with their international obligations. The Delegation supported the African Group and the Development Agenda Group's proposal contained in document SCP16/7 and SCP/16/7 Corr. The Delegation hoped that the seminar on the relationship between patent systems and challenges related to availability of medicines in developing countries and LDCs should provide focused insight about specific challenges to availability of medicines in those countries arising from the patent system, impact of patent systems on the facilitation of innovation on medicines for the treatment of diseases predominantly prevalent 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 supported the GRULAC proposal regarding the revision of the 1979 WIPO Model Law for Developing Countries on Inventions contained in document SCP22/5. The Delegation believed such revision would enable WIPO's technical and legislative assistance to better focus on full utilization of the available flexibilities which evolved after 1979.

23. The Delegation of India observed that the 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 the issuance of frivolous patents that added unnecessary costs and confer unwarranted market distortions. The Delegation was of the opinion that issuance of valid patents to encourage inventions, disclosure, and economic development should be the final objective of patent systems. The Delegation believed that development of patent systems and use of patent rights should operate in a balanced and objective manner and should meet the goal of providing the protection for moral and material interests of inventors, and at the same time, should assist the development aspects of the society. The Delegation reiterated that harmonizing IP laws across countries with asymmetric distribution of IP assets served the interests of rent seekers who were predominantly in developed countries rather than that of the public in developing countries. The Delegation restated its belief that policy flexibility was a *sine qua non* if enlightened societies were to ensure that the intended beneficiaries, the public in each country, would not be worse off as a result of such protection. The Delegation attached great importance to the work of the SCP and noted the work program for the current session, in which important issues such as exceptions and limitations to patent rights, patents and health and transfer of technology were retained in the agenda. The Delegation reaffirmed its views expressed in the last SCP session, in particular, on the issues related to exceptions and limitations, quality of patents, patents and health, client-attorney privileges and transfer of technology. The Delegation believed that in the absence of an obligation on technology transfer, asymmetric intellectual property rent flows would become a permanent feature and the benefits of IP protection would forever eluded consumers in developing countries. The Delegation stated that disclosure in a patent should have divulged the technological information in such a manner, so that a skilled person could translate the information into commercial reality without undue burden of experimentation or further innovation. The Delegation considered disclosure was the *quid pro quo* of the patent system. The Delegation pointed out that, unfortunately, transfer of technologies almost always required transfer of accompanying trade secrets as well, thereby casting doubt about the true efficacy of patents as a stand-alone system for technology transfer and knowledge sharing. The Delegation took the opportunity to recall the objectives of the TRIPS Agreement and its mandate that protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. The Delegation took note of document SCP/22/4 concerning a study on the sufficiency of disclosure under the transfer of technology and expressed the wish to share its view in details on that document during the discussion. In the context of flexibilities of the system and exceptions and limitations, the Delegation recalled the Synthesis Report of the

Secretary General of the United Nations, The Road to Dignity by 2030: On the Post-2015 Agenda, where it was mandated 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*". Furthermore, the Delegation mentioned its mandate to ensure that the global intellectual property regimes and the application of the TRIPS flexibilities were fully consistent with and contributed to the goals of sustainable development. The Delegation appreciated the painstaking work undertaken by the Secretariat in collecting information on exceptions and limitations, but at the same time, it reiterated that it was time that such information was properly analyzed to distil out the contribution of exceptions and limitations to the development. The Delegation reaffirmed its full support to the work program as proposed by the Delegation of Brazil through document SCP/19/6. While the Committee discussed the issues of patents and health, the Delegation recalled the Resolution adopted by the General Assembly of the United Nations on September 25, 2015 "Transforming Our World: the 2030 Agenda for Sustainable Development" and its Goal 3b, that was: "Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all". The Delegation further recalled the objective of the TRIPS Agreement contained 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 reiterated its appreciation to the Secretariat for their work related to patents and health and further took the opportunity to reiterate its support to the proposal submitted by the African Group and the DAG contained in document SCP/16/7. The Delegation was keen to take part in the discussion on disclosure of INN. The Delegation believed that those issues had deep implications in public health and availability of essential medicines. Concerning feasibility study on the disclosure of INN in patent applications and/or patents and on the issue of a study related to Markush formulae, the Delegation reiterated the huge impediment created by them in healthcare industry by creating mysterious cobweb of unreal compounds to be discovered in future thus stifling innovations in the field of pharmaceutical technology. On the issue of quality of patents, the Delegation took note of the sharing session on experiences of experts from different regions on inventive step assessment in examination, opposition and revocation procedures; however, the Delegation reiterated that the study on inventive step and the sharing session must not be construed as a tool for harmonization of the substantive issues of patents, including the inventive step criterion. The Delegation reiterated its view that every Member State retained its right to define the inventive step in its own way to utilize the patent system to maximize the benefit to the inventors as well as to the members of the society. As far as quality of patents and related documents were concerned, the Delegation reiterated that the quality of examination needed to improve substantially in conformity with policy objectives of a country and the sharing of work of other patent offices was not the remedy for improving the quality of patents. The Delegation rather believed that the sharing of work of other offices could weaken examination processes and capability of patent offices in developing countries. Consequently, the Delegation was of the opinion that steps should be taken to build capacity among patent offices of developing countries for enabling them to perform their quasi-judicial functions, according to their national laws, in the best manner possible. Therefore, the Delegation stressed that work sharing should not become an area for norm-setting in future. On the issue of client-attorney privileges, the Delegation reaffirmed its views that the issue was of substantive nature and could be governed by national laws, and therefore, should be discontinued from the work of

the Committee. On the proposal by the GRULAC, contained in document SCP/22/5, the Delegation believed 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 the TRIPS flexibilities. The Delegation expressed its willingness to participate in the Committee's deliberations in a constructive manner.

24. The Delegation of the Russian Federation expressed the wish that the discussion of the agenda items was held in a constructive way. The Delegation stated that the Committee's work should be directed to the study of practical issues related to innovative development and noted that the relevant topics were: exceptions and limitations to patent rights, quality of patents, including opposition systems and confidentiality of communications between clients and their patent advisors. However, the Delegation further noted that all other topics on the agenda deserved discussion at the Committee. The Delegation expressed its view that a further step in the Committee's work could be work on systematization of information received from Member States on the basis of studies prepared by the Secretariat, for example, based on document SCP/23/3. In particular, it was of utmost importance for the Delegation to study various methodologies employed by offices in patent examination via concrete practical examples. The Delegation stated that such approach would contribute to mutual understanding of the methodologies employed.

25. The Delegation of South Africa supported the statement made by the Delegation of Nigeria on behalf of the African Group and reiterated that while it acknowledged the importance patents played in fostering innovation and boosting economic performance, countries needed to be mindful that excessive patent protection hampered innovation and limited developing countries' access to new technologies and knowledge in their pursuit of economic growth. The Delegation fully supported discussions on all agenda items in order to facilitate a better understanding amongst Member States. The Delegation placed importance on the critical issue of patents and health in light of the challenges faced in adequately addressing public health concerns such as access to reliable and affordable medicines. The Delegation observed that millions of people across the world in both developed and developing countries still died from preventable and treatable diseases. In that regard, the Delegation looked forward to the seminar scheduled on patents and health with a view to better understand the challenges faced by developing and least developed countries and the possible solutions thereof. The Delegation was of the opinion that the SCP should be cognizant of the debilitating impact diseases posed on sustainable development and the achievement of the 2030 Agenda for Sustainable Development. The Delegation further looked forward to discussions on exceptions and limitations based on Member States' experiences, and hoped to learn how various countries used limitations and exceptions in addressing public policy issues. The Delegation considered that that topic was of particular interest to South Africa as they were currently working on their IP policy, which sought to develop an IP framework that truly benefitted all people in South Africa with particular reference to poverty, inequity and persons of vulnerability. The Delegation believed that another issue of importance for South Africa was technology transfer necessary for promoting local technology development, and looked forward to discussions on quality of patents. The Delegation further noted that it was interested in learning the different practices on issues relating to client and attorney confidentiality.

26. The Delegation of Cameroon believed that intellectual property and the patent system in particular provided tangible support for the economic and social development of Member States. The Delegation noted that the patent system should take great care to ensure that the right balance that was required for a better climate of cooperation for development could be achieved without restricting the space governed by national legislation. The Delegation of Cameroon supported the proposal of the African Group on patent issues and public

health, technology transfer and technical assistance. The Delegation further believed that it was important to define the quality of a patent. The Delegation specified that such a definition should not be academic or normative in nature, and it should allow for a more balanced use of the patent system so that it could respond to the social, economic and development needs of countries; in particular, to those of developing countries and least developed countries. The Delegation of Cameroon supported the proposal of the Delegation of Brazil, as seconded by the Delegation of Iran and many other delegations. Instead of relying on the contributions of countries alone with regard to the use of exceptions and limitations, the Delegation shared the view that it would be more effective if the Secretariat were to become more involved in the collection of said data by questioning other sources, including those within WIPO itself, and by including not only success stories but by also listing difficulties encountered, in order to draw up a non-exhaustive document on that issue. The Delegation stated that Cameroon was a member of the African Intellectual Property Organization (OAPI), which acted as a single office for seventeen States. The Delegation drew the attention to the fact that most of the issues discussed in the SCP would be on the agenda of the session of the Administrative Council of OAPI from December 6 to 15, 2015, as proposed amendments to the Bangui Agreement would be discussed. The Delegation reminded that such Agreement was a supranational law which regulated intellectual property law in each of the seventeen countries party to the Agreement. The Delegation pointed out that the issues on the agenda would include, *inter alia*, the removal of the provisions establishing a supplementary protection certificate for medicines, regulation of an opposition system, exhaustion of rights and issues related to technology transfer. The Delegation of Cameroon expressed its wish that the outcome of the discussions at the twenty-third Session of the Committee would be both positive and consensual and resulted in a more balanced use of the patent system.

27. The Representative of the Center for International Intellectual Property Studies (CEIPI) attached great importance to the work of the SCP. Among the agenda items, the Representative considered two agenda items particularly interesting: exceptions and limitations to patent rights and communications between clients and their patent advisors. As to the former, the Representative noted that exceptions and limitations to patent rights were essential for the good functioning of a balanced patent system. As to the latter, at that point the Representative observed the fact that such issue was left to national legislation was problematic, and therefore stressed the need to find an international solution to that problem. The Representative added that his observation did not reduce in any way the importance of the other agenda items.

28. The Representative of TWN quoted the Max Planck Declaration on Patent Protection according to which the spike in patent filing “creating backlogs at patent offices, this phenomenon leads to patent thickets, legal interdependencies, market entry barriers, royalty stacking and increased litigation, all of which ultimately generate impediments to research and commercial applications.” The Representative further noted that, the Declaration continued by saying “The overall social benefit of innovations are reduced while an imbalance emerges between those able to cope with resulting insecurities and related costs, such as multinational enterprises with their own patent departments, and those who cannot, such as small and medium size enterprises or individual inventors.” and “the patent system faces an increasing friction with ancillary public policy goals such as protecting the environment, preserving biodiversity and ensuring affordable access to medicines.” In addition, the Representative stressed that the Economics magazine had reflected the same feelings in its editorial dated August 8, 2015, where it was stated that “Today’s patent regime operates in the name of progress; instead, it sets innovation back. It is time to fix it.” The Representative further quoted a statement of the USFTC according to which “The Patent Office should function as a steward of the public interest, not as a servant of patent applicants. The PTO (Patent and Trademark Office) must protect the public against the

issuance of invalid patents that add unnecessary cost and may confer market power." The Representative was pleased to note that the UN Secretary General had set up a new 16 member high level panel to examine access to medicines as a follow up to the Recommendations of the Global Commission on the HIV Law which recommended a review of the TRIPS Agreement. Consequently, the Representative was of the opinion that the work program of the SCP as well as the activities of the Secretariat in the area of patents, should be driven by the realities and evidence rather than ideological obsessions to patents. The Representative noted that the work program of the SCP should reflect the reality and work towards to reform the patent regime to fit for its ordinal purpose rather than a mechanism of 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 stated that it was regrettable that more than seven years since the SCP reconvened in 2008, there had been no substantive progress in the SCP on developing a balanced work program on any of the issues that were identified by the SCP in 2008. The Representative observed that the current work program of the SCP contained critical issues, and it offered an opportunity to reform the functioning of the patent regime to reflect the above mentioned realities; however, the Representative was of the opinion that developed countries had made a systematic objection against making progress in those areas. The Representative viewed the seminar on patents and public health as a useful initiative; however, he considered that it was not enough since, in his opinion, what was really required was a concrete work program to address the concerns on patents and access to medicines. Fully recognizing the abilities of the panelists, the Representative express his regret for the non-representation of panelists from developing and least developed countries. The Representative was of the opinion that while discussing the issues on access to medicines in that context, developing and least developed countries' representation was important, and it could not be limited only from the panelists from Europe. The Representative considered that there was scholarship and capability in developing and least developed countries to share their views. The Representative concluded it was absolutely important for multilateral organizations, such as WIPO, to reflect the spirit of multilateralism.

29. The Representative of Innovation Insights agreed that the Committee's work must be grounded on evidence, not ideology. For that reason, the Representative expressed her appreciation for the very practical approach adopted for the current session of the SCP. In particular, the Representative was of the opinion that bringing in experts to exchange views with Member States on technical issues helped to ground deliberations in evidence. The Representative hoped that seminars and sharing sessions involving experts would continue to be organized as part of the Committee's work. The Representative found it crucial to hear from the private sector, and in particular from innovators across sectors and from countries at all levels of development. The Representative was of the opinion that the Committee's work could be benefitted from the experience of private sector actors with different types of business and IP management models, whether using patents, facing the patents of others in the marketplace or, as was often the case in the real economy, both. The Representative considered that a practical topic worth discussions in the SCP was, among others, patent-related collaboration among IP offices. The Representative mentioned that, for instance, the United States of America and Brazil recently announced their intention to create a Patent Prosecution Highway and suggested that it could be interesting to hear from the Delegations of those countries about such initiative and to learn more about similar collaborative efforts elsewhere in the world. The Representative believed that collaboration could help offices to use scarce resources more effectively and enhance patent quality through, for instance, identification of additional prior art. The Representative observed that a quality patent was one that deserved to be granted under the laws of the relevant jurisdiction. In closing, the Representative announced a side event to be held on the third day of the SCP during which speakers from Kenya and Switzerland would discuss how IP

management could advance the achievement of development goals by public private initiatives.

30. The Delegation of Brazil, following the intervention of the Representative of Innovation Insights, stated that a bilateral agreement between Brazil and the United States of America was a pilot project for a period of two years in some specific fields of technology, and that such agreement could not be classified as a PPH agreement in any manner. The Delegation further pointed out that it did not want to bring that subject to the discussion of the SCP.

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

31. Discussions were based on document SCP/23/2.

32. The Secretariat noted that since the twenty-second session of the SCP, information concerning certain aspects of national/regional patent laws had been received from the following Member States and Regional Offices: Azerbaijan, Belarus, Chile, Croatia, the Republic of Moldova, Paraguay, Poland, Saudi Arabia, United Kingdom and the European Patent Office (EPO). The Secretariat informed the Committee that the SCP electronic forum website had been updated accordingly.

33. The Delegation of the United Kingdom thanked the Secretariat for updating the website, taking into account the changes to its patent law which had come into effect on October 1, 2014. The Delegation explained that those changes were related to the exception to patent rights in respect of acts for obtaining regulatory approval from authorities. The Delegation noted that those changes would allow companies to use a patented product when carrying out testing or other activities to provide information to the regulatory authorities who would decide whether drugs should have been given market authorization. The Delegation further noted that companies would also be allowed to use a patented product in testing or other activities carried out to supply information for health technology assessments.

34. The Delegation of Poland thanked the Secretariat for updating the information on some aspects of the law on patents in relation to Poland. The Delegation noted that their update related to the amendment to the Industrial Property Law on August 24, 2015. The Delegation stated that one of the amendments was the adoption of the grace period concept. It explained that, following those amendments, in addition to a non-detrimental disclosure linked to the priority, Poland had in its law, like other countries, a new provision to the effect that a patent could be granted for an invention if the invention was disclosed not earlier than six months preceding the filing of a patent application and if it was due to or in consequence of an evident abuse in relation to the applicant or his legal predecessor. The Delegation noted that new provision had become effective as from December 1, 2015.

35. The Delegation of Chile noted a difference between the current Chilean legislation resulting from the amendments to its law in 2007 and the previous legislation. The Delegation explained that the previous law established a grace period of six months, meaning that the disclosure of the invention that had occurred during that period would not be considered affecting the novelty and inventive step of the invention. The Delegation specified that, according to the current law, that period had been extended to twelve months. The Delegation stated that, without prejudice to the modifications in 2007, Chile was in the process of updating its national patent law and therefore in the next years, further modifications would be notified to the Secretariat.

36. The Delegation of Paraguay thanked the Secretariat for updating the database containing information on the national legislation on patents of Paraguay. The Delegation specified that Paraguay implemented the Decree No. 8069/2011 that appeared also in the compilation of Intellectual Property laws of Paraguay on the WIPO webpage. The Delegation noted that the Decree 8069/2011 broadened and modified the previous decree No. 14201/01. The Delegation illustrated the principal aspects of Decree 8069/2011. First, the Delegation stated that Article 2 increased the time period for carrying out the formal examination of patent applications from 45 to 90 working days. The Delegation explained that such change had been made to harmonize the provision of law on the formal examination with Article 58 of the Law on Patents No. 1630 of 2000, according to which a patent applicant had a time period of three months to submit priority documents: the new amendment of the Paraguayan law would allow the patent office to undergo the formal examination of the patent application after the expiration of such deadline. The Delegation further referred to Article 5 of Decree 8069, according to which the final result of the substantive examination would be notified to the patent applicant through a decision of the Directorate of Patents and the patent applicant might bring an appeal against such decision within the timeframe as established in Law No. 1630 of 2000. The Delegation pointed out that in the previous Decree No. 14201/01, in case of refusal, it was not possible to bring an appeal at administrative level; therefore the patent applicant was obliged to appeal the decision of refusal before the *Tribunal de Cuentas* (Courts of Accounts). The Delegation further explained that Article 10 of the new Decree provided for a special procedure in case of substantive examination of pharmaceutical patents. The Delegation specified that it was necessary to obtain a decision of the Ministry of Health, which had a deadline of 100 working days to issue such decision. In addition, the Delegation stated that Article 11 of Decree 8069/11 established the amount of fee for substantive examination.

37. The Delegation of Argentina noted that with respect to exceptions and limitations, eight exceptions were provided under Article 36 of the Law 24481 of Argentina. The Delegation however observed that in addition to those eight exceptions, there could potentially be other exceptions under Article 41 of that Law, provided that such exceptions did not unreasonably conflict with a normal exploitation of the patent and did not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.

AGENDA ITEM 5: EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

38. The Secretariat introduced document SCP/23/3.

39. The Delegation of Mexico was pleased to note that Mexico was one of the countries that had contributed to the document and expressed its wish to summarize that contribution with a specific focus on those exceptions which, in its view, had been extremely useful to the Mexican patent system. The Delegation stated that the Government of Mexico had adopted the regulatory exception, also known as the Bolar clause or Bolar exception. The Delegation noted that Article 25 of the Industrial Property Law of Mexico regulated the content of the exclusive rights conferred by a patent. The Delegation further pointed out that there was a provision in the health commodities regulations, according to which it was possible to request the registration of a generic form of a drug whose active substance or ingredients were protected by a patent, in order to undertake studies, tests and experimental production within three years prior to the patent's expiration, with the understanding that it would be possible to obtain the sanitary registration only after the patent expiration date. The Delegation explained that it was possible to import the primary or active substance which was protected by a patent in order to ensure that generic drugs could be produced in a

timely manner for the Mexican market without any infringement of patent rights. The Delegation further noted that the Mexican legislation also provided the exception of the patent rights with respect to granting of a license of public utility in case of national emergency. The Delegation stressed that in such cases of urgency, it was necessary to work hand in hand with the health authorities so that the necessary drugs could be produced in order to serve the Mexican society.

40. The Delegation of Colombia acknowledged that Colombia was one of the countries which had contributed to the preparation of document SCP/23/3, and summarized its contribution. Specifically, the Delegation explained that its contribution was based on the possibility to use the exception and limitation to patent rights in cases where public interest was declared with respect to a particular medication protected by a patent granted by the Colombian patent office. The Delegation noted the case related to the medicine for the treatment of HIV known as Kaletra, consisting of the combination of two active ingredients, lopinavir and ritonavir. The Delegation explained that the patent on Kaletra had been granted by the Colombian patent office to Abbott Labs, and subsequently in 2008, two non-governmental organizations had requested that public interest be declared in order to grant a compulsory license for that patented drug. The Delegation stated that the regulatory authority, the Ministry of Health, through its Technical Committee, had not seen any reasons why that medicine should be declared of public interest fundamentally for the three points which were illustrated on page 3 of document SCP/23/3. The Delegation noted that in 2012, however, a national judicial authority had ordered the Ministry of Health to initiate a proceeding against Abbott Labs in relation to the reference price of the concerned drug. The Delegation explained that the patent holder had been found to infringe the conditions of sale of that drug because it had been maintaining the internal price that had been beyond the maximum allowable price. The Delegation noted that such situation had involved inspection and monitoring, which were undertaken in Colombia by the same Ministry that had granted the patent, but through another agency, i.e., the Consumer Protection Agency. The Delegation concluded by stating that an administrative sanction had been applied to the patent holder for having sold the medicine above the established price.

41. The Delegation of Portugal explained that the Portuguese law provided as limitations to the patent rights the acts performed exclusively for trial or experimental purposes. The Delegation pointed out that a new law had been adopted in order to resolve disputes concerning industrial property rights relating to originator medicines and generic drugs, including injunctive procedures. The Delegation stated that since such legislation had come into force, companies must resolve their disputes through mandatory arbitration courts. The Delegation explained that after the submission of a marketing authorization by a generic company, the patent proprietor had 30 days to present an opposition before the arbitration court; and after the communication of the opposition, the generic company had 30 days to reply. The Delegation noted that the arbitration decision could be appealed before the competent court of law. The Delegation explained that the law clarified that acts concerning the granting of marketing authorization, selling price to the public and reimbursement of medicines were not contrary to the rights relating to patents or supplementary protection certificates, and that the law made clear that marketing authorizations applications, selling price to the public and reimbursement of medicines could not be rejected due to the existence of industrial property rights.

42. The Delegation of El Salvador illustrated their contribution to document SCP/23/3 and noted that the Salvadorian legislation on patents included the possibility of using patented inventions for experimental, scientific research, academic or educational purposes. The Delegation pointed out that such law also allowed the granting of compulsory licenses in case of public needs. The Delegation specified that compulsory licenses had to be granted by the Tribunals of the Republic and therefore it was not possible to grant them at the

administrative level; however, the Delegation stressed that the government's participation was required, since the government authorities had to promote the grant of a license of that nature. The Delegation observed that no compulsory license had been granted in El Salvador, and therefore the country had no experience in the use of such licenses to date. In relation to the use of patents for experimental, scientific research, academic or educational purposes, the Delegation noted that a lot of work had been carried out to promote the use of that flexibility. The Delegation explained that, as a result of that work, some national inventors had referred in their patent applications to pending patent applications and patents in force, as part of the state of the art of their inventions. The Delegation believed that a great deal of progress had been made, although it was not yet documented, in the area of education. The Delegation observed that courses on scientific matters were increasing in number, innovation was being promoted also at the University level, and much was being realized, for instance workshops on patent drafting and on promotion of using patents.

43. The Delegation of Greece, speaking on behalf of Group B, observed that out of the nine responses received for the preparation of document SCP/23/3, only five had come from developing countries or LDCs, and regretted the limited feedback provided by Member States, especially from those who had requested it. The Delegation noted that while recognizing the importance of appropriate exceptions and limitations to be applied to very limited and specific circumstances, it was concerned that exceptions and limitations were sometimes regarded as a tool for development in themselves. The Delegation was of the opinion that exceptions and limitations could actually achieve its original purpose in an appropriate manner only in conjunction with an effective patent protection. The Delegation believed that such aspect should be always kept in mind when the SCP had to deal with that subject matter. The Delegation observed that an enormous amount of work in that area had been done by WIPO, including the SCP, and that the Committee had already had a great number of valuable references which could be used in considering domestic arrangements fitting to specific circumstances. The Delegation suggested that if Member States found interesting provisions of other Member States in the documents prepared by WIPO, they ask those countries the reason behind those provisions and how they were responding to the circumstances. The Delegation considered that such dialogue could deepen the understanding on those provisions in a comprehensive manner, and exceptions and limitations could actually be understood in the holistic context of patent protection.

44. The Delegation of Romania, speaking on behalf of the CEBS Group, thanked the Secretariat for the compilation prepared on Member States' experiences and case studies on the effectiveness of exceptions and limitations, in particular in addressing development issues. The Delegation noted that though the number of respondents was quite low, the compilation offered a good basis for discussion. The Delegation considered that exceptions and limitations represented a very limited area against the whole background of the patent system and not many national cases or experiences had been presented on that topic. Consequently, the Delegation was of the opinion that the result was that there was no evidence of their possible contribution to the development of a country. The Delegation reiterated that a deeper understanding of those issues and of their application was only possible if they were addressed in conjunction with the topic of patentable invention. The Delegation believed that the SCP needed to make more progress on the criteria of patentability, i.e., novelty, inventive step and industrial applicability.

45. The Delegation of Brazil, speaking on behalf of GRULAC, stated that exceptions and limitations to patent rights were a very important topic for its Group. The Delegation observed that the Delegations of Mexico, Colombia and El Salvador had shared their national experiences and that since the 14th session of the SCP, the Committee had the opportunity to hear the experiences of other members of GRULAC. The Delegation believed

that after so much work had been done on that field, it was time that the Secretariat prepared an analysis of the exceptions and limitations that had proven to be effective to address development concerns. The Delegation suggested that such study would take into account not only the last compilation but also the previous compilations, i.e., all the work that had been done in the Committee as well as academic studies and inputs that could be found from elsewhere. The Delegation proposed, as a second step, and on the basis of those analyses and the study, the development of a non-exhaustive manual on that topic that would serve as a reference to Member States of WIPO.

46. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States, thanked the Secretariat for preparing document SCP/23/3 on Member States' experiences and case studies on the effectiveness of exceptions and limitations. While the European Union and its Member States believed that those documents would serve as a useful reference, the Delegation noted with regret that the document contained information from only nine Member States. As regards exceptions and limitations in general, the Delegation stressed 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, the Delegation stressed the importance of addressing 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.

47. The Delegation of Nigeria, speaking on behalf of the African Group, thanked the Secretariat for document SCP/23/3 which contained a compilation of Member States' experiences in the area of exceptions and limitations to patent rights and in particular for addressing development challenges. The African Group did not have a statement on that agenda item, but reiterated what had been said in its general statement that it was time for more robust discussion in that area and supported the proposal put forward by the Delegation of Brazil. The Delegation called for the Secretariat to move towards the next phase of their proposal, which was an analysis by the Secretariat on the uses of exceptions and limitations, when and how they were used and any challenges in the capacity of Member States to use those exceptions. The Delegation further proposed, in a second phase, to create a manual that could provide useful guidance for Member States in the implementation and use of exceptions and limitations to patent rights. The Delegation stated that since that would be a meaningful way forward for the work of the Committee in the area of exceptions and limitations, it fully endorsed that proposal. The Delegation expressed its hope that the SCP could come to the future work that had been indicated by the Delegation of Brazil and supported by the African Group.

48. The Delegation of Ghana noted that compulsory licensing was a regulatory mechanism that allowed public authorities to authorize the use of patented pharmaceuticals by other parties without the consent of the right holder. The Delegation observed that the compulsory licensing mechanism was an issue that had occupied trade policy discussions in the last decade. The Delegation explained that patent law of Ghana placed several restrictions on grant of compulsory licenses by the Minister for Justice. The Delegation noted that firstly, before adopting a decision to grant a compulsory license, the Minister had to contact the patent holder. Secondly, a request for a compulsory license, except in cases of national emergency or extreme urgency, had to be accompanied by evidence that the patent holder had refused to grant such a license on reasonable commercial terms and conditions within a reasonable period of time. Thirdly, the Delegation noted that the patent law of Ghana allowed the compulsory licensing mechanism to be used predominantly for the supply of the Ghanaian market. The Delegation specified that Section 13 of the Patent Act of Ghana gave exclusive rights to inventors but that those rights could be limited on the

ground of public health. The Delegation stated that, in 2005, Ghana had used that important part of the Patent Law to grant a compulsory license on ARV drugs for importation from India to Ghana, and that thanks to such a measure, the cost of the drug had reduced by 50% when it had been imported to Ghana.

49. The Delegation of Singapore thanked the WIPO Secretariat for preparing document SCP/23/3 detailing Member States' experiences and case studies on the effectiveness of exceptions and limitations. The Delegation considered that intellectual property was a key economic driver for Singapore. The Delegation was of the opinion that a robust and balanced IP regime encouraged creativity and innovation, and also encouraged foreign investments. The Delegation noted that Singapore provided for exceptions and limitations to patent rights, in accordance with the TRIPS Agreement. For example, the Delegation stated that Singapore provided for compulsory licensing under Section 55 of its Patents Act. The Delegation explained that under Section 55, a compulsory license could be granted to remedy an anti-competitive practice, subject to prescribed conditions being met. The Delegation further illustrated Section 56 of the Singapore Patents Act, under which a patented invention could be used by the government or its authorized party for: (i) a public non-commercial purpose; or (ii) during a national emergency or other circumstance of extreme urgency. The Delegation further stated that, in Singapore, there was an exception for experimental purposes in Section 66(2)(b) of its Patents Act, as well as what was commonly known as the Bolar provision. In that respect, the Delegation pointed out that Section 66(2)(h) of the Singapore Patents Act stated that what would otherwise had been an infringement was not an infringement if it was done to support an application for the marketing approval for a pharmaceutical product. The Delegation stressed that the TRIPS Agreement provided flexibilities that enabled each Member State to tailor its patent laws on exceptions and limitations to patent rights in order to best fit its own socio-economic conditions and priorities. The Delegation believed that document SCP/23/3 would serve as a useful reference to Member States as they assessed their own situation and needs.

50. The Delegation of Iran (Islamic Republic of), was of the opinion that exceptions and limitations to patent rights were very important for developing countries, since they provided some flexibilities in the intellectual property system in order to recognize national needs and to adopt national legislations on patents based on the country's economic and social situation. The Delegation believed that it was crucial for Member States to determine the exceptions and limitations that were in line with their own needs so that the highest level of economic development could be achieved. In that respect, the Delegation supported the proposal made by the Delegation of Brazil that the SCP should undertake a study analyzing how the various exceptions and limitations were utilized by different countries in addressing various public policy objectives, particularly public health, food security, etc.

51. The Delegation of Romania stated that, in 2008, the so-called "Bolar exemption" regarding drugs was introduced in the Romanian Patent Law. The Delegation noted that according to that provision, "it shall not constitute an infringement of the rights provided for in the law, the carrying out of the tests and studies necessary for obtaining the authorization for placing a medicament on the market, as well as the practical requirements resulting therefrom; the acts concerning research and development of information contained in the patent, on condition that they are meant exclusively for experiments or studies which intend to evaluate the technical data from patents". The Delegation explained that the Romanian Patent Law also provided for compulsory licensing, under which, upon request by any interested person, the Court of Bucharest could grant a compulsory license after four years had elapsed from the filing date of the patent application, or after three years had elapsed from the grant of the patent, which ever period expired later. The Delegation clarified that such provision applied only in cases where the invention was not exploited or was insufficiently exploited in the territory of Romania, and where the owner of the patent could

not justify his or her inaction. The Delegation pointed out that a compulsory license could be also authorized by the Court of Bucharest in national emergency cases, in other cases of extreme emergency or in cases of public use for non-commercial purposes. The Delegation specified that up to date, the Bolar exemption had not been invoked in relation to patent infringement proceedings, and no compulsory license had been granted by the Court of Bucharest.

52. The Delegation of China thanked the Secretariat for preparing document SCP/23/3 and the countries that had shared their experiences on effectiveness of exceptions of limitations. The Delegation considered that information was very valuable for countries for reference and learning, as well as a good basis for the SCP discussions. The Delegation believed that exceptions and limitations to patent rights constituted a very important part in most of the patent laws around the world, since they provided a balance within the IP system. The Delegation noted that while they did not have many real cases on that topic, they had provided to the Secretariat the relevant provisions under the Chinese law on that issue. In particular, the Delegation stated that the information they provided to the Secretariat included Article 69 on the Bolar exception and other provisions on exhaustion of rights and compulsory licenses. The Delegation hoped that all countries would continue to share the information on cases of exceptions and limitations, since that would be a valuable reference for Member States to improve their patent laws. The Delegation supported the proposal made by the Delegation of Brazil, and suggested that Secretariat continue to collect and consolidate information provided by countries on that issue.

53. The Delegation of India considered that, like any rights, patent rights could not be absolute and that they carried also accompanying obligations that had to benefit public at large. The Delegation believed that those rights and obligations would balance out each other. The Delegation observed that there was no uniformity in economic problems which could rise in different countries at any time or even in the same country at different periods of its history. The Delegation therefore stated that the actual conditions should be taken into account for the precise adjustments and rectification of the imbalance which the patent system was apt to produce, if left uncontrolled. From the angle of development of the exceptions and limitations, the Delegation noted that in order to protect the public interest, Articles 7 and 8 of the TRIPS Agreement allowed every Member State to enact exceptions and limitations in its legislation. The Delegation appreciated the work of the Secretariat in compiling the exceptions and limitations provisions of different countries. The Delegation took the opportunity to reiterate that exceptions such as parallel imports, compulsory licenses, government use and the Bolar exception provided the necessary instruments for the protection of not only public health and nutrition, but also in other areas of vital socioeconomic importance, namely the environment and technology. The Delegation reiterated its support to the studies proposed in the proposal of the Delegation of Brazil, and requested the Secretariat to continue to develop working documents that would address potential flexibilities and exceptions and limitations, which would be used for addressing the development concerns. The Delegation noted that since scientific and research institutes could be in a good place to use research exceptions and civil societies involved in public protection could be good sources of information regarding use of exceptions, the Secretariat should take into account the experience of those institutions in compiling such information.

54. The Delegation of the United States of America expressed its appreciation to those who had submitted experiences and case studies on the effectiveness of exceptions and limitations, in particular, in addressing development issues to the SCP electronic forum. The Delegation observed that the national experiences summarized in document SCP/23/3 sought to build on the earlier work of the SCP, such as document SCP/21/3 on exceptions and limitations to patent rights regarding acts for obtaining regulatory approval from authorities, SCP/21/4 Rev. and 5 Rev. which had covered exceptions and limitations to

patent rights concerning compulsory licenses and/or government use, SCP/21/6 which had covered exceptions and limitations relating to farmers' or breeders' use of patented inventions, and SCP/21/7 which had covered exceptions and limitations regarding exhaustion of patent rights. The Delegation stated that exceptions and limitations in the US patent law were not for the purpose of addressing development issues, and for that reason, it had not submitted information to the SCP electronic forum. The Delegation, however, as described in the various SCP/21 studies, pointed out that in the United States of America, there were exceptions and limitations that were aimed at promoting research and development including the development of new and generic medicines. The Delegation noted that two important exceptions and limitations had been included in the Hatch Waxman Act of 1984, which had facilitated entry into the market of generic drugs while promoting the discovery of innovative or pioneered drugs. The Delegation explained that prior to 1984, few generic drugs had been on the US market, mostly because the clinical trial investment necessary to demonstrate safety and efficacy of medicines had been too costly. The Delegation further explained that prior to 1984, competitors could not immediately enter the market upon the expiration of a patent, because testing and other activities necessary to receive the US Food and Drug Administration (FDA) approval before the patent expiration could infringe a patent. The Delegation stated that in 1984 the Hatch Waxman Act, formerly known as the Drug Price Competition and Patent Term Restoration Act of 1984, had been passed with two goals: (i) to provide incentives to brand name drug companies to produce innovative drugs; and (ii) to offer an expeditious route for approval of low cost generic drugs. The Delegation explained that the Act had included a provision to allow for testing and other activities necessary for regulatory approval, the so-called "Bolar exception", and for a simplified application to be filed by a generic drug company to receive a marketing approval once a patent expired, i.e., abbreviated new drug application (ANDA). The Delegation further explained that, in addition, the act provided for a period of market exclusivity for innovative and generic applicants, a mechanism that allowed for resolution of patent disputes, and patent term restoration for certain new drugs. The Delegation believed that those changes to its law had been extremely successful, since the pharmaceutical industry in the United States of America remained strong and continued to innovate, while the generic pharmaceutical industry had grown. The Delegation specified that according to the FDA, more than 8 in 10 prescriptions filled in the United States of America were for generic drugs. The Delegation further emphasized that use of generic drugs was expected to grow over the next few years, as a number of popular drugs would come off patent. The Delegation noted that because generic drug makers were not required to repeat clinical trials of new drugs and did not pay for advertising, marketing and promotion, generics were usually substantially less expensive than brand name drugs. The Delegation reiterated that the United States of America did not employ patent flexibilities for the purpose of development, but for other purposes such as to foster research and development and stimulate the economy. The Delegation considered that for many countries, development issues were not necessarily their principle or only concern. The Delegation believed that any further work on that topic should not be limited to the utilization of flexibility for development but should be open to other goals as well. In its opinion, exceptions and limitations were not the only type of patent flexibilities that could be employed: for example, provisions such as data protection and patent term extensions were also flexibilities which should be included in the study. The Delegation did not support the proposal by the Delegation of Brazil concerning a study on the analysis by the Secretariat of the effectiveness of exceptions and limitations. If such a study were to be conducted, the Delegation believed that the study should be based on the submissions from and experiences of Member States. The Delegation noted that, at that point, only a small minority of WIPO Member States had made submissions and not all of those had provided data on the result of any exceptions and limitations that they had. Consequently, the Delegation considered that there was insufficient information upon which WIPO could conduct such a study. The Delegation further noted that members had agreed that work of the SCP would not be normative at that

time while the proposed manual on exceptions and limitations would be a norm-setting exercise. As a result, the Delegation was of the opinion that such a proposal was outside of the agreed scope of the work of the SCP. Once and if members would have agreed to resume the norm-setting nature of the SCP's work, the Delegation expressed its openness to reconsider that proposal.

55. The Delegation of Chile was of the opinion that exceptions and limitations were very important because of their value in the patent system. The Delegation welcomed document SCP/23/3 and its content together with the other documents and discussions before the Committee. The Delegation acknowledged the relevance of the document that had been shared by Member States. The Delegation believed that it constituted a good basis for continued discussions on the functions of exceptions and limitations. Along the lines of what had been stated by the Delegation of Brazil on behalf of GRULAC, the Delegation expressed its wish to explore the issue into more details and to include other topics such as the concrete use of exceptions and limitations as well as other ideas that might improve the understanding of the patent system by Member States.

56. The Representative of TWN quoted the last Report by the Special Rapporteur in the field of cultural rights on intellectual property policies and the right to science and culture to the UN General Assembly, according to which "whereas from the perspective of trade law, exclusions, exceptions and flexibilities under international intellectual property law, such as the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights, remain optional, from the perspective of human rights, they are often to be considered as obligations." The Representative noted that such a statement demonstrated the importance of exceptions and limitations. The Representative noted that while the decision of the twenty-second session had instructed the Secretariat to make a compilation of Member States' experiences and case studies on the effectiveness of exceptions and limitations, in particular, in addressing the development issues, and such a decision had not provided any instruction on how to do the compilation and remained silent on the methodology to follow, it had been up to the Secretariat to compile information from various sources instead of depending only on responses from Member States. The Representative was of the opinion that, under many jurisdictions, some exceptions and limitations such as parallel importations, research exception and the Bolar exception were operationalized by private actors, such as individuals, firms or R&D organizations, without informing the patent office. The Representative considered that patent offices did not have any information on the concrete use of such exceptions and limitations. The Representative further noted that patent oppositions, compulsory licenses or government use were initiated by private actors. The Representative therefore believed that patent offices had little or limited knowledge about the constraints faced by the private actors in using those exceptions. The Representative was of the opinion that the Secretariat should have compiled the information from various sources, including public literature, and invited contributions from NGOs, civil society organizations and business associations. The Representative called upon the Secretariat to open up the process and invite submissions from NGOs and civil society organizations as well as academics and other stakeholders. The Representative further requested the Secretariat to look at the existing literature in that area and use it for the compilation of the document. The Representative understood that the WIPO had provided technical assistance to its Member States in the area of exceptions and limitations and believed it was time for the Secretariat to share its experience in the use of exceptions and limitations. The Representative stated that, in his view, the Secretariat might carry out certain evaluation regarding the success of effectiveness of the use of exceptions and limitations when carrying out its technical assistance. The Representative therefore requested the Secretariat to share such evaluations, even if they were not formal. The Representative made reference to the proposal by the Delegation of Brazil contained in document SCP/14/7, which complemented the proposed work program on patents and

health, where Brazil had called attention to lack of policy coherence in some countries, in comparison to those which had used compulsory license to promote access to medicines. The Representative asked a question as to the role that WIPO could play in addressing such lack of policy coherence. The Representative drew the attention of the Committee on bilateral trade pressures that might hinder the use of exceptions and limitations to promote public health needs.

57. The Delegation of the Russian Federation stated that the Russian Federation had provided detailed answers to the Secretariat's questionnaire at the 20th session which were reflected in document SCP/20/13. The Delegation believed that the material that had been prepared for the present session was quite interesting and that a number of countries such as Colombia had given detailed examples of exceptions and limitations in their submissions. The Delegation reiterated that the Russian legislation provided for the issuing of compulsory licenses in case of national emergencies, among other grounds, but that such provision had never been used. The Delegation expressed its interest in practical studies and exchange of experiences among Member States. In particular, the Delegation suggested the Secretariat to study impediments to the use of compulsory licenses and governments use exception. In that light, the Delegation supported the proposal for a manual made by the Delegation of Brazil.

58. The Delegation of South Africa referred to the statement made by the Representative of TWN, and requested the Secretariat to shed some light on WIPO's role in ensuring policy coherence on intellectual property across different fora.

59. The Delegation of Pakistan supported the statement made by the Delegation of South Africa.

60. In relation to the question raised by the Delegation of South Africa, the Secretariat responded that WIPO, being a specialized agency of the United Nations, was an organization which was driven by its Member States. That meant that the policy coherence and cohesion of the Secretariat's work came from its Member States. The Secretariat stated that it received the policy guidance from its Member States through several different structures within WIPO, such as the Program and Budget Committee, the Coordination Committee and the WIPO General Assembly.

61. The Representative of Innovation Insight noted the concept of business model neutrality. The Representative believed that there were many possible business innovation and IP management models. In her view, skewing the patent system to reflect the needs of one sector and just one business model was not a strategic IP policy over the medium to long term. The Representative was of the opinion that the key was to have a patent system that could support innovation in all of its forms, i.e., a patent system that was business model neutral. The Representative concluded that the SCP could consider examining with a great degree of granularity the impact of specific IP policy choices on the building of technological and innovative capacity over the medium to long term.

AGENDA ITEM 6: QUALITY OF PATENTS, INCLUDING OPPOSITION SYSTEMS

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

63. The Delegation of Greece, speaking on behalf of Group B, informed that it had no statement on behalf of its group but added that it would be interesting hearing the proposals by the Delegations of the members of the Group on their national capacity.

64. The Representative of ARIPO stated that ARIPO was a regional patent office with a number of Member States, most of which were small countries and LDCs. The Representative believed that the Committee was a forum where experiences in processing patent applications could be shared. The Representative stated that ARIPO depended on work sharing to process patent applications, since it had a small number of examiners. The Representative observed that a certain number of patent offices were more equipped, for instance the European Patent Office had about 4000 examiners covering all fields of technology, and therefore it was important to share the results of that work. The Representative pointed out that work sharing did not mean relying blindly on the examination result about the patentability of an invention prepared by another patent office. Quite the contrary, the Representative noted that it was possible to verify the results of the examination carried out by another patent office in the light of its own national or regional patent law. For that reason the Representative was of opinion that work sharing was crucial to process patent applications in small countries as well as in those countries that had not enough staff in their patent offices. The Representative further observed the difficulty in carrying out the task of identifying prior art in those patent offices.

65. The Delegation of India stated that the patent quality was not finally determined by the instrumental efficiencies, but by the appropriate application of formal and substantive issues of respective States commensurate to their laws. The Delegation believed that the problem with the deterioration of patent quality was not mainly due to inadequate infrastructure, but to the lowering standards of patentability and examination practices. The Delegation quoted the case KSR v. Teleflex decided by the US Supreme Court, according to which "We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts." The Delegation was of the opinion that changing of the threshold was the everyday reality in the world of patents, and therefore, the standards, hypothetical or real, should be changed so that technologically significant patents which would continuously boost the growth, were issued. The Delegation stated that a mere arithmetical application of the standards applied in one country could not be any solution in another. One Delegation believed that the Committee should insist that the quality be viewed from the public point of view as well, understanding "public" as those who were direct or indirect beneficiaries and those who were direct or indirect sufferers of the same. To advance discussions on quality of patents, the Delegation considered that the SCP needed to advance a common understanding on what was meant by "quality of patents", since that terminology might have many different meanings: efficiency of patent offices in disposing patent applications; or the quality of patents granted, i.e., how to ensure that patent offices did not grant patents of questionable validity, among others. The Delegation noted that presumption of validity of granted patent might be a standard practice in one jurisdiction but might not be an acceptable standard in the others. The Delegation emphasized that the Committee should concentrate on opposition system as well, i.e., how the opposition systems contributed to the development of the quality. The Delegation further sought studies on different thresholds in national patent legislations for "sufficiency of disclosure" as a problem linked to patent quality (and, in the Delegation's view, leading to patent backlogs, as it required further work by examiners). The Delegation believed that that would lead to identification of practical means for addressing issues related to insufficient disclosure. In the context of the work sharing, the Delegation stated that although India used the results of search and examination conducted in other foreign patent offices, the examiners of the Indian Patent Office were bound to do their own search and examination as required in their

law. The Delegation did not believe that automatic validation of patents granted in other jurisdictions would enable India to issue the patents in conformity with the standards as prescribed in its Statute. The Delegation therefore expressed its disagreement to such proposals.

66. The Delegation of Iran (Islamic Republic of) raised three points in relation to the item of quality of patents. First, the Delegation noted that a common understanding had to be found by the Committee in relation to the expression “quality of patents” as a requisite for further discussions at the SCP on that issue. Secondly the Delegation reiterated it did not agree to any kind of harmonization with regard to quality of patents and patentability requirements as well as any other aspect of substantive patent law. The Delegation believed that work sharing and Patent Prosecution Highway (PPH) were not a remedy for patent quality, since those tools should take into account the different legal frameworks and resources of patent offices in developed and developing countries. The Delegation further noted that work sharing and PPH should not lead to undermining the autonomy of national offices to conduct a comprehensive search and examination. The Delegation concluded that work sharing and PPH, being a procedural issue, could not be discussed as a substantive issue in the SCP. The Delegation, as a third and final point, supported further discussions on opposition systems, and requested the Secretariat to prepare a compilation of models on opposition and administrative revocation systems.

67. The Delegation of the United Kingdom noted that a certain number of Delegations felt that the discussions on quality of patents would benefit from an agreed definition of quality within the Committee. In that regard, the Delegation noted that it would welcome an agreement to launch a questionnaire as proposed in document SCP/18/9, which included a question relating to the definition of quality. In its opinion, such initiative would help the Committee to reach an agreed definition on quality, if that was required.

68. The Delegation of the United States of America noted that during the twenty-first session of the SCP, the United States of America shared its experiences in international work sharing collaboration. In response to the comments by some Member States that the proposals before the SCP should be in writing, the Delegation stated that its proposal on the study on worksharing had been submitted to the SCP and contained in document SCP/23/4. The Delegation observed that at the basic level, work sharing was a tool for patent offices to limit the amount of repeated work they carried out by reusing, to the extent possible, the work previously generated in related patent applications by other offices. The Delegation noted that after the first office carried out the search and examination of a patent application, those results were used by other offices to facilitate their own later search and examination of a related application. The Delegation stressed that benefits of work sharing could be especially significant when the offices involved had different capabilities and strengths. The Delegation observed, as an example, that offices which operated in different languages or had special expertise in different technical fields could help each other to carry out a better search and examination, and pointed out that searching the prior art relevant to certain patent applications could be simpler and more efficient for some offices than it was for others. The Delegation believed that, in part, that could be because access to national collections of prior art, availability of patent examiners that could understand certain languages, and availability of examiners having specialized technical expertise could not be uniform across all offices. The Delegation noted that even large offices such the USPTO could have difficulties finding and using prior art that was in foreign languages and/or which was located in national collections of other offices. In its opinion, developing every capability in every office could be difficult or impossible, and prohibitively costly. With respect to the PPH, which was one example of work sharing, the Delegation updated Member States on its positive experiences. The Delegation explained that the PPH had begun as a bilateral agreement between the USPTO and the Japanese Patent Office (JPO) in 2006. The

Delegations pointed out that since that year, the Program had expanded significantly. The Delegation stated that at the beginning of 2015, the USPTO had begun work sharing arrangements under the PPH Program with the Romanian State Office for Inventions and Trademarks (OSIM), and the Estonian Patent Office (EPA). The Delegation stated that, in addition, the USPTO and National Institute of Intellectual Property (INPI) of Brazil, had agreed to establish a two year PPH pilot program that was the center piece of the June 2015 U.S. – Brazil Commercial Dialogue Joint Statement on Patent Work Sharing signed by the U.S. Secretariat of Commerce, Penny Pritzker, and the Brazilian Minister of Development, Industry and Foreign Trade, Armando Monteiro. The Delegation observed that such program complemented the efforts under way in both Brazil and the United States of America to improve patent quality, reduce patent backlogs and shorten patent pendency, i.e., the time between filing a patent application and its grant, by leveraging the patent expertise and work product of patent examiners at the both national patent offices. The Delegation reiterated that the reuse of search and examination results under the PPH was carried out while respecting the national sovereignty of the 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 was of the opinion that because of those safeguards, concerns that the PPH called for the automatic acceptance of patentability decisions reached by another office were unwarranted. With respect to its proposals to study the effect of work sharing on quality and efficiency and to amplify the capabilities of patent offices, the Delegation noted that it originally had made those proposals from the floor, as part of the discussion on work sharing during the twenty-second session of the SCP. Following that discussion, the Delegation had submitted those proposals in writing as contained in document SCP/22/4. To better understand the potential of work sharing on the operation of patent offices, the Delegation proposed that the SCP direct 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 examinations and in granting high quality patents by leveraging the work carried out in the other offices. For that study, the Delegation suggest that the Secretariat would have collected information from Member States on their experience with work sharing programs and 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. The Delegation, as an example, suggested that the focus could have been on how limited capabilities in one office could have been amplified through the use of work sharing. The Delegation pointed out that the study it proposed to be carried out by the Secretariat would be addressed the tools that had been used by offices to share information, such as, the WIPO Centralized Access to Search and Examination (WIPO CASE), the Global Dossier and other electronic dossier systems, and what other shortcomings and benefits offices had encountered in using those tools. The Delegation further proposed that the study would investigate what type of work product shared between offices had been found to be useful by examiners and how best to share such work products. To make work sharing more concrete and more understandable by the members of the SCP, the Delegation further requested that when the completed study would be presented to the Committee, the Secretariat should organized a practical demonstration of those tools. The Delegation drew the attention of the Committee to the fact that a further aspect of its proposal addressed sharing examiner search strategies. When performing automated searches of the prior art, the Delegation observed that examiners prepared a set of search queries to discover the most relevant prior art. The Delegation noted that search terms and related logic used were generally preserved in the application file and that it would be beneficial for national offices to have access to the search logic used by offices that had already carried out the examination of a related application. The Delegation therefore proposed that the SCP conduct a study on the views of Member States concerning sharing search strategies. The Delegation suggested that such study could involve, for example, a

survey of the Member States. The Delegation explained that a third aspect of the study addressed prior art collection availability. The Delegation believed that access to as much of the relevant prior art as practical was fundamental to carrying out high quality search. However, it observed that certain prior art was only found in national collections of certain countries, which were not usually available to other offices. In order to find possible solutions to such problem, the Delegation proposed 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.

69. The Delegation of the Republic of Korea supported the proposal of the United States of America. The Delegation reiterated that advancing the work on quality of patents was an important issue to improve the patent system. The Delegation was of the opinion that further work in that area would be beneficial to all WIPO Member States. The Delegation believed that among the many subtopics related to patent quality, work sharing was particularly important, since it could be one of the most effective solutions for enhancing the quality of patents. The Delegation observed that various work sharing programs had been launched mainly in prior art search areas. The Delegation noted that thanks to those programs, participating countries could minimize examination resource by reducing duplicated work and quality of examination had been improved, since the coverage of prior art search was expanded through the cooperation between examiners in different offices. The Delegation further pointed out that the programs not only had allowed participating offices to access literature and even traditional knowledge in other regions with different languages and cultures but also proved to be beneficial to participating countries in other areas, such as classification. The Delegation emphasized that work sharing would give advantages to all Member States and stakeholders of patent community. The Delegation considered that developing countries could benefit from the utilization of resources of other countries and also increase their capacity by cooperating with more experienced countries. The Delegation believed that work sharing was a very useful means for the capacity building for developing countries, while for developed countries, it could contribute to the reduction of the burden of high volume of patent applications to be examined. In its view, also patent applicants and the general public would benefit from work sharing, by possibly expecting more stable and predictable patent rights. The Delegation noted that some Member States were reluctant to agree to discuss work sharing due to the sovereignty issues. With that respect, the Delegation emphasized that work sharing was not related to the sovereignty issues and further stressed that the final decision to grant a patent belonged to each country. The Delegation explained that work sharing was only a tool to help the decision on patent grant by providing useful information to the patent office and reducing workload on activities other than the final decision making. The Delegation further emphasized that work sharing was not aimed at harmonizing substantive patent law. The Delegation supported the proposal made by the Delegation of the United States of America, contained in document SCP/23/4 and requested that the Secretariat conduct studies on work sharing including the circumstances and how the implementation of work sharing could assist in enhancing quality of patents.

70. The Delegation of Australia thanked the Delegation of the United States of America for its proposal on work sharing, and fully supported it. The Delegation stated that, like many offices, IP Australia had limited resources, and, in line with global trends, the demand for patents in Australia was growing on. The Delegation noted that at IP Australia work sharing was seen as an efficient way of managing workloads. In particular, the Delegation pointed out that work sharing allowed Australian patent examiners to use work products of another office as a head start in examination, helped them to learn from experiences of other offices in conducting search, and focused their efforts on complex cases first filed in Australia. The Delegation stressed that work sharing did not mean that one office simply accepted work of another office, and with that regard, specified that each office needed to take into account its

own laws and domestic requirements. Instead, the Delegation considered 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 search and examination. The Delegation believed that work sharing produced better quality patents because examiners from across the world could uncover relevant prior art in foreign languages or specialized technical fields that could be difficult to find. In order to better understand how work sharing could strengthen the capabilities of patent offices, the Delegation fully supported the proposal from the United States of America requesting the Secretariat to conduct a study on 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 examinations and in granting higher quality patents by leveraging work carried out in other offices. In its opinion, two key elements were required to support effective work sharing: access and trust, and in particular, access to search and examination information, and trust in such information. The Delegation believed that investigating the tools that had been used by offices to share their work products would greatly assist other offices to seek to participate in work sharing. The Delegation further referred to the WIPO CASE as one of the examples of tools allowing online access to the work of another office. The Delegation noted that WIPO CASE was an online platform that provided participating offices quick and efficient access to a large variety of search and examination documents. It was the view of the Delegation that having trust in the work of another office was also a key element under pinning effective work sharing. The Delegation considered that making available details of how examiners search applications such as through the sharing of an examiner's search strategy, would lead to an increase in trust in the search conducted by another office and would help offices to learn from the experiences of other offices in conducting searches. Lastly, the Delegation welcomed a study analyzing the benefits and possible impediments to making national collections available. The Delegation was of the opinion that it was important that offices had access to as much of the relevant prior art as practical. Accordingly, the Delegation fully supported the proposal from the United States of America as outlined in document SCP/23/4.

71. The Delegation of the United Kingdom stated that work sharing among patent offices helped improve quality by giving examiners a head start, ensuring that prior art found by another office was not missed, reducing duplication of effort and improving efficiency. The Delegation clarified that the UK Intellectual Property Office (UKIPO) did not grant patents based on the work of another office without doing further work of their own. Rather, the Delegation observed that work sharing allowed examiners of the UKIPO to build upon the work already done at another office, and with such assistance, it was only possible for quality of search and examination to be improved. The Delegation specified that in any case, the final decision of whether or not to grant a patent rested solely with the UKIPO, which assessed the patent application against UK law. The Delegation supported the proposed study outlined in paragraph 12 of document SCP/23/4, which would help provide evidence to determine any effect that work sharing had on the efficiency of search and examination and quality of granted patents. The Delegation further supported the survey proposed in paragraph 15 of the document concerning sharing of search strategies. The Delegation noted that the UKIPO supported the sharing of search strategies by patent offices as well as allowing other patent offices to make use of the search logic already carried out. The Delegation believed that such measures provided transparency to third parties, providing reassurance that a full and proper search had been carried out before a patent was granted, helping to ensure that patents were granted with a high presumption of validity. The Delegation noted that technical changes to allow the UKIPO to share its national search strategies had been planned. In addition, the Delegation supported the study proposed in paragraph 16 of the document, which, in its view, would help to ensure that all offices had access to the widest range of prior art.

72. The Delegation of Romania, speaking on behalf of the CEBS Group, shared the view that work on increasing quality of patents would be necessary for the benefit of all Member States. It stated that the CEBS Group was in favor of launching a questionnaire on the quality of patents based on the proposals made by the Delegations of Canada, the United Kingdom, Denmark and the United States of America. The Delegation believed that a compilation of the answers would certainly result in a useful document. The Delegation further supported the proposal made by the Delegation of Spain at the nineteenth session of the SCP. With regard to work sharing programs, the CEBS Group thanked the Delegation of the United States of America for their eloquent presentation of its proposal that the Delegation fully supported.

73. The Delegation of Japan stated that at the JPO, in order to reduce disparities in terms of decisions among examiners as well as to increase the stability of patent rights, the "Quality Policy" and "Quality Manual" had been created, and that all JPO examiners conducted examinations in compliance with the fundamental Policy and Manual. The Delegation further illustrated some of the JPO's initiatives relating quality management. First, the Delegation mentioned that all notices prepared by examiners in the various technical fields were checked and approved by directors in charge of their respective technical fields, before sending out the notices. In particular, the Delegation pointed out that when preparing notices to which close attention should be paid, examiners consulted with their directors and other examiners before preparing the notices. The Delegation observed that conducting consultations might promote consistent operational practices of examinations in terms of decisions on patentability. The Delegation declared that in fiscal year 2014, around 83,000 consultations had been conducted in the examination departments. The Delegation further noted that, in order to review the quality of examinations, after all notices were checked by directors, Quality Management Officers conducted quality audits on randomly selected notices before those notices were sent to applicants. The Delegation clarified that when any deficiencies were found in the audits, they would be corrected and the notices would be sent to applicants. The Delegation explained that in addition to those practices, the JPO, by giving feedback to examiners in charge about the results of the audits, was working to enhance the capabilities of examiners for further improving examiners' decisions. The Delegation emphasized that the JPO was aiming to ensure the granting of more stable rights by certain synergy effects created by appropriate decisions made by examiners in compliance with the examination guidelines and the JPO's initiatives for managing the quality of examinations. The Delegation further observed that enhancing the quality of patents required a large amount of time and resources of IP offices. Therefore, the Delegation believed that work sharing between IP offices was important utilization of time and resources in an efficient manner. For those reasons, the Delegation strongly supported the proposal made by the Delegation of the United States of America on the study of work sharing.

74. The Delegation of China noted that there were many subjects on the topic of quality of patents. The Delegation thanked all Delegations for their suggestions. The Delegation shared the view that improving the quality of patents was crucial to improve the patent system. The Delegation believed that the capacity of each office was the pre-condition of improving patent quality, and that the substance of discussion under that agenda item should be further enriched. The Delegation suggested that countries carry out more information sharing exercises and discussions concerning capacity building of patent offices, which would facilitate better exchanges and sharing among Member States. For example, the Delegation expressed its wish to hear more from other countries about their experience concerning the use of IT such as patent databases, search and examination tools, as well as the provision of technical to developing countries, the training and exchange of patent examiners, including the development of quality management and control system for patent offices.

75. The Delegation of Mexico agreed with a number of the arguments put forward by other Delegations as to the importance of work sharing. The Delegation believed that the SCP was the ideal forum for the presentation of the different, alternative methods of work sharing and considered that among those, each patent office could choose the most appropriate method for them. The Delegation, therefore, supported the proposal made by the Delegation of the United States of America.

76. The Delegation of Colombia expressed its agreement with the statement made by the Delegation of Mexico and supported the proposal made by the Delegation of the United States of America. The Delegation drew the attention of the Committee to the fact that work sharing was not a new topic and that, the PCT could be the oldest example of work sharing between patent examiners. The Delegation observed that work sharing had evolved into different forms, for example, the various PPH which had been undertaken by a number of offices at the bilateral level, or in the framework of a multilateral agreement. The Delegation stated that Colombia had recently established the PPH arrangements with various patent offices, among which, the most recent was the one with the Republic of Korea. The Delegation noted that Colombia was considering signing the PPH arrangements with the European Patent Office and with the four patent offices of the countries party to the Pacific Alliance. The Delegation believed that the Secretariat should update information in the area of work sharing by creating a database providing a snapshot of what was happening in relation to work sharing around the world. The Delegation observed that many countries had not used that tool, began recurring to work sharing.

77. The Delegation of Georgia expressed its full support for the proposal made by the Delegation of the United States of America and for the statement made by the Delegation of Romania on behalf of the CEBS Group. The Delegation further expressed its wish to share the experience of the Georgian IP office. The Delegation stated that, being the Georgian IP Office relatively small, it had limited capacity as for search and access to some sophisticated databases. For that reason, the Delegation believed that the results and information which the other offices might have supplied were crucial for the work done by their IP Office. The Delegation further considered that such information could be beneficial for the offices having the same constraints of the Georgian IP Office, and emphasized that while work sharing implied sharing of information, the power to decide whether or not to grant a patent, remained up to the national IP office.

78. The Delegation of Nigeria, speaking on behalf of the African Group, expressed the wish to clarify that the African Group did not oppose the concept of work sharing. The Delegation, however, believed that such a practice had worked effectively in bilateral and plurilateral agreements, and preferred that work sharing continued to work in that way. The Delegation stressed that the African Group might consider further proposals on work sharing in the future work and expressed its intention to eventually discuss it in that moment. The Delegation reiterated that the African Group was not against work sharing and, quite the contrary, saw the merit in it. The Delegation further specified that some African countries were looking at work that had been done by patent offices of other countries or regions.

79. The Representative of TWN stated it was crucial that Member States engaged in a discussion in order to reach consensus on the meaning of the word “quality”. The Representative was of the opinion that without a common understanding of that word, it would be difficult for the Committee to move forward. The Representative considered that it was important to protect quality of patents in order to avoid granting patent protection to frivolous inventions. The Representative believed that the solution to guarantee quality patents was not work sharing among different patent offices, since patentability criteria were defined by national legislation and those might be different from one country to another. In

that regard, the Representative was of the opinion that opposition systems should be considered as a mechanism to insure quality of patents. The Representative observed that some studies on opposition systems had already been prepared but that there was no information available on how opposition systems resulted in avoiding the granting of frivolous patents, in particular in the public health sector. The Representative therefore stated the Secretariat should have provided case studies on that specific topic. Further, the Representative of TWN made reference to the proposal of the Delegation of the United States of America on a study analyzing the benefits and possible impediments of making national collections of prior art available to all offices, for example, through an IT portal. With that regard, the Representative observed that certain kind of databases, for instance those containing information on traditional knowledge, were protected databases and therefore not accessible to the public at large. The Representative expressed the concern that if those databases were made accessible to the public in general, the possibilities of bio piracy might have increased.

80. The Representative of ARIPO stated that the meaning of work sharing had been misunderstood, since that did not mean validation of patents granted by other offices. The Representative further shared the experience of his regional patent office in relation to work sharing and stated that ARIPO, despite the fact that used the work carried out by other offices to grant patents, always based its decision on its own legislation. The Representative believed that work sharing was essential for an efficient patent system. The Representative noted that for a certain number of countries, there was need of technical assistance with regard to quality control and capacity building concerning examination of patent applications. The Representative considered that it was essential that WIPO provided a database, such as the WIPO CASE, where patent offices could access all of the available prior art, as proposed by the Delegation of the United States of America in its opinion, such initiative would be extremely important. With regard to traditional knowledge and bio piracy, ARIPO was of the opinion that making national collections of prior art available to all offices would not increase, but instead reduce, the risk of bio piracy, since thanks to such a tool, it would have been possible to take into account traditional knowledge as part of prior art, and, therefore, it would be possible to avoid the grant of invalid patents.

81. The Chair took note of the large support for the proposal on work sharing made by the Delegation of the United States of America.

82. The Delegation of Iran (Islamic Republic of) thanked the Delegation of the United States of America for their proposal, but reiterated its disagreement in relation to it. In its view, work sharing was a procedural aspect of the patent grant procedure and therefore, believed that the Committee was not the appropriate forum to discuss that topic.

83. The Delegation of India, speaking in its national capacity, reiterated that the sharing of work of other offices could weaken examination process and the capability of patent offices in developing countries. The Delegation believed that to improve the quality of patents, steps should be taken to build capacity among patent offices of developing countries for enabling them to perform their quasi-judicial functions according to their national laws in the best manner possible. The Delegation further stated that work sharing should not become an area for norm-setting in the future.

84. The Delegation of Greece expressed its support for the proposal made by the Delegation of the United States of America.

85. The Representative of Innovation Insights believed that patent quality was a critical topic for the Committee. The Representative stated that Innovation Insights was a business organization and therefore it was their wish to underscore that patent quality was important

for innovative firms. The Representative was of the opinion that poor quality patents, i.e., patents that did not deserve to be granted under the law of the relevant jurisdiction, created uncertainty in the marketplace and could deter investment and collaboration. The Representative noted that firms wanted quality patents in their own portfolios and in the portfolios of those in the market. The Representative expressed its availability to share in more detail perspectives on patent quality across sectors. The Representative observed that if the SCP work could not move forward on the important topic of quality without a definition of the term "quality", it might be the moment to dedicate time to that issue. In its view, it was an issue of IP offices applying their domestic laws correctly.

Sharing session on inventive step assessment in examination, opposition and revocation procedures

86. The Chair opened the sharing session on experiences of experts from different regions on inventive step assessment in examination, opposition and revocation procedures.

87. The Delegations of Spain, the United Kingdom, the United States of America and Colombia gave presentations describing their respective experiences on inventive step assessment in examination, opposition and revocation procedures. There presentations are available at: http://www.wipo.int/meetings/en/details.jsp?meeting_id=35699.

88. The Delegation of the Russian Federation commended the Secretariat for the preparation of the sharing session as well as the speakers who took the floor during that session. The Delegation expressed its wish to share some general information related to its experience regarding the assessment of inventive step criterion. The Delegation explained that the assessment of the inventive step in the Russian Federation related to the use of the notion of expert and the application of the national methodology of assessment of the inventive step. The notion of expert in the Russian Federation referred to a hypothetical person possessing general knowledge of the relevant art, having access to all prior art, possessing work experience and familiar with experiments which were usual in the relevant art. The Delegation stated that the general knowledge of the relevant art was understood as knowledge predominantly based on information available in manuals, monographs and textbooks. The Delegation further explained that an invention was recognized to involve an inventive step if an expert in the art had not identified known solutions having characteristics coinciding with the distinctive features of the invention. An invention was also recognized to involve an inventive step if relevant known solutions were identified but the relevance of their characteristics for the technical result claimed by the applicant was not confirmed. The Delegation stated that the algorithm of examination on the basis of distinctive features included: (i) identification of the closest analogue (prototype); (ii) identification of characteristics differentiating the invention from the prototype; (iii) identification of prior art characteristics coinciding with the distinctive features of the invention; and (iv) analysis of such solutions from the point of view of availability of information confirming known relevance of distinctive features for the technical result claimed by the applicant. Further, the Delegation stated that the second applicable algorithm of examination was based on the "problem and solution" principle. In the Russian Federation, an examiner was entitled to choose the most appropriate algorithm of examination. The Delegation further noted that, according to the current legislation, any objection by an examiner concerning, in particular, the lack of inventive step, should be supported by arguments of technical nature with reference to technical literature. Reference to technical literature was not required only if the arguments of the examiner were based on general knowledge of relevant art. The Delegation stated that the existing practice of application of the above algorithms of examination of inventions was set out in the Guidelines for the Examination of Patent Applications. Further, the Delegation stated that the analysis of the quality of examination conducted by ROSPATENT had confirmed that the assessment of inventive step

significantly affected the quality of patents. Since the question of what was meant by quality of patents had been raised repeatedly by delegations of various countries, the Delegation was of the view that it would be appropriate to address that issue. In that regard, the Delegation stated that in the Russian Federation, two concepts were applied: "quality of examination of application for the grant of a patent for an invention" and "patent quality". The Delegation explained that the first concept was broader and involved assessment of the office's examination process, including assessment of the timeliness of the examination, the quality of all documents prepared in the course of the examination, and the quality of the decision to grant a patent and, therefore, the quality of the patent. In the view of the Delegation, a patent for an invention could be considered of quality if it could not be successfully challenged in the manner prescribed by law. Under its law, the Delegation stated, a patent could not be successfully challenged if the patented invention complied with all the criteria of patentability, the description of the invention for which the patent was granted met the requirement of sufficiency of disclosure, and the claims under which the patent was granted did not extend beyond the disclosure of the invention presented on the filing date. The Delegation continued that the assessment of the quality of a patent for an invention could be implemented by an oversight agency. Noting however that such assessment would be very labor intensive, the Delegation stated that the ROSPATENT evaluated the quality of a patent on the basis of an indirect indicator – the number of satisfied objections filed against the patent. Specifically, that indicator was calculated as a ratio of the number of satisfied objections to the number of filed objections. Further, the Delegation stated that the quality of patents directly related to the quality of the examination process, in particular the quality of assessment of inventive step. In the Russian Federation, a large share of patents was challenged on the basis of lack of inventive step. Noting that, in their practice of assessment of inventive step, the examiners faced the cases which were not regulated by the guidelines for the examination, the Delegation highlighted the high value of information provided in document SCP/22/3. In the opinion of the Delegation, the document could be used to improve national examination methodologies. However, noting that the document lacked description of practical examples, the Delegation proposed to supplement it with such examples on the basis of common model applications developed by the Secretariat for all offices. The Delegation clarified that, for such examples to be understood by all offices, it would be appropriate to consider the inventive step of simple and generally understood objects, such as brushes, sharpeners, thermometers, etc. From the point of view of the Delegation, another issue that deserved special analysis within the framework of assessment of the inventive step was the issue of how additional data and evidential information submitted by the applicant could be taken into account in determining inventive step, described in paragraph 121 of document SCP/22/3.

89. The Delegation of Japan expressed its appreciation for the presentations made on the topic of inventive step which were beneficial for all Member States. The Delegation stated that, in Japan, regulations on inventive step were designed to exclude inventions that ordinary persons skilled in the art would easily be able to create inventions to which patents were granted. That was because granting patent rights to such inventions was useless in terms of any technological progress to society and prevented any progress coming forth from such inventions. The Delegation further noted that in examining inventive step, the Japan Patent Office (JPO) did not employ the so-called "problem-solution approach". The Delegation stated that although there were some methods for examination of inventive step, the JPO, through its long experience of examiner exchange program with many foreign IP offices, had recognized that such various methods created no material difference on the results of examination regarding inventive step when examiners found the same prior arts. The Delegation emphasized that in order to grant high quality patents, the following elements were essential: (i) the basic concepts of and judgment standards on inventive step must be clearly stated in the examination guidelines; and (ii) when making decisions on inventive step in examination processes, uniformed judgments without any discrepancies

must be made in line with the examination guidelines. The Delegation further stated that, in order for IP offices to check whether or not their examiners made appropriate decisions on inventive step, it was essential to establish a framework for managing the quality of examination so that IP offices could check the examination results before sending them to applicants. In conclusion, the Delegation stated that Japan was interested in having a better understanding of the other offices' practices and would like to continue the discussions on those issues in a constructive manner.

90. The Delegation of Romania stated that the inventive step requirement had been introduced in the Romanian Patent Law in 1991. The Delegation noted that during the substantive examination procedure, the office examined novelty, inventive step and industrial applicability. The Delegation stated that from its introduction, the inventive step criterion assessment in the examination procedure had been subject to continuous evolution. The Delegation noted that the Romanian Patent Office almost always applied the problem-solution approach in order to decide whether an invention involved an inventive step, which consisted of the following steps: (i) determining the closest prior art at the relevant date, filing date or priority date, as the case may be; (ii) establishing the objective technical problem to be solved by the invention, by studying the differences between the claimed invention and the closest prior art and; (iii) considering whether or not the claimed invention starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person in the art. The Delegation clarified that the evolution of the examination procedure in the Romanian Office towards the problem-solution approach had been achieved in time as a consequence of gaining experience during annual trainings organized by the EPO for patent examiners from different technical fields and different levels of experience (beginners, intermediates and advanced) as well as a consequence of the exchange of practical experience with examiners from other offices. The Delegation stated that, at present, its office was able to organize trainings for examiners from patent offices of neighboring countries, such as, for instance, Bosnia Herzegovina, Republic of Moldova, and to carry out search reports with opinion on patentability for countries such as Slovenia and the Republic of Macedonia. The Delegation further noted that, although the most subjective criterion of patentability, the inventive step represented a way to differentiate the quality of patents, by their contribution level to the state of the art. That was reflected in the Romanian patent system in the existence of two ways of protecting the inventions, namely, by patents or utility models. In particular, the Delegation explained that, in the Romanian practice, if, after performing the substantive examination of a patent application it had been ascertained that the invention having as subject matter a product did not involve an inventive step, the Romanian Patent Office could not take a decision to reject the application before having sent the applicant a notification informing the applicant the possibility of transforming the patent application into a utility model application. The Delegation stated that, in Romania, utility models were registered without substantive examination. According to the Utility Model Law No. 350/2007, any technical invention could be protected by the utility model protected on condition to be new, to pass the level of simple ordinary skills and to be industrial applicable. Further, the Delegation noted that due to the inventive step criterion being the most subjective of the patentability criteria, it was most frequently invoked in revocation or invalidation procedures in its country. While judges in Romania were periodically trained in relation to the evolution of assessing the patentability criteria, in litigation cases on patentability, the courts usually requested a so-called "technical point of view" of the examination division of the Patent Office.

91. The Delegation of Morocco stated that the protection of industrial property in Morocco was governed by the provisions of Law No. 17-97 on the Protection of Industrial Property, as amended and supplemented by Laws Nos. 31-05 and 23-13. The Delegation stated that that law provided for the protection of industrial property rights in accordance with the pertinent international standards set out in the international treaties to which Morocco was

party, including the WTO TRIPS Agreement and treaties administered by WIPO. The Delegation continued that, in the field of patents, applications filed with the Moroccan Office of Industrial and Commercial Property were followed by a preliminary search report with a patentability opinion. The report was drafted on the basis of the claims filed, taking into account any description and drawings provided. The report cited documents from the state of the art relevant to the application. Each citation was made in relation to the claims that it addressed, and those citations underpin the opinion formed with regard to the patentability requirements. The Delegation further stated that, once established, the preliminary search report with patentability opinion was notified to the applicant, who, under Article 43(1), could file further claims or submit comments in support of the claims retained, within a period of three months with effect from the date of notification of the preliminary search report and patentability opinion. The application, together with the preliminary search report, would be published 18 months after the filing date. Third parties had two months to file any observations relating to the patentability requirements. After the application had been published, the examiner must consider any changes introduced by the applicant and/or any third party observations, with a view to establishing a second search report, known as the final search report with patentability opinion. That report would provide the final decision either to grant a patent or to reject the application. The Delegation stated that the aim of the search was to define the relevant state of the art with a view to establishing whether and, if so, to what extent novelty and inventive step were present in the claimed invention for which protection was sought. That process ensured the applicant of legal certainty and prevented the office from granting patents to applications devoid of innovation. The Delegation continued that, the search was conducted using collections of documents and internal and external databases. Mostly they included patent documents from a range of countries, supplemented by articles from periodicals and any other non-patent literature. The patentability opinion that accompanied the search report would state whether the claimed invention met the requirements of novelty, inventive step and industrial applicability. Further, the Delegation provided information as regards the assessment of novelty criterion in Morocco. Specifically, the Delegation stated that, in its country, the concept of novelty was governed by Article 26 of Law No. 17-97 as amended and supplemented by Law No. 23-13. Under Article 26(1), an invention would be considered to be new if it would not form part of the state of the art. The claimed invention must be examined and compared with the state of the art as of the filing date. The first step involved delimiting the state of the art. In that regard, Article 26(2) provided that “the state of the art shall comprise everything accessible to the public by means of a written or oral description, use or any other means before the filing date of a patent application in Morocco or of a patent application filed abroad with a valid priority claim. The content of patent applications filed in Morocco on a date that is earlier than the date referred to in subparagraph 2 above and published on or after that date shall also be considered to form part of the state of the art.” The Delegation further quoted a provision which stated that where a priority was claimed: “for the right of priority to have the effect, the date of priority shall count as the date of filing of the patent application for the purposes of Article 26(2) and (3)”, and stated that, in such cases, the date of reference for delimiting the state of the art was the first filing date, i.e., the priority date of the application, and that the assessment of novelty was made in relation to that date. Further, the Delegation stated that Article 26(2) and (3) did not exclude the patentability of substances or compositions included in the state of the art for use in surgical or therapeutic procedures or diagnostic methods, insofar as the use in any of those methods did not form part of the state of the art. The Delegation noted that, accordingly, any specific use in surgical or therapeutic procedures and diagnostic methods was acceptable insofar as it did not form part of the state of the art. As regards the assessment of inventive step criterion, the Delegation informed the Committee that, in Morocco, the concept of inventive step was governed by Article 28 of Law No. 17-97 as amended and supplemented by Law No. 23-3. Under that provision, an invention was considered to possess inventive step if, for a person skilled in the art, it did not obviously result from the state of the art. The Delegation noted that what

was excluded from the assessment of inventive step was the content of patent applications which were filed in Morocco on a date prior to the filing date of the patent application but which were only published on or after that date. In relation to the method used for assessing inventive step criterion, the Delegation stated that the Moroccan legislation defined neither a method for assessing inventive step nor the threshold for inventive step. Examiners most often applied the problem-solution approach by following those five steps: (i) identifying the most relevant prior art; (ii) identifying the difference between the prior art and the invention; (iii) determining the technical effect brought about by the difference; (iv) establishing the "objective technical problem" to be resolved; and (v) examining whether the invention would have been obvious to a person skilled in the art taking into account the technical problem and the most relevant prior art. In relation to a person skilled in the art, the Delegation explained that that notion was defined as a practitioner of the relevant technical field, who possessed of average knowledge and ability and was aware of what had been common general knowledge in the art at the relevant date. The person was also presumed to have had access to all elements of the state of the art, particularly the documents cited in the search report, and to have had available the means and capacity that was normally associated with the technical field to carry out routine work and experimentation. Finally, the Delegation noted that a person skilled in the art had the same degree of knowledge for assessing inventive step and sufficiency of disclosure requirements.

92. The Delegation of the Dominican Republic stated that on May 8, 2000, the Dominican Republic had enacted Law No. 20-00 on Industrial Property incorporating patentability requirements into its national legislation. It superseded Law No. 4994 of 1911, which had no provisions governing substantive examination and which granted only patents of confirmation or revalidation. The Delegation stated that, in relation to a definition of a person skilled in the art, Article 6 of Law No. 20-00 on Industrial Property contained the concept of a specialist or a person skilled in the art; however, it did not provide any further definition of that concept. That provision red: "An invention has inventive step if, for a specialist or person skilled in the relevant technical field, the invention is neither obvious nor obviously derived from the state of the relevant art." The Delegation noted that, as regards the methodology used to evaluate inventive step, the problem-solution approach was applied, in line with the Manual for the Organization and Examination of Patent Applications of the Industrial Property Offices of Countries of Central America and the Dominican Republic. Further, the Delegation stated that when an objection cited a lack of inventive step (no unexpected technical effect), the applicant could submit comments in that respect and, for example, in the case of pharmaceutical-chemical applications, provide a comparative analysis of biological activity (CI50) with regard to the closest prior art or another type of analysis, depending on the problem at hand, where the applicant deemed it to be material in mounting a defense against an objection. The Delegation stated that the legal basis for that resided in Article 22(5) of Law No. 20-00 on Industrial Property, which stated the following: "(5) If any of the requirements for granting the patent are not fulfilled, the National Office of Industrial Property shall notify the applicant so that he or she may, within a period of three months, complete the documentation filed, correct, modify or divide the application, or present such comments or documents as he or she may deem advisable.". As regards the utility models, the Delegation explained that that type of protection was granted for technical inventions whose inventiveness was less than that required for inventions but which proved beneficial to technological work. In that respect, the National Office of Industrial Property had issued Resolution No. 62 of August 8, 2006, which stipulated that when conducting the substantive examination of an application for a utility model, inventive step was not examined and thus the same strict criteria as for patents were not used.

93. The Delegation of Chile thanked the Delegations which made the presentations as well as other Delegations which had shared their experiences on inventive step assessment in examination, opposition and revocation procedures. The Delegation reminded the SCP that

it had shared its national experience on the issue at the previous session. The Delegation noted that the presentations had highlighted the importance of discussing each of the dimensions involved in the patent system, particularly those which were related to the quality of patents. The Delegation stated that, for Chile, the issue of quality of a patent corresponded to both, to form as well as to substance. In particular, the Delegation considered that both the efficiency and efficacy of the administrative procedures of the patent office when they processed applications as well as correct analysis of the criteria for patentability contributed to granting of quality patents. Likewise, the conditions of the office and the quality of applications were elements which had effect on the result. Therefore, the Delegation was of the view that the Committee should consider each and every one of the elements which contributed to the granting of quality patents in a balanced manner and that they should be part and parcel of its future work. The Delegation stated that only in that way, the Committee could understand the benefits of carrying out the detailed analysis of the patentability requirements, the flexibilities, as well as advantages and disadvantages of implementing the different mechanisms and models of work sharing among the offices. In conclusion, the Delegation stated that, although the work of the Committee was confined to fact-finding and not lead to harmonization at that stage, it was necessary that it continued working on different topics on its agenda. In addition, the Delegation expressed its belief that the work of the Committee should be carried out in a balanced manner corresponding to the interests of all Member States.

94. The Delegation of Germany thanked the Delegations of Spain, the United Kingdom, the United States of America and Colombia for their interesting presentations. The Delegation stated that the presentations could build a useful basis for broader and better understanding of the issue under consideration. Therefore, the Delegation expressed its wish to continue to exchange experiences from different regions on the issue. Noting further that the presentations had been highly valuable as they had highlighted the convergences as well as differences with regard to the details of the examination of the inventive step criterion, the Delegation stated that the Committee should focus its attention on those details.

95. The Delegation of Mexico thanked the Secretariat for the excellent work in producing the study on the inventive step criterion as well as all the delegations for their excellent presentations. The Delegation informed the SCP that, in its country, a problem-solution approach was used for determining the inventive step, the steps of which had been well explained in the presentations of the Delegations of Colombia and Spain. The Delegation further expressed its great interest in continuing studying the issue which directly supported the daily work of the patent offices.

96. The Delegation of India, with respect to the quality of patents, stated that a sharing session on the sufficiency of disclosure should also be considered as one of the agenda items. The Delegation noted that the studies concerning inventive steps and sufficiency of disclosure had been both conducted under the issue of quality of patents. From that point of view, a sharing session on the sufficiency of disclosure was equally important for the Delegation and should be given its due consideration. Further, the Delegation stated that, as the inventive step requirement was the final gatekeeper of the patentability, lowering the standard of the hypothetical addressee would lower the level of inventive step. The Delegation observed that there was no single formula defining the standard of the skilled person and the notion of the skilled person varied significantly from one country to another. Referring to its statement made at the previous session of the SCP, the Delegation quoted the statement made by the Supreme Court of the United Stated of America that “A person of ordinary skill is also a person of ordinary creativity, not an automaton”. The Delegation further stated that in the light of the teaching of the KSR which the Intellectual Property Appellate Board (IPAB) had relied upon, it was not difficult to understand the decision of the IPAB, which had stated that: “He does not need to be guided along step by step. He can

work his way through. […] he is neither picking out the 'teaching towards passages' like the challenger, nor is he seeking out the 'teaching away passage' like the defender". The Delegation continued that the notion of the skilled person appeared almost everywhere in the patent statute: in understanding novelty, inventive step, industrial applicability, claim construction and sufficiency of disclosure. The Delegation questioned whether such person always lacked inventive ingenuity in all fields of technology in evaluating the inventive step, and whether that person was the same in all legal issues. Further, the Delegation referred to some examples which, in its view, could shed some light on those questions. In particular, the Delegation stated that, in 1989, in Genentech's Patent [1989] RPC 147, it had been held that the notional team for considering obviousness might have wider skills than the team required for sufficiency, and that Lord Mustil had commented that "Where the art by its nature involves intellectual gifts and ingenuity of approach, it would, I believe, be wrong to assume that the hypothetical worker is devoid of these gifts". Further, the Delegation stated that, in a paper, "The Skilled Addressee", presented at the 26th Annual Conference at Intellectual Property Society of Australia and New Zealand, held on September 2012, the Honorable Justice John Middleton asked the question, "Must the skilled addressee always be non-inventive?" While replying the question in negative, the Honorable Justice had referred to a number of judgments including that of Genentech. The Delegation continued that, in the opinion of the Honorable Justice, in some fields, for example, with regard to pharmaceutical or veterinary patents, courts had recognized that the skilled addressee (or team) might have PhD qualifications in a relevant field of science. In such fields, the skilled addressee might also have a capacity for original research. The Delegation noted that, in highly technical fields, such as biotechnology or pharmaceuticals, a degree of inventiveness, ingenuity or initiative was effectively a prerequisite for being involved in that field in the first place. The Delegation stated that in such circumstances, the concept of the utterly non-inventive skilled addressee was potentially very artificial. The Delegation continued that the difference of such standards was even noticed by the decisions of the Court of Appeal of the EPO in *Schlumberger Holdings Limited v Electromagnetic Geoservices* (AS [2010] EWCA Civ 819) where it had been confirmed that in some instances, the technical backgrounds of the skilled person for inventive step on the one hand, and the skilled person for claim construction and insufficiency on the other, may not be the same. The Delegation concluded that the TRIPS Agreement was silent on the issue of the skilled person and allowed WTO Members to formulate their own standards.

97. The Delegation of China thanked the four Delegations for sharing their national experiences relating to the assessment of inventive step criterion and also the Secretariat for very good analysis of the national practices on issue contained in documents SCP/22/3. In that regard, the Delegation drew attention of the Committee to paragraph 19 of document SCP/22/3 Summary, which provided the detailed information regarding the assessment of inventive step in China. The Delegation stated that in its country, with regard to inventive step, the relevant laws and guidelines for patent examination were applied in the examination, reexamination and invalidation procedures.

98. The Delegation of Greece thanked the Delegations that had presented their national experiences on inventive step assessment in examination, opposition and revocation procedures, and other delegations for their interventions on that issue. The Delegation highlighted that inventive step was a very core part of substantive patentability requirements and that exclusive rights should be awarded only to the invention whose contribution to the society deserved it. The Delegation stated that, in that regard, exchange of practices and information among experts on that issue was useful. In its view, further deepening of understanding on the practices relating to inventive step in respective offices could lead to a fundamental basis upon which international work sharing and collaboration could be built. The Delegation noted that understanding on the methodologies employed for evaluating

inventive step by various offices was critical not only for the use of examination results of other offices, but also for the use of search results.

99. The Delegation of Spain expressed its wish to comment on the exchange of experiences relating to the evaluation of inventive step. In particular, the Delegation stated that it was interesting to see that in common law countries the manner in which inventive step was examined was determined by case law, while in civil law countries, the situation was more static. The Delegation stated that, in civil law countries, the law should be interpreted without too much intervention from the courts. Further, the Delegation noted the relevance of appropriately determining the state of the art and the importance of avoiding "*ex-post facto*" analysis. In that regard, the Delegation stated that its attention had been drawn to the dynamic character of the person skilled in the art in the United States of America. Further, the Delegation observed that according to continental European law, a person skilled in the art was more static and less time was spent in defining the said person. The Delegation found it also interesting to learn about the "rationales" created by the case law of the United States of America. In particular, the Delegation stated that one felt a healthy sense of envy when looking at the technical level of the judgements made in case law of that country concerning the evaluation of inventive step. Further, referring to the presentation made by the Delegation of Colombia which had indicated that in that country they did not examine inventive step in the case of utility models, the Delegation noted that, in Spain, while inventive step was a requirement for obtaining the utility model protection, the required level was lower than for patents. Further, the Delegation reiterated that once it became possible to include topics of substantive patent law with a significant technical component in the work of the Committee, as was the case with inventive step and sufficiency of disclosure, it was of maximum interest to all Member States independent of their level of development that discussions on those topics be continued. Referring to the statement made by the Delegation of India, the Delegation invited Member States to propose new studies on inventive step and sufficiency of disclosure. The Delegation was of the view that it would be desirable to further explore the issues contained in document SCP/22/3 and to include, for example, more information on case law, focusing on certain areas which posed greater difficulties when assessing inventive step, taking fully into account the contributions made by Member States. Further, the Delegation encouraged other Member States to suggest activities that were related to inventive step and could be included in a new study, for example, as it had been proposed by the Delegation of the Russian Federation, a series of simple, additional examples of evaluation of inventive step to supplement document SCP/22/3.

100. The Representative of TWN stated that, for the time being, what he understood by the term "quality" was the prevention of patenting of frivolous inventions. The Representative referred to the presentation made by the Secretariat on the issue of inventive step at the previous session and noted that various methods for assessing inventive step were employed by various offices. In that regard, the Representative stated that the critical point was to determine what were the advantages and disadvantages of those methods in preventing frivolous patents. The Representative stated that, for instance, the problem-solution approach had a disadvantage of undermining the technological advancement. Further, the Representative posed some questions in relation to the presentations made on the subject of inventive step during the sharing session. In particular, he asked the Delegations of Spain and the United Kingdom whether their practices on assessment of inventive step varied from the practice of the EPO. Further, in relation to the presentation made by the Delegation of the United States of America, he observed that practical examples for each rationale elaborated by that Delegation were missing. Further, the Representative disagreed that cDNA should be patentable, as due to technological advancements, it became easy to make it, unlike in the past. Further, referring to the KSR decision in the United States of America, the Representative questioned how the Delegation

could justify the patenting of cDNA in light of the rationales elaborated in that decision. He finally asked whether the USPTO had done any analysis of whether there had been any decrease in the grant of patents in the post KSR period.

101. The Delegation of Spain responded to the question posed by the Representative of TWN that, while each of the Member States of the EPO had their own patent laws, their examination practices were largely harmonized with the practice of the EPO. In addition, the Delegation stated that its office followed the EPO's guidelines for examination and the decisions of the EPO Boards of Appeal.

102. The Delegation of the United States of America responded to the question posed by the Representative of TWN that it would be pleased to provide detailed examples on various rationales that came out from KSR case if the topic would remain on the agenda of the SCP in the future sessions of the SCP. Regarding the request of data on patents in the post KRS period, the Delegation stated that, at that point, it could not provide specific information. In addition, with regard to the statement made by the Representative of the TWN, the Delegation underlined that "frivolousness" was not one of the tests for whether something was patentable or not. Typically, the Delegation stated, the criteria for patentability were novelty, non-obviousness (or inventive step), usefulness (or industrial applicability) and various requirements for clarity and support of the claims.

103. The Representative of CIPA stated that there were a number of reasons for provision of opposition procedures in various patent laws. If an opposition procedure was provided in a country as a check of quality of granted patents, then, the Representative stated, it was only useful for that purpose if there was a specified time limit for filing the oppositions. As an example, the Representative noted that, prior to 1977, it had been possible to file oppositions within three month after the grant of the patent in the United Kingdom, and that there had been many oppositions filed at that time. The Representative observed that, according to the current law in that country, opposition could be filed at any time during the life of the patent, and that virtually no oppositions had been filed.

AGENDA ITEM 7: PATENTS AND HEALTH

104. Discussions were based on documents SCP/16/7, SCP/16/7 Corr., SCP/17/11 and SCP/21/9.

105. The Secretariat presented document SCP/21/9 and reported on the progress made in the PATENTSCOPE Chemsearch Project.

106. The Delegation of Nigeria, speaking on behalf of the African Group, thanked the Secretariat for their preparation for the seminar on the relationship between patent systems and, *inter alia*, challenges related to availability of medicines in developing countries and LDCs, including on the promotion of innovation and fostering of the requisite technology transfer to facilitate access to generic and patented medicines in those countries. The Delegation stated that, with due respect to the panelists and in full recognition of their expertise and professionalism, it would like to reiterate the importance of insuring a balance in the panel representation in such events in the future, especially, as the subject was primarily related to developing countries and LDCs. Nevertheless, the Delegation looked forward to engaging in the resourceful seminar. The Delegation further noted that, in the work of the SCP, one of the primary areas for the African Group was the subject of patents and health. The Delegation stated that the African Group and the Development Agenda Group had submitted proposal contained in documents SCP/16/17 and SCP/16/7 Corr. in 2011 which contained a work program comprising of studies, information exchange and

technical assistance aimed at facilitating the use of the patent system and its flexibilities to meet public health needs and priorities of developing countries and LDCs, corresponding to Development Agenda recommendations 1, 7, 9, 14, 31 and 40. The Delegation continued that, whereas the updated proposal was to be submitted at the twenty-third session of the SCP, the African Group had decided to wait and possibly take counsel from the robust discussion and ideas anticipated at that session's half day seminar on patents and health. To that effect, the updated proposal would be made available in advance of the twenty-fourth session of the SCP. The Delegation stated that access to safe, affordable and effective medicine and the requisite technology transfer to facilitate the amelioration of accessibility had remained a fundamental problem for developing countries and LDCs in their request to achieve fair level of self-sufficiency in such a critical area of public health. The Delegation expressed its hope that the seminar could sensitize the issue of the role of the patent system *vis-à-vis* difficulties faced in accessing essential medicines by developing countries and LDCs and giving a due account to the TRIPS flexibilities. The Delegation stated that, in the few and far in between instances where flexibilities in the patent system had been used, they had witnessed the positive scale of treatment of public health diseases in the developing world that accessible, safe affordable and effective generic medicines could serve, for instance, in the case of treating the HIV virus. The Delegation continued that the WHO list of essential medicines which included many patented and costly medicines for life threatening diseases heightened the need to address that concern in an effective and sustainable manner. The Delegation underscored that access to health, safe and affordable medicines had long been a United Nations recognized Human Rights. The Delegation continued that it was also recognized in the UN 2030 Sustainable Development Goals, the TRIPS Agreement, the Doha Declaration on TRIPS Agreement and Public Health, the Development Agenda recommendations and by the WHO. The Delegation stated that WIPO, as a specialized agency of the United Nations, had equal responsibility in facilitating access to safe and affordable medicines, promoting innovation and fostering the requisite technology transfer to mitigate gaps thereof in developing countries and LDCs. The Delegation stated that the African Group hoped that that matter which bordered on life and living dignity would be treated with integrity and moral responsibility it deserved. In relation to the future work on patents and health, the Delegation stated that the African Group would like to see a more ambitious program, specifically as contained in the African Group and Development Agenda Group proposal. In particular, the Delegation wished to see at the twenty-fourth session of the SCP a study by leading independent experts examining the challenges and constraints faced by developing countries and LDCs in making full use of the public health related patent flexibilities both in the pre-grant and in the post-grant stage, and at the twenty-fifth session, an information exchange session on national experiences relating to the use of health related patent flexibilities for promoting public health objectives or the challenges thereof. The Delegation wished to reiterate its call for a study assessing the benefits of mandatory disclosure of INN in patent applications. In conclusion, the Delegation, expressed its belief that those steps would significantly advance the work of the Committee and prepare the ground work for future activities with the objective of minimizing risks to the life and facilitating sustainable health systems in developing countries and LDCs through existing flexibilities in the international patent system.

107. 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, and that patents were strongly linked with innovation. The Delegation stated that although the incentives provided by the patent protection were critical for R&D in the field of pharmaceuticals, R&D for the pharmaceutical compounds having a very small market may require additional incentives. The Delegation stressed that the future work of the Committee on that topic had to keep the whole context in mind without focusing on one specific issue only. In particular, the Delegation stated that, in the discussion of facilitating access to generic and patented medicine, it would be interested in better understanding why

unpatented medicines did not reach the intended patients. The Delegation stressed that, the availability of safe and effective medicines was a multifaceted problem, which impinged on many areas of law, national policy, physical infrastructure, social, education and economic factors, to name only a few. The Delegation stated that, while the SCP would not be expected to take action on those non-patent issues which were not within its mandate, it would nevertheless benefit from an understanding of where its action fit within the broader range of factors influencing access to medicines. Further, the Delegation stated that, as it had explained at the previous session, work sharing could make more sense in that technical field because of more divergence of information which respective offices could access. In that context, Group B continued to believe that the study by the Secretariat focusing on the difference of information and how to overcome those differences in the field through work sharing was also a right way forward under that agenda item. The Delegation stated that the current international framework did not give countries the policy space to impose new patentability criteria beyond the current requirement to provide an adequate written description, so that one of ordinary skill in the art could make and use the invention. With regard to the INN issue, the Delegation stated that as shown in document SCP/21/9, an INN was often assigned years after a patent application had been filed and sometimes granted, and thus, in many instances, INN could not form part of the original disclosure of innovative drug applications. The Delegation welcomed the newly launched PATENTSCOPE Chemsearch Project to develop tools to assist searchability of published patent documents using an INN keywords, and expressed its belief that investment in those technologies was the best way forward.

108. The Delegation of Romania, speaking on behalf of the CEBS Group, stated that generally, the CEBS Group believed that the approach to the connection between patents and health should be balanced, taking into account also the interests of patent users, and should avoid any duplication with the work conducted by other organizations, such as the WHO and WTO. The Delegation stated that, in terms of substance, it would support the Committee giving further consideration to the proposal made by the Delegation of the United States of America, contained in document SCP/17/11. As to the feasibility study on the disclosure of INN in patent applications and/or patents, the Delegation expressed its full support to the findings presented in document SCP SCP/21/9, which referred both to the impossibility of doing such a disclosure at the time of the filing and to the fact that providing such indication would not necessarily help the patent searcher identify what he/she was looking for, and that available databases and more complex IT tools could be instrumental for such endeavors. The Delegation looked forward to the seminar on patents and public health, hoping that it would be illustrative of the benefits of patents for stimulating research and the development of new medicines, including for developing countries and LDCs. In its view, there were numerous other factors extraneous to the patent system that could negatively impact the availability of medicines in those countries.

109. The Delegation of Luxemburg, speaking on behalf of the European Union and its Member States, thanked the Secretariat for the feasibility study on the disclosure of INN in patents applications and/or patents, contained in document SCP/21/9, which had been submitted to the twenty-first session of the SCP. The Delegation wished to reiterate its position expressed at that session. In particular, the Delegation stated that it had studied the document and that on the basis of the information provided by the study, it appeared that the case for a disclosure requirement of INNs had not been made. The Delegation observed that the costs and benefits were unclear, and the study highlighted other limitations. Further, the Delegation continued that, according to the preliminary findings, it was impossible to disclose, at the time of filing, the future corresponding and yet to be published INN in patent applications filed before the publication of the Recommended INN. The Delegation noted that, in that scenario, the preliminary findings pointed to the major challenge of how to retroactively link the corresponding INN information to such applications without unduly

burdening applicants and patent offices. The Delegation stated that, in addition, the mere indication of INN in patent applications was not sufficient to find out, with one click, what a patent searcher was looking for. At the same time, the study pointed to the fact that patent searchers had developed methodologies to search patents for a medicine, primarily using publicly available databases, and that increasing sophistication of IT tools might significantly contribute to a simpler and more cost efficient patent search in the fields of chemistry and pharmacology. Concerning the subject of patents and health in general, the Delegation was looking forward to the seminar on patents and health. The Delegation expressed its hope that the seminar would provide useful information in relation to challenges and opportunities faced. In closing, the Delegation expressed its wish to emphasize 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 the proposal of the Delegation of the United States of America.

110. The Delegation of South Africa aligned itself with the statement made by the Delegation of Nigeria on behalf of the African Group and expressed its appreciation for hosting of the half day seminar on patents and health at the following day of the SCP meeting. The Delegation stated that due to the debilitating impact of diseases, public health was a common concern. The Delegation stated that while the right to health was firmly entrenched in human rights, millions of people still lacked access to safe and affordable medicine. Providing access to life saving medicines was and should be both a health and developmental priority. The Delegation continued that taking into account that there were multitude of factors affecting the availability, affordability and accessibility of essential medicines, it was imperative that IP policy was grounded in a developmental approach specific to a country's socioeconomic imperatives. The Delegation informed the Committee that the South African Constitution committed the government to provide access to healthcare and that the government had undertaken initiatives over the years to address the country's high health burden and that it focused its attention on drafting a policy that optimized a balance of rights of patent holders and needs of general public. The Delegation continued that, in order to assure that the granting of patents did not unnecessarily extend the life of patents and blocked a generic competition, South Africa had declared its intention to pursue a patent examination system instead of the current depository system which had been opened to abuse. Further, noting that it was World AIDS Day, the Delegation drew attention of the Committee to the steps South Africa had taken to address the crippling AIDS epidemic in the 1990's, by adopting the Medicine and Related Substances Act which employed the TRIPS flexibilities, parallel importation, reduced prices and promoted price transparency. The Delegation recalled that the amendment of that Act prompted the WHO to hold discussions on the TRIPS Agreement on public health culminating in the public health discussions which affirmed the use of flexibilities. Further noting that 2030 Agenda for Sustainable Development, in particular, Sustainable Development Goal 3 targeted to ensure healthy lives and promote well-being for all, the Delegation stressed that the Committee should be mindful that developing countries continued facing a dual burden of both non-communicable and infectious diseases and that concerted, coordinated and collaborative global action was required to address pressing health challenges. The Delegation concluded that, in that regard, it supported the call made by the Delegation of Nigeria on behalf of the African Group for a more ambitious work program in the Committee.

111. The Delegation of Nigeria aligned itself with the general statement of the African Group as well as the statement of that Group on patents and health. The Delegation emphasized that, in the face of consistently increasing public health challenges, it was important to address the institutional policy and capacity constraints to the use of patent related flexibilities in addressing public health challenges. The Delegation stated that it was a dear concern for developing countries and LDCs to ameliorate the prevalent situation in a functional, pragmatic and sustainable way. Further, the Delegation noted, though at a lesser

extent, public health issues and the challenge of access to safe and affordable medicines had been also faced by developed countries, and therefore, the problem of patents and health was a collective global concern and responsibility. The Delegation expressed its hope that the upcoming seminar would significantly shed light on the process and challenges faced by developing countries and LDCs and provide balance and functional ideas for solutions. Finally, the Delegation reiterated its full support to the statement made by the Delegation of Nigeria on behalf of the African Group and looked forward to the adoption of the program.

112. The Delegation of the United States of America expressed its support to the statement made by the Delegation of Greece on behalf of Group B. The Delegation stated that as it had been indicated by the Delegation of South Africa, there were multiple factors that impacted access to medicines and therefore there was a need to understand the overall picture. The Delegation noted that WIPO's role was not to interpret the flexibilities contained in the laws of Member States. In relation to the feasibility study on the disclosure of INN in patent applications and/or patents, the Delegation referred to its detailed response given in paragraph 135 of document SCP/21/12. Specifically, the Delegation stated that it did not support a requirement to disclose the INN in patent applications and noted that the feasibility study did not address whether a country, a contracting party to the Patent Cooperation Treaty (PCT), the Patent Law Treaty (PLT) or other relevant bilateral or multilateral agreements could impose such an additional requirement. The Delegation was of the view that such a requirement would not be permitted by, for example, the PLT. The Delegation expressed its belief that the resources would be better spent to further facilitate access to the information by enhancing the searchability of patent documentation as demonstrated by the PATENTSCOPE Chemsearch Project. Noting further that that project would be very useful, the Delegation expressed its concern that patent examiners and others were not able to conduct a search and identify relevant patent applications or patents. In particular, the Delegation noted that document SCP/21/9 indicated that some patent offices seeking to search chemical and pharmaceutical inventions might experience certain difficulties due to the complexity and expense involved in finding prior art patents relevant to those inventions, although many offices were currently able to conduct such searches. The Delegation stated that that highlighted the value of one office helping another office to conduct search and examination and that such assistance could take the form of a training exercise. In that respect, the Delegation welcomed the South Africa's intention to pursue a patent examination system and expressed its willingness to assist in patent examiners training. The Delegation stated that, in addition to trainings, however, there was a need to expand the knowledge and search tools of examiners. Noting that PATENTSCOPE could be such a tool, the Delegation however stated that an examiner might not have access to search databases or understanding of the language that was needed. Thus, the Delegation proposed the SCP to carry out a study to determine how cooperation between various patent offices could be used to facilitate the search and examination of patents by offices that under current circumstances might encounter difficulties in doing so. As part of that study, the Delegation proposed the SCP to gather information on what kind of work product offices currently conducting search and examination generate, and how and under what circumstances that information could be utilized by other offices to simplify, improve or complete their own search and examination.

113. The Delegation of India, with respect to the agenda item on patents and health, reiterated its previous stand and expressed its support to the work program as proposed in document SCP/16/7. The Delegation further referred to the studies on the disclosure of INN in patent applications and/or patents and the sufficiency of disclosure (documents SCP/21/9 and SCP/22/4, respectively), and noted that those studies had several shortcomings, particularly, in their dealings with respect to the overbroad claims covered under Markush structures. To redress those shortcomings, the Delegation requested the Secretariat to

revise document SCP/21/9 specifically focusing on the feasibility of disclosure of INNs in patent applications where the INN was known to the applicant. Further, the Delegation quoted a question asked by Honorable Lord Justice Jacob in Dr. Reddy's Laboratories v Eli Lilly in the context of a single molecule buried in the generic Markush formula of a prior art covering million compounds: "Where does a wise man hide a leaf? He replied himself 'In a forest.' It is, at least faintly, ridiculous to say that a particular leaf has been made available to you by telling you that it is in Sherwood Forest. Once identified, you can of course see it. But if not identified you know only the generality: that Sherwood Forest has millions of leaves." The Delegation stated that in that case, the cited molecule covered nearly 10^{12} compounds. The Delegation stated that, in 1935, it had been realized by another author (V.I. Richard, Claims Under the Markush Formula, 17 J. Pat. Off. Soc'y 179, 190 (1935)) that: "[T]he extent to which the patent professional * * * made use of the Markush formula indicated that its application had gone far afield of the original intent. It was like a fire which had spread beyond control. It became the medium through which totally unrelated substances could be assembled under the guise of a genus. * * * If one member were found to be old or inoperative, that one was stricken from the group, and the diminished group reasserted with renewed vigor. In such a case the search required was for as many individual species as there were members recited in the group". Further, the Delegation stated that, in 1955, one Court of the United States of America had recognized the problem and quoted: ''the original rigid, emergency-engendered restrictions have been progressively relaxed through the years to the point where it is no longer possible to indulge in a presumption that the members of a Markush group are recognized by anyone to be equivalents except as they possess at least one property in common which is mainly responsible for their function in the claimed relationship.'' (Ruff, 256 F.2d at 599, 118 USPQ at 348). The Delegation thus emphasized that, in all jurisdictions, whether acknowledged or not, that problem had been recognized. Therefore, the Delegation had been requesting that a study be conducted on cost and benefit of patenting overbroad Markush formula. The Delegation proposed that the study could broadly be divided into two areas: one relating to such issues of patent law like inventive step, and the other would be the relationship of overbroad Markush formula with the sufficiency of disclosure requirement. The Delegation continued that another set of questions could be addressed in relation to the Markush formula: (i) the issue of actual enablement of the compounds covered in the Markush formula; (ii) the support requirements; (iii) requirements of industrial applicability; (iv) actual scope of such claims in the context of the generic versus specific disclosures; and (v) their contributions in the development of essential medicines. In conclusion, the Delegation stated that such study would fall under the scope of not only the quality of patents but also under patents and health and transfer of technology *vis-a-vis* the sufficiency of disclosure.

114. The Delegation of Japan aligned itself with the statement made by the Delegation of Greece, on behalf of Group B. With regard to INN, the Delegation stated that, in case INN were to be included in patent applications, that should be done not only from the perspective of enhancing accessibility to prior arts but also by taking into account the extent that the workloads of both applicants and IP offices would increase. In addition, the Delegation noted that its possible impact on the interpretation of the scope of rights needed to be considered. The Delegation stated that, in other words, the issue should be discussed carefully by considering its advantages and disadvantages. From the perspective of enhancing the efficiency of patent search, the Delegation was of the view, that INN had some effects as supplements to the existing search methods. In the opinion of the Delegation, the mandatory disclosure of INN however could have more disadvantages at present than the advantages, when considering the possible increased workload on applicants and IP offices. With respect to differentiated handling of new first-in-class medicines and improved medicines, the Delegation stated that there were some concerns that the mandatory disclosure of INN for only improved medicines for which applications

were filed after INN was published might have some problems with the principles of non-discrimination under Article 27(1) of the TRIPS Agreement.

115. The Delegation of the Russian Federation stressed the importance of the research presented in document SCP/21/9, and noted the main conclusions of the study on the subject, which could provide a strong basis for further work. In particular, the Delegation stressed the following points: (i) there was no requirement for the indication of the INN to determine the active substances in the patent applications and/or patents in the national and regional patent laws; and (ii) the timeframes of the INN procedures and the patenting procedures did not match. Thus, the Delegation stated, if the claimed invention related to a pharmaceutical composition for which the corresponding INN had been allocated, the applicants could voluntarily indicate that INN at the time of filing the application. The Delegation stated that at that stage, there would not be additional costs or burden on the applicant. However, in case the corresponding INN had not been assigned at the time of filing the application, the requirement to disclose the INN retroactively would unduly burden the applicants and patent offices. In the view of the Delegation, on the basis of the information provided in document SCP/21/9, it was not possible to positively conclude that there was a need for disclosure of INN in patent documents. However, the Delegation proposed to continue studying the issue. In addition, the Delegation noted that an INN keyword search should be used as an auxiliary, but not an exhaustive search tool. Finally, the Delegation supported further discussion on patents and health at the Committee.

116. The Delegation of China stated that as it was a World AIDS Day, it made the discussion on the issue of patents and health even more significant. The Delegation noted that while stimulating innovation, the patent system should also protect public interests, particularly on access to essential medicines. The Delegation expressed its strong support to the proposal made by the African Group, suggesting the Committee to further carry out studies and information sharing exercise to allow better understanding of the health related flexibilities offered by international treaties, and to facilitate the process of improving public health related patent legislation and practice of the Member States. The Delegation, meanwhile, looked forward to the presentations and insights of the experts at the seminar which would take place the following day. As regards the INN issue, the Delegation noted that the feasibility study prepared by the Secretariat served as a very good basis for future discussion. In particular, the Delegation stated that the analyses in the report enabled Member States to have an understanding of the *status quo* of the issue. The Delegation also noted that while the feasibility study presented some preliminary findings, it did not provide clear conclusions. In addition, the Delegation expressed its appreciation to the Secretariat for its update on PATENTSCOPE Chemsearch Project which, on its view, was one way to address the issue. The Delegation expressed its hope that the Secretariat would continue listening to comments made by all stakeholders, and continue conducting more in-depth studies and comprehensive, multi-perspective analyses on the necessity and feasibility of INN disclosure so as to provide better recommendations for clearer understanding of relevant issues by the Member States.

117. The Representative of KEI stated that after five years of secret negotiations, the final text of the Trans-Pacific Partnership (TPP) had been released in November 2015. The Representative further stated that, in the context of patents and health, bilateral and plurilateral agreements such as the TPP continued to be a cause of great concern. He noted that the TRIPS plus measures of the TPP had been designed to make drugs, vaccines, diagnostic tests and other medical technologies more expensive, often by broadening and extending the monopoly protections conferred by intellectual property rights. In his opinion, such harmful impacts would affect all countries, and predictably, the higher prices would limit access to known efficacious treatments for diseases. In particular, the Representative stated that the TPP provisions included: (i) Article 18.37(2), which changed the WTO

standard for patents by mandating that patents to be granted for new uses or methods of using known products; (ii) Article 18.48(2), which required an effective extension of the patent term beyond the 20 years from the filing date required by the WTO; (iii) Article 18.50, which created a WTO TRIPS plus obligation of at least five years of market exclusivity on the test data used to register products, effectively ensuring monopolies when there were no patents on the product; (iv) Article 18.52, which was designed to extend non-patent exclusivity to eight years, for biologics; (v) Article 18.74, which was the TPP's aggressive standard on damages, which was TRIPS plus provision mandating that judicial authorities had the authority to consider "any measure of damages that the rights holder submits" including "suggested retail price." The Representative continued that the provision in the TPP concerning damages from infringement was particularly concerning, if it was interpreted by the Investor State Dispute Settlement (ISDS) to limit the effective implementation of liability rules that were based upon statutory limitations on the remedies for infringement. He stated that, for example, the United States Biologic Price Competition and Innovation Act (BPCIA) had provisions, designed to induce transparency of patents on biologic drugs that limited the damage for infringement to a reasonable royalty, in some cases. He reported that, recently a member of the United States Congress (Representative Eshoo) had asked the United States to explain how the current United States law was consistent with the TPP provisions on damages. And, he also stated that, a Senator Bernie Sanders had proposed legislation in the United States Senate to expand access to hepatitis C virus (HCV) treatments for veterans, by limiting the compensation to patent holders when prices for products were excessive and if the outlay on the products would exceed the budgetary resources available for veterans. The Representative continued that the TPP appeared to limit the ability of the United States Congress to take measures that were legal under the WTO rules, but apparently in conflict with the TPP. He summarized that that directly concerned two important issues in the United States, the current law seeking to induce transparency of patents on biologic drugs, which was designed to reduce the risks facing investors in biosimilar products, and a proposed change in the United States law that was designed to protect veterans from access constrained by the excessive prices of drugs. The Representative further noted that those issues were relevant to the joint proposal submitted by the African Group and the Development Agenda Group contained in document SCP/16/7. That document, he stated, referred to flexibilities under Article 44 of the TRIPS Agreement, including those cases where injunctions were not made available to stop infringements, and governments or courts allowed infringements to take place, subject to some limited and reasonable compensation to the patent holder. The Representative observed that, the United States of America was a country where Article 44 flexibilities were used most frequently to overcome patent monopolies - including since 2006 - several cases involving medical devices and diagnostic tests. The Representative continued that, in developing modules on state practice, it had urged the Secretariat to 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 Agreement, including cases where non-voluntary authorizations to use patents replaced injunctions to enforce exclusive rights. 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 term extension, *sui generis* exclusivity, damages and the investor state dispute system (ISDS). He stated that such study should examine the impact of patent monopolies on the prices of, *inter alia*, hepatitis C medicines and cancer medicines, as well as limitations and exceptions to remedies for infringement contained in Part III of the TRIPS Agreement, which was the area facing new challenges from norm on remedies for infringement included in the TPP. Finally, the Representative noted that TPP Article 18.41, entitled "Other Use Without Authorisation of the Right Holder" provided that "The Parties understand that nothing in this Chapter limits a Party's rights and obligations under Article 31 of the TRIPS Agreement, any

waiver or any amendment to that Article that the Parties accept." He stated that that provision protected the use of compulsory licensing, under Part II of the TRIPS Agreement, as a limitation on the right, rather than the remedies to infringement of those rights. He continued that, the positive assurances that the TRIPS flexibilities found in Part II of the TRIPS Agreement, for compulsory licensing of rights, would be protected in the TPP, made the assault on the TRIPS Part III flexibilities regarding the enforcement of rights even more surprising. He wondered what the TPP negotiators were trying to accomplish. He further stated that the trade negotiators of the United States America had claimed that concerns over the TPP on the issue of damages, from a legal point of view, were wrong and that governments could by statute limit the damages for infringement, to a different standard than the one put forth in the TPP. The Representative stated that it would be good to clear that point before any government decided whether or not to be bound by the TPP, and requested the delegations of TPP member countries shed light on that important question.

118. The Representative of TWN stated that it was most appropriate to discuss the topic of patents and health on the day of the World AIDS Day. The Representative wished to take the opportunity to pay homage to thousands of people who lost their lives due to HIV/AIDS. He stated that the cause of those deaths had been primarily due to lack of access to affordable medicines. In particular, he stated that the lack of access to medicines was due to high prices resulting from patent protection. Further, the Representative noted that the HIV/AIDS crisis was a lesson which should be kept in mind and that the same mistakes should not be repeated. He continued that, however, the outcome of the TPP negotiation had shown that the lesson had not been learned. The Representative was of the opinion that since the conclusion of the TRIPS Agreement, there was little evidence to support the role of patents in facilitating access to medicine. In his view, patents also failed to attract funds to meet the needs of developing countries. He stated further that the minimum standard of protection under the TRIPS Agreement eliminated the chance of generic version of patented medicines elsewhere in the world. In his view, the question of access to medicines was no longer limited to developing countries and stated that, for example, the population of Spain was demanding access to hepatitis C medicine, showing that the problem existed in developed world too. The Representative further stated that it would be extremely difficult to ensure access to patented medicine in an era of economic austerity. In his opinion, the high prices of medicine threatened the sustainability of Europe's public health system. The Representative urged that it was the time to rethink about the role of patents in the context of affordable and sustainable healthcare systems. He further quoted the recommendations of UNDP's Global Commission on HIV and Law which stated that "TRIPS has failed to encourage and reward the kind of innovation that makes more effective pharmaceutical products available to the poor, including for neglected diseases. Countries must therefore develop, agree and invest in new systems that genuinely serve this purpose, prioritizing the most promising approaches including a new pharmaceutical R&D treaty and the promotion of open source discovery." The Representative further stated that, against that finding, the Commission had recommended that "The UN Secretary General must convene a neutral, high-level body to review and assess proposals and recommend a new intellectual property regime for pharmaceutical products. Such a regime should be consistent with international human rights law and public health requirements, while safeguarding the justifiable rights of inventors […]". The Representative stated that responding to that recommendation, on November 19, 2015, the UN Secretary General had appointed 16 members of High-Level Panel and expressed his hope that the Panel would suggest a clear pathway on the issue. The Representative continued that the Sustainable Development Goal 3 in the UN Assembly Declaration entitled "Transforming our World: the 2030 Agenda for Sustainable Development" was "to ensure healthy lives and promote well-being for all at all ages". In that regard, he stated that one of the means of implementation of that goal was the use of TRIPS flexibilities. The Representative continued that WIPO as a specialized agency of the United Nations had an obligation to assist Member

States in effective use and means of implementation. The first step, he stated, was the recognition of the problem. The Representative stressed that Member States needed to recognize that the patent had a negative externality with regard to access to medicine. With regard to the proposal of the Delegation of the United States of America which had stated that there were many determinants relating to access to medicine and that there were few patents on essential medicines list, the Representative observed that the revised essential medicine list contained many medicines which were under patent protection in many countries. He supposed that, in the United States of America, the use of TRIPS flexibilities and, in particular, the issuance of the compulsory license on some of those essential medicines would be supported. Against that background, the Representative urged Member States to support the proposal made by the African Group and the Development Agenda Group, and stated that what was needed was a clear solution to address the issue of patents and access to medicine in a sustainable manner. Finally, with regard to the INN issue, the Representative stated that the disclosure of INN could clearly add value to the assessment of inventive step, and that, currently, no international agreement preventing the mandatory disclosure of INN existed.

Seminar on the relationship between patent systems and, inter alia, challenges related to availability of medicines in developing countries and LDCs, including on the promotion of innovation and fostering of the requisite technology transfer to facilitate access to generic and patented medicines in developing and least developed countries.

119. Pursuant to the decision taken at the twenty-second session of the SCP, a half-day seminar was organized during its twenty-third session on the relationship between patent systems and, *inter alia*, challenges related to availability of medicines in developing countries and LDCs, including on the promotion of innovation and fostering of the requisite technology transfer to facilitate access to generic and patented medicines in those countries. The seminar was moderated by Mr. Zafar Mirza, Coordinator, Public Health, Innovation and Intellectual Property, Word Health Organization. The Seminar consisted of the following three segments:

(a) presentations by the following experts:

- Dr. Margaret Kyle, Professor, MINES ParisTech., France;
- Ms. Ellen ’t Hoen, a lawyer and an independent consultant in medicines policy and law, Netherlands;
- Mr. Corey Salsberg, Head, International IP Policy, Novartis International AG, Switzerland; and
- Dr. Brian William Tempest, Editor of Journal of Generic Medicines and former Chief Mentor, Vice Chairman, CEO, Managing Director and President Ranbaxy Laboratories (India), United Kingdom.

(b) panel discussions with participation of the above experts; and

(c) question and answer session.

120. Mr. Mirza expressed his thanks for having been nominated the moderator of the seminar. Mr. Mirza noted that the WHO played a central and strategic role in the interface of public health and intellectual property and remarked that over the years the collaboration between the WHO, WTO and WIPO had strengthened, for example through the preparation of trilateral documents and the organization of different events to discuss different aspects of

the interface between public health and intellectual property. Mr. Mirza noted that while the Doha Declaration had been agreed under the auspices of the WTO, WIPO, through its own mandate, was responsible for promoting innovation through different ways and also had a Development Agenda which promoted those discussions in an appropriate context, especially in low and middle income countries. Mr. Mirza noted that WHO's involvement in that area was through global strategy and plan of action for public health, innovation and intellectual property. In his view, those elements had established a link between the three organizations in the area of public health and intellectual property. Mr. Mirza remarked that there were still ground needs with reference to innovation for health technologies, including medicines, vaccines, medical devices and equipment, etc. He noted that access to treatments had improved but not enough and that there were still millions of people waiting for accessing the appropriate treatments. Mr. Mirza said that, however, during the last fifteen years, a lot of progress had been made and new institutions had been created, for example there had been new medicines, patent pools, partnerships, and new access programs had been created in the private and public sector. Mr. Mirza then stressed that the WHO played an important role in addressing issues related to the lack of innovation and lack of access to medicines and other health technologies, especially for diseases which were exclusively or disproportionately predominant in developing countries, where the markets were weak, and hence the private sector was less interested in investing to develop the innovations that were needed to treat those diseases.

121. Mr. Mirza's opening statement was followed by presentations by the four experts mentioned above. Their presentations are available at: http://www.wipo.int/meetings/en/details.jsp?meeting_id=35600.

122. Mr. Mirza observed that although the TRIPS Agreement provisions were generally referred to as minimum requirements for patent protection, they had established a higher level of protection than what had been available in many countries, for example in relation to the duration of patents and the types of inventions that could be patented. Mr. Mirza said that when the TRIPS Agreement was being negotiated, it was expected that a high level of patent protection would increase and encourage more innovation in all fields of industry but also in pharmaceuticals. He then noted that still 20 years after the TRIPS Agreement, there had been an Ebola epidemic in Western Africa but there had not been medicines, vaccines or specific diagnostic tools available. Upon that background, Mr. Mirza asked Mr. Salsberg how, in his view and in the view of the big pharmaceutical industry, the high level of patent protection had benefitted, if it had benefitted, the people in low and middle-low income countries, especially for the development of those innovative treatment which were really needed.

123. Mr. Salsberg stated that a pharmaceutical company was a business in a for-profit industry. He noted that from the pharmaceutical industry's perspective, the problem with diseases like Ebola was not a patent-based problem, but it was due to the lack of a market of a for-profit model. Mr. Salsberg explained that in addition to the possibility of obtaining patent protection on a compound for the treatment of a disease, there were other issues that created additional barriers for marketing those medicines in LDCs such as access to healthcare and general poverty. In Mr. Salsberg's view, in the case of diseases like Ebola and other neglected diseases, the solution could probably not be found in the traditional patent system but it might be necessary to use other incentives including private initiatives as well as public-private collaborations to address neglected disease such as partnerships with governments and institutions like the WHO. As an example, Mr. Salsberg referred to the Novartis Institute for Tropical Diseases which was a philanthropic organization that targeted specific tropical diseases and had pricing mechanisms to sell those drugs at cost.

124. Ms. 't Hoen observed that an increasing number of health problems had begun to fall

into the category of neglected diseases, even though a large number of people had been affected and thus represented important health challenges. She noted that children with HIV, of which there were millions, was a category of neglected patients; that the development of new antibiotics was also an area of neglect; and that diabetes and the availability of human and animal insulin was also a huge problem. Ms. 't Hoen stressed that although she understood that a pharmaceutical company might not find a commercial interest in developing treatments for new infectious diseases such as Ebola, a lot of the money was tied up in the patent system. In Ms. 't Hoen's view, the one-size-fits-all innovation financing mechanism through the patent system was not efficient, but greater variety of financing mechanisms was needed.

125. Mr. Mirza highlighted the problems that an African Health Ministry was facing in dealing with the patients of Hepatitis C. Mr. Mirza explained that the standard medicine available, Technivie, had been patent protected until 2013 and had had a price of $15,000 to treat one patient for one year; after expiration of the patent, India had started to produce it at $430 per year while the cost of production had been estimated at around about $30 or less than $30. Mr. Mirza observed that those generic companies producing the medicine were still doing it at a very high cost and local producers had not been able to start producing it at a cheaper cost due to lack of cooperation for transfer of technology. Mr. Mirza stressed that India had played an important role in terms of making first line antiviral medicines available in the continent of Africa, but that still 64 per cent of patients in India with HIV/AIDS did not have access to antiviral medicines. Mr. Mirza asked Mr. Tempest about his views on that issue.

126. Mr. Tempest noted that the situation in India was bizarre because India supplied half the medicines that were in the US market but the poor people in the villages could not access to the medicines because they were too expensive, even when the cost of a blister was one dollar. He underlined that India was the only BRICS country that did not have an universal health care coverage and stressed the need to develop a healthcare system in order to allow greater access to medicines. Mr. Tempest noted that many medicines were available around the world including most of the developing countries, but they were not available in the villages, even though there was enough capacity for manufacture. Referring to Mr. Mirza's comments on the cost of India's generic version of Technivie, Mr. Tempest pointed out that producing a medicine at $30 and selling it out at $430 was not the usual sort of margins in the generic industry, and that in the future, Bangladesh might become an important player in the production of generics, since it could also use the TRIPS flexibilities to produce and sell patented products to other LDCs.

127. Mr. Mirza asked Mr. Salsberg about Novartis approach in terms of technology transfer to developing countries so that they could really start developing their products locally and reduce prices.

128. Mr. Salsberg noted that in addition to patents, there were other elements that played an important role in making a medicine such as technology transfer, including know how, trade secrets and manufacturing expertise. He continued that one way to do that was to have strong local IP rights which encouraged innovators to come there first and partner with local companies and do local clinical trials to help build the expertise and the know-how that was needed for those young companies in developing countries to start becoming more sophisticated. Mr. Salsberg said that in many countries, for example Brazil, there were strong technology transfer programs and formal technology transfer agreements in place. However, Mr. Salsberg noted that local manufacturing might in some instances not be the best solution to the access problem. He stated that while some countries like India had developed a strong generic industry, in other cases, having a local manufacturing industry might not be commercially viable.

129. Mr. Mirza invited Ms. Kyle to comment on the lack of data about the access situation in developing countries and LDCs and the possible solutions that, in her view, might serve to tackle that issue.

130. Ms. Kyle asserted that the lack of data was a challenge particularly when carrying out cross country studies where roughly comparable data from multiple countries were needed. She said that there were websites that made available a list of all the products that had been approved, when they had been approved, and from which manufacturer; however she noted that even basic information like that could be a challenge for a researcher to track down. She continued that information on prices or quantities was more difficult to obtain. Ms. Kyle explained that even in cases where the government was the largest purchaser, that information was not always shared, and in cases where medicines were not distributed by the government, the information was usually available in a very diffuse network which made it expensive and cumbersome to track it down. Ms. Kyle said that in those instances, international organizations could play a role in trying to coordinate the collection of that information making it widely available to researchers in a transparent way.

131. Mr. Mirza stressed that information on access to medicines would be useful for researchers, and also for local as well as external investors who needed to know what was the market size for different therapeutic categories in order to make their investment decisions.

132. Ms. Kyle pointed out that it was shocking that there was no entry of medicines in many African countries where the margins should be extremely attractive. In her view, that fact might suggest that the fixed cost for a generic company to get into that market were enormous. Ms. Kyle suggested that collecting additional information on the tax situation and the process for obtaining regulatory approval such as time and the level of transparency and difficulty was also important for understanding why there was no entry of medicines.

133. Mr. Salsberg stated that a Novartis initiative to improve access to medicines was to link different medicines, some of which were patented and some were not. He explained that bundling those medicines might work in a broader application and could help make market conditions more attractive and increase the capability to earn a return, especially where a particular product did not have an attractive market on its own.

134. Mr. Mirza invited Ms. ’t Hoen to comment on the link between the Medicines Patent Pool, which was expanding to Hepatitis C, and the essentials medicines list which had increased to include patent protected medicines, and how that link could work and what benefits it could render.

135. Ms. ’t Hoen stressed that one of the problems on access to medicines was the lack of transparency about pricing. Ms. ’t Hoen noted that in the case of HIV, there were organizations such as UNITAID and the Global Fund that had collected information about prices and sources for those medicines that, coupled with registration data, helped to identify where the low cost sources were. She said that for other diseases, however, there were cases where governments negotiated prices but those prices were not made public. Ms. ’t Hoen noted that in some cases, effective measures to improve the availability of a medicine had been implemented, such as the case of Novartis drug Coartem where there had been a significant price differentiation between high income markets and the rest of the world. Ms. ’t Hoen stated that it would be desirable that such an approach expanded to cancer drugs patent portfolio, rather than applying a charitable approach where companies donated medicines to low income countries. Ms. ’t Hoen affirmed that when patents were a barrier to access, that could be tackled with collaborative agreements and licenses such as

the Medicines Patents Pool, with lower royalty rates for LDCs and low income countries, especially in the case of WHO listed essential medicines. She suggested that an essential medicines patent pool model where licenses were available for those medicines that were on the WHO essential medicines list could be created. Ms. 't Hoen's observed that in the absence of collaboration, more compulsory licenses might be requested for cancer drugs.

136. Mr. Salsberg pointed out that in order to be able to implement a tiered pricing or differential pricing model, it was important to be cautious with regard to parallel importation to avoid that those drugs that were geared towards a certain population that needed lower prices were not diverted to those that should pay more. He further noted that such an approach might also trigger reference pricing issues, for example, if some countries would automatically drop their prices when they saw a lower price in another country.

137. Ms. Kyle argued that the pricing issues referred to by Mr. Salsberg would not be a policy problem for developing countries to solve. In her view, relatively rich countries should accept that they were going to pay higher prices because keeping reference pricing in poorer countries was undermining access in those countries.

138. Ms. 't Hoen added that in order to apply differential pricing, fair pricing policies were also needed in high income countries that were progressively less able to pay for lifesaving medicines.

139. Mr. Mirza stated that in terms of patent law developments at a global level, LDCs had recently been given extension of the transitional period for granting pharmaceutical patents until 2033. Mr. Mirza asked the panel experts, how, in their view, those countries should use that time extension to take measures in their countries, with reference to patent law, aimed at strengthening the access situation to medicines and other health technologies which were needed by their populations, for example through local production or other measures.

140. Mr. Tempest said that in order to make effective use of the flexibility available, LDCs could access an active pharmaceutical ingredient (API) source, the bulk active ingredients, in order to make the tablets using local manufacture, which had made great progress in recent years particularly across Africa. In his view, the API was a key element that needed to be researched.

141. Ms. 't Hoen emphasized that it was important to look at the possibilities under the paragraph 6 mechanism of the Doha Declaration, which would allow the trading of medicines within an entire region, for example across the 40 African unions. Ms. 't Hoen was of the view that the mechanism under paragraph 6 should be included in health policies, not only be run by the Ministry of Industry, in order to improve production and availability of essential medicines.

142. Mr. Salsberg stated that although that flexibility had been extended, he would encourage LDCs to adopt patent systems more prominently and more quickly. Mr. Salsberg noted that Novartis was not the only company that filed patents but did not enforce them, so offering patent protection for pharmaceutical products should not be a barrier, but would attract companies to launch medicines in those countries. He continued that such approach would in the long term incentivize local companies to build the necessary capabilities to start using the patent system for their own development and create the incentives to develop local remedies for local diseases.

143. Ms. Kyle recalled that there were other barriers to access in poor countries besides a patent system that needed to be tacked over the next 15 years, such as the lack of widespread health insurance, good distribution channels or reasonable taxes in place.

144. Mr. Mirza thanked the panel experts for their contributions.

145. The Chair opened the floor for the question and answer session.

146. The Delegation of India thanked the experts for their presentations. The Delegation stated that the patent specification was a vehicle for transfer of technology. The Delegation posed two questions to the panel. First, the Delegation asked the experts whether, in their opinions, the disclosure of INN in patent applications was beneficial from the point of view of pharmaceutical patents particularly in those cases when the INN was known to the patent applicant and when the patent application contained secondary innovations such as further derivatives or further formulations of an already developed compound. Secondly, with regard to pharmaceutical patent applications concerning small molecules or biological material, the Delegation invited the experts to comment on how and to what extent Markush claims, which in some cases had covered nearly almost billions of compounds, contributed to the transfer of technology.

147. Mr. Salsberg stated that, in his view, INN were not relevant to patentability and could not be properly placed in patent applications. Mr. Salsberg underlined that INN did not often exist in the case of compound patents, because they had not been generated before the compound patents were filed. Mr. Salsberg was of the opinion that disclosing the INN in the patent application would create more burdens than benefits, and in any case, that information was made available by the WHO. In relation to Markush groups, Mr. Salsberg believed that the patent system needed to be open to all types of innovations in order to maximize the incentives to invent in all different directions, and therefore, Markush claims should be available.

148. Mr. Tempest observed that, in general, doctors' prescriptions in Europe had an INN number of medicines on them, and the products bought by consumers also had the INN on them. He noted that, however, in developing countries generic medicines usually had the brand name on it and the INN underneath, and that the medical schools in those countries often educated doctors with the brand names rather than the INN. In his view, changing the system in a country from prescribing the local brand name to prescribing the INN would allow a pharmacist to find substitute products more easily.

149. Ms. 't Hoen stated that, in her view, disclosing the INN in a patent application when the INN was known was a good idea and would improve transparency in the patent system.

150. The Delegation of Pakistan noted that the patent system was meant to promote innovation and there was supposed to be a balance between how well it promoted innovation and how well it catered to the public welfare, especially in relation to health. The Delegation pointed out that affordability of medicines for patients both in developed and developing countries had decreased. The Delegation also noted that the WHO had reported a decrease of antibiotics development. In the Delegation's view, the patent system seemed to have failed on both accounts where innovation was concerned and also where affordability was concerned. The Delegation continued that although the Medicines Patent Pool might help to ensure affordability, the pool did not cater to middle income countries. The Delegation invited the experts to share their views on what could be done in relation to the patent system to address those issues.

151. Ms. 't Hoen stated that the exclusion of some countries from the Medicines Patent Pool was the result of voluntary agreements between the parties. She continued that between 95% and 97% of the people with HIV were covered by the Medicines Patent Pool licenses, which showed a significant level of coverage. Ms. 't Hoen also noted that the

Medicines Patent Pool licenses allowed the sub-licensees to supply medicines to countries that had used the TRIPS flexibilities, which could lead to licenses to all low and middle income countries, although that would require government actions as well.

152. Mr. Salsberg stated that the failure of antibiotics development was not a failure of the patent system but it related to the lack of an underlying market for the antibiotic, such as in the case of Ebola. He continued that a second problem with that kind of treatment was that it was a one-time treatment that people generally used once in their lives.

153. Ms. Kyle seconded Mr. Salsberg's statement and noted that the situation with antibiotics was not just about the patent system but it concerned other problems in the market that could not be tackled solely by changing the intellectual property system.

154. Ms. 't Hoen suggested that in the case of antibiotics, delinkage models offer a different way of incentivizing and financing research and development. She noted that alternative financing would avoid access problems caused by price, because companies would not need to recoup the investments in the R&D of the product by increasing prices and sales volumes.

155. The Delegation of the United States of America recalled that the United States NIH had been the first patent holder to share its intellectual property with the Medicines Patent Pool. The Delegation believed that it was important to make contributions to the Medicines Patent Pool to support their efforts in providing access to HIV treatments. The Delegation noted that, however, the US government was cautious about the expansion of patent pools. The Delegation continued that essential medicines included many alternative medicines and not just complimentary medicines. The Delegation explained that in relation to patent pools, the US Department of Justice was concerned with competitive issues and made a differentiation between patent pools for medicines that could be administered together versus competitive products. The Delegation stated that the US Department of Justice was less favorable towards the creation of pools with competitive products, because they feared that those patent pools might cause significant potential harms, discourage research and development and overall, lead to an increase in cost. The Delegation then asked Ms. 't Hoen whether the Medicines Patent Pool considered antitrust and competition issues in deciding which products should be included.

156. Ms. 't Hoen clarified that she was not speaking on behalf of the Medicines Patent Pool. Ms. 't Hoen remarked that it had been very important for the Medicines Patent Pool that the US NIH had recognized that the pool was a viable model and had sought collaboration with it. She then stated that while the scope of the Medicines Patent Pool had recently expanded, she did not believe that expanding it to the WHO essential medicines list was being discussed. Ms. 't Hoen noted that the Medicines Patent Pool was similar to a clearinghouse of licenses or a collective licensing mechanism and thus very different from the kind of standard patent pools that the US Delegation had referred to. In her view, anticompetitive concerns were not very relevant to the Medicines Patent Pool, which was a voluntary licensing mechanism for the purposes of generic production and sale in specific countries in compliance with the terms and conditions of the license agreement.

157. The Delegation of Brazil thanked the experts for their presentations. In relation to the future balance of the IP system and the production of generics and biosimilars, the Delegation asked the experts about their views on how access to high cost biosimilar medicines could be ensured in developing countries and LDCs, and how the Bolar exception and other exceptions and limitations could be applied to those new medicines that were much more costly to develop in order to improve the development of the generic versions of those medicines.

158. Mr. Salsberg highlighted that because biologic material was not as easy to copy as small molecules, it was more difficulty to develop biosimilar drugs. He remarked that producing biosimilars required a high degree of expertise. Mr. Salsberg stated that the same patent rights applied to biologics and other types of drugs and that the regulatory data exclusivity that had been discussed in the Trans-Pacific Partnership (TPP) agreement would not introduce higher exclusivities than those available for small molecules in those countries in general. In his view, the situation with biosimilars hardly implicated the TRIPS framework or flexibilities.

159. Ms. Kyle expressed her agreement with Mr. Saldberg's statement. She stated that patents were not the only barrier to entry for biosimilars in developing countries. In Ms. Kyle's opinion, there were other barriers such as the complexity of manufacturing and imitating originator medicines. She then noted that the patent system should ensure that there was competition after the expiration of patents, and thus the Bolar exception should be applied to all medicines to set the barriers to entry as low as possible.

160. Mr. Salsberg seconded Ms. Kyle's views with regard to the application of the Bolar exception to biosimilars.

161. The Delegation of Nigeria thanked the experts for their presentations. The Delegation noted that the experts had all agreed that a patent could be one of the barriers to access to affordable, safe and effective medicines. Following up with the question by the Delegation of Brazil, the Delegation of Nigeria asked Ms. 't Hoen, Ms. Kyle and Mr. Tempest what steps they would recommend to mitigate the lack of access to new medicines and health technologies in developing countries and LDCs. The Delegation then recalled other elements that had been cited as potential impediments to access to medicines such as social structures, infrastructure, health systems, insurances, etc. In that context, the Delegation stressed that the patent system was supposed to foster innovation and serve a teaching function, and therefore, even if there were no data on the access situation, effective health systems or insurances, the markets of developing countries and LDCs should not be ignored in situations like the Ebola virus, which had existed for about 40 years and still a treatment had not been developed. Upon that background, the Delegation asked Ms. Kyle and Mr. Salsberg why the lack of social infrastructure systems and buying power to make a medicine profitable or commercially viable in developing countries and LDCs could be the reason to ignore those markets.

162. Ms. Kyle remarked that the fact that there were no market incentives was something that had to be dealt with by local governments and the international community, since profit-oriented pharmaceutical companies could not possibly establish a health system or other necessary structures. She clarified that she had not suggested that non-commercially viable markets were not important and should be ignored, however, what she and other experts had noted was that the patent system was not able to address those other issues that also posed barriers for accessing medicines.

163. Mr. Salsberg echoed what had been said by Ms. Kyle.

164. The Delegation of South Africa thanked the experts for their presentations. The Delegation noted that the Doha Declaration had recognized that public health could take precedence over the rights of private IP holders and more recently the 2030 Development Agenda had made a call for action. The Delegation asked the experts how pharma companies would be responding to that call, since the achievement of the Sustainable Development Goals (SDGs) was a collaborative global effort with specific reference to developing countries where millions of people were still dying from preventable and treatable

as well as new diseases.

165. Mr. Salsberg stated that Novartis was constantly trying to come up with new programs to address global health needs and had made 15 of the company's medicines for non-communicable diseases, some of them patented, available to developing countries. He noted that, although he was proud of the fact that they had reached hundreds of millions of patients every single year through those programs, that was not a sustainable model to suggest that the for-profit private sector should be shifting most of its business to those low cost and philanthropic models. Mr. Salsberg stressed that there should be a balance in order to create a long term sustainable model.

166. The Delegation of Vietnam thanked the experts for their presentations. The Delegation asked the experts how, in their views, WIPO could play a role on the issues discussed, for example by sponsoring research, and how it could affect price and access to medicines in developing countries.

167. Ms. 't Hoen stated that the name and mission of WIPO was somewhat restricted by the fact that it was called the World Intellectual Property Organization and not the World Innovation Organization. She noted that, nonetheless, WIPO had an important role in exploring a larger variety of incentives for innovation in health in such a way that both innovation and access could take place. In her view, WIPO should explore alternative models together with other institutions like the WHO and WTO and other stakeholders. Ms. 't Hoen acknowledged that WIPO played a very important role in guiding countries in the development of their own legislations and implementation of patent laws at the national level. She observed that the WIPO Model Law could be updated to reflect the TRIPS Agreement and subsequent legal developments that would ensure that local patent laws walked hand in hand with the health priority, and in that way, would help countries to make their intellectual property legislation and policy responsive to public interests.

168. Mr. Tempest suggested that health departments should be advised to give regulatory approval for generic products as quickly as possible after patent expiry, and also, that countries should put in place a local intellectual property law that did not allow evergreening in order to encourage the production of generics.

169. Ms. Kyle noted that there were still a lot of open questions, for example, what was the role of secondary patents, under what conditions they acted as a barrier to access in certain markets, which alternatives could be used to reward that kind of incremental innovation, how to balance the potential delay in generic competition that might result, or the role of the Bolar exception, etc., and that WIPO could play a role in obtaining data and information in relation to those issues.

170. Mr. Salsberg remarked that it was very important to leave open incentives to develop incremental innovations. He noted that taking an old drug and repurposing it for new uses, reducing side effects or developing more convenient ways to increase patient compliance were very important innovations that helped patients.

171. The Delegation of Greece thanked the experts for their presentations. The Delegation referred to the point raised by Ms. 't Hoen that governments had not yet used the existing flexibilities available under patent law.

172. The Delegation of Kenya thanked the experts for their presentations. The Delegation stressed that there were several countries especially developing countries and LDCs which had attempted to utilize the flexibilities in the TRIPS Agreement and had started developing some generic drugs, but they had not been able to meet the demands for different reasons.

The Delegation believed that the transfer of know-how and other relevant information from the patent owners to the manufacturer was very important when transferring the technology so that it could reach a wider population. The Delegation asked Mr. Salsberg about his views and experience on the transfer of technology and know-how to developing countries and LDCs.

173. Mr. Salsberg stated that he knew there had been cases of transfer of know-how in countries like Brazil. He explained that in countries such as Kenya, instead of a licensing approach, the Novartis access program was carried out to get to patients who had signed the program.

174. Mr. Tempest expressed his view that one of the problems with Kenya was that it had a very strong patent legislation, and therefore, generic products made in India could be sold in LDCs such as Uganda but not in Kenya.

175. The Delegation of China asked the experts whether there were research materials, information or data available to prove that the limitations and exceptions were beneficial for improving access to medicines in developing countries.

176. Ms. ‘t Hoen said that she had studied the use of flexibilities such as compulsory licensing, government use and the use by LDCs of the option to not grant product patents on pharmaceuticals under paragraph 7 of the Doha Declaration. She asserted that there had been widespread use of those flexibilities, particularly in the case of HIV, which had helped to create a large market very quickly and take away concerns of suppliers about potential legal actions against the supply of those medicines. Ms. ‘t Hoen, however, stated that how widespread those flexibilities might be used in other diseases remained to be seen.

177. Mr. Salsberg pointed out that at least in relation to diseases other than HIV, new information and new studies suggested that the use of compulsory licensing had not been widespread and the price of medicines manufactured based on compulsory licenses were in some cases no lower and sometimes higher than in the absence of compulsory licenses.

178. The Delegation of Chile thanked the experts for their presentations. The Delegation pointed out that in her presentation, Ms. Kyle had mentioned that one of the major difficulties for pharma companies was the generation of the information that had to be presented to the regulatory authorities in each country. The Delegation asked Ms. Kyle whether those safety and efficacy studies were usually produced once for the main countries where the medicine was going to be launched and how the existence of evidence showing that it would be easier to reproduce that information in secondary markets would affect the conclusions of Ms. Kyle’s study.

179. Ms. Kyle noted that it was generally possible for originators or for any firm to potentially use similar data or use the same data for regulatory approval in multiple markets, which was generally cheaper for the originator who had already developed those data for one market, and thus the marginal cost for launch in an additional country was lower than for a completely new generic company that did not already have the clinical trial data.

180. The Delegation of Nigeria recalled that the African Group and the Development Agenda Group had requested that the Secretariat undertook a study to examine the constraints of the use of patent related flexibilities for public health purposes in developing countries and LDCs. The Delegation invited the experts to share their views on the role or the benefit that such a study would have on the issue of patents and access to affordable, safe and effective medicines.

181. Mr. Tempest expressed his opinion that such a study could be useful and remarked that developing countries should explore all the opportunities offered by the flexibilities and should take advantage of them with the support of other parts of the United Nations like the WHO.

182. The Representative of UNCTAD noted that in recent years, there had been a tendency in multinational pharmaceutical companies to integrate certain generic companies, for instance from India, within their value chain, for example through outsourcing certain R&D activities to save costs. The Representative asked Mr. Tempest whether in his opinion that situation might encourage Indian companies to start focusing on the development of innovative drugs, shifting their attention away from the production of affordable generics; and how that situation might affect Sub-Saharan African countries that had been relying on the supply of medicines from India.

183. Mr. Tempest stated that there was a trend in some of the Indian pharmaceutical companies to continue their evolution from the manufacture of APIs through generics to difficult generics and to molecules. He remarked that, however, there was a huge number of Indian companies and that only one or two at the top were moving towards innovation while there were more mid-size companies that wanted to get FDA approval to sell their products in markets outside of India. Mr. Tempest asserted that there would be a continuing supply of molecules for the developing world coming out of India. He then said that in the case of biosimilars, Korean companies were probably going to be stronger, which would be a challenge for Indian companies in the next five or six years.

184. Mr. Salsberg stated that it was important to encourage generic companies to move to an innovative model. He noted that innovative companies helped to develop the economy, grow industries and create jobs, and ultimately led to the development of new medicines that could later become generic medicines.

185. The Representative of MPP expressed her gratitude to Mr. Mirza, the Chair and other panelists for the recognition of the efforts made by the MPP. The Representative stated that the mandate of the MPP had recently extended by UNITAID to work on Hepatitis C and tuberculosis. She announced that the MPP had recently signed its first license on Hepatitis C for the drug Daclatasvir (DCV) for 112 countries. The Representative said that information on the progress and improvements achieved in terms of real access for patients, the licenses granted, and also on terms and conditions for accessing the MPP licenses for HIV and other diseases could be found in the MPP website in the HIV field as well. The Representative underlined that the MPP licenses included middle income countries, between 60 and 98 middle income countries in the HIV licenses, plus all the low income countries. She then said that it was difficult for the MPP to include some upper middle income countries because the MPP was a voluntary mechanism and governments in upper middle income countries also had other measures to take in different situations to solve those access problems.

186. The Representative of MSF stated that in the case of biosimilars and biological drugs, attention should also be given to patents on processes and methods and not only to product patents, since the increasing number of process and method patents on biological technologies also posed a barrier to the entry of competitors. She remarked that it had been frequently argued that strong IP systems were necessary to attract investment in innovation but that, in her view, such statement might be misleading because a company's investment decisions could be based on multiple factors and thus whether the existence of a strong IP system was the final determinant for foreign investment was debatable. The Representative then stressed that the SCP should also look closer into how the patent system was operating from the inside, for example the patentability criteria, Markush claims, patentability of

secondary patents, etc., which could have an overarching impact on a number of policy options such as the implementation of the TRIPS flexibilities.

187. The Representative of TWN stated that two panelists had argued that there were various determinants to access and that patents were not the only barrier. He stated that in his view, patents were the main barrier for the generic availability of new medicines or patented medicines. The Representative continued that since the introduction of product patent regimes, the availability of generics had been reduced, and that before ensuring access, it was necessary to ensure that the products were available. The Representative noted that Ms. Kyle's paper, based on a macro picture with generalized data, argued that the impact of the TRIPS Agreement had not been so negative. The Representative asked Ms. Kyle whether there was any evidence that after the TRIPS Agreement or after the introduction of product patent regimes monopolies were increasing due to patents, for example in relation to the availability of generic competition. The Representative then pointed out that the licenses of a patent pool came with more conditions than compulsory licenses, and therefore, using the TRIPS flexibilities on compulsory licenses was a better option than privately negotiating voluntary licenses.

188. Ms. Kyle stated that her paper focused on the availability of any drug, whether it was manufactured by the generic or by the originator company. She explained that because patents helped originators to launch a medicine in the market more quickly, that effect out-weighted the effect of blocking generics from the market. Ms. Kyle then said that other studies of patent monopolies that she had mentioned in her presentation had found that in the case of India, patents had not had an effect on prices and access.

189. Mr. Salsberg seconded the statement made by Ms. Kyle and added that in practice, when an innovator launched a medicine, they paved the way for the generic, since the generic manufacturer could rely on the data in the market. He then said that in the United States of America, there had been an increase in generic medicines from 19% in 1984 to about 85% of the market since the adoption of the Hatch-Waxman Act.

190. Ms. 't Hoen stated that it should not be overlooked that the compulsory license mechanism only came into play when a voluntary license had not been possible, for example, because the patent holder had refused to negotiate. In her view, voluntary licenses such as those issued by the Medicines Patent Pool were more efficient than requesting compulsory licenses in each country where the patented medicine was needed.

191. Mr. Tempest noted that the availability of generics was driven by the availability of the API source, provided that a company could make the product without generating any patent conflict. He stated that when India did not have patents, companies used to launch generic molecules in six months after the US launched a molecule.

192. The Chair thanked the speakers and closed the seminar.

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

Sharing session concerning confidentiality protection applied to different types of patent professionals and to national and foreign patent advisors

193. The Chair opened the sharing session concerning confidentiality protection applied to different types of patent professionals and to national and foreign patent advisors.

194. The Delegation of Japan gave a presentation on the protection of the confidentiality of legal advice between patent attorneys and their clients in common law countries and civil law countries, and based on a handout prepared by the Delegation, explained different potential scenarios where cross-border issues in relation to confidentiality of communications might arise.

195. The Delegation of Spain gave a presentation on an amendment of the Spanish legislation with regard to the confidentiality of communications between clients and their patent advisors or patent agents. The Delegation remarked that so far, international recognition of the right of non-disclosure of communications between patent agents and their clients had not been achieved, but nevertheless, discussions of the issue in various fora, such as the SCP and Group B+, had been fruitful and had led for instance to recent changes in the Spanish Patent Law. The presentation by the Delegation of Spain is available at: http://www.wipo.int/meetings/en/details.jsp?meeting_id=35699.

196. The Delegation of Switzerland thanked the Delegations of Japan and Spain for describing the situations in their countries, giving case examples and underlining the importance to find international regulation on the client-attorney privilege. The Delegation recognized the importance of a strong protection of the patent attorney-client privilege, and noted that according to the Swiss Federal Court, the legal professional secrecy promoted the public interest, because it assisted the administration of justice by allowing clients to confide frankly in their lawyers. The Delegation observed that if the client did not unreservedly trust his lawyer and if the lawyer was not aware of all the material circumstances, it was difficult or even impossible for him to properly represent the client in either advisory work or in a lawsuit. The Delegation explained that in Switzerland, patent attorneys had been subject to professional confidentiality since the entry into force of the Federal Act on Patent Attorneys on July 1, 2011. The Delegation continued that the Swiss legislature adopted the Patent Attorneys Act based on the understanding that a qualified expert advice in patent matters was key for Switzerland as a location for innovation. The Delegation noted that under that law, only persons with proven expertise were allowed to use the professional title of a patent attorney and that before taking up that occupation, they had to register themselves in a patent attorney register and prove that they possessed the required professional qualifications, which allowed the public to choose the professional and competent service provider. The Delegation stressed that that law served to protect non-disclosure concerns of the person being advised by imposing an obligation of secrecy on the patent attorney. The Delegation stated that according to the relevant provision (Article 10 of the Act), patent attorneys were obliged to maintain confidentiality concerning all secrets that were entrusted to them in their professional capacity, or which came to their knowledge in the course of their professional activities, and they should also assure that persons assisting them maintain professional confidentiality. The Delegation highlighted that the secrecy obligation reflected the fact that patent attorneys not only received highly confidential information during consultation and representation, including information on inventions or business secrets associated with invention, but also generated highly confidential information during preparatory work for filing a patent application, consultation and representation. The Delegation remarked that for the client it was of great economic importance that such information was protected, since the client needed to unreservedly trust in the confidentiality of the patent attorney in order to disclose all relevant information. The Delegation pointed out that in Switzerland, the patent attorney-client privilege was unlimited in time, implied in relation to any person, and applied for patent attorneys in employment, where the employer was considered as the privileged receiver of the information and not the employed patent attorney. The Delegation explained that professional confidentiality extended to the facts that had been entrusted to the patent attorney in order to carry out the mandate or to the facts that the patent attorney noticed during the exercise of his profession; however, the privilege only covered the documents and materials that had been confided for the purpose

of the mandate and the practice of the patent attorney's profession. According to the Federal Court, it meant that neither those documents could be seized nor could the patent attorney be compelled to testify in civil court proceedings on confidential matters that had arisen out of his profession. The Delegation said that in Switzerland, the violation of that professional secrecy was a criminal offense and according to the code of criminal procedure in criminal proceedings, a patent attorney might be relieved from the duty to testify if he could show a justified interest in maintaining confidentiality; further, in 2013, Switzerland had additionally regulated that the parties and third-parties in a civil proceeding were also no longer obliged to release documentation arising from communications with patent attorneys. The Delegation emphasized that due to the increase in international trade and the related IP questions, the Swiss provision on professional secrecy also intended to address the problems that patentees were facing in cross-border activities and improve their activities in cross-border court proceedings. The Delegation observed that professional secrecy had national character and could not be retained once a patent matter crossed the border. In the Delegation's view, the actual situation at the international level showed that protection of confidentiality did not exist in every country, and where it existed, the protection was not always applied to foreign attorneys or not to the same extent as to domestic professionals. The Delegation considered that that situation was unsatisfactory with respect to certainty, predictability, the safeguard of sensible information and trust in the patent attorney-client relationship, which impeded a full and frank communication between a client and his advisor and thus compromised the quality of legal advice with impact on patent prosecution and quality of the patent. The Delegation recalled that during the twenty-first session of the SCP, practitioners from several countries, including Canada, Switzerland, Brazil and India, had underlined the importance and urgency to find a solution for the cross-border issues of professional secrecy. The Delegation reiterated that the principal purpose of the privilege was to encourage full and frank communication between patent advisors and their clients, which was of great importance, since patent attorneys or advisors needed to know all relevant facts in order to provide their clients with appropriate legal advice; further, providing such sound advice encouraged the client to take an informed decision and conform his behavior to the law, which ultimately promoted the broader public interest in improving the observance of law and administration of justice. The Delegation considered that the issue of confidentiality of communications was important to the SCP, since that privilege might impact the quality of the patent prosecution process and the quality of the patent to be issued. In that regard, the Delegation remarked that a patent attorney or counselor played an integral role throughout the entire patent prosecution process and thus a counselor or an attorney and his client should work together in an open and trustful environment in order to prepare an accurate patent application complying with the requirements for patent grant, but also to avoid malfeasance in prosecution that might result in penalties to both parties. The Delegation highlighted that during the patent prosecution process, the patent attorney generated documents, such as a draft patent application or memorandum which provided an opinion on patentability, and also represented the client before the industrial property office (IPO) in questions concerning non-compliance with the requirements, deficiencies or corrections. With regard to the question of whether the patent attorney privilege reduced the disclosure, the Delegation emphasized that disclosure in a patent application needed to be distinguished from the disclosure within a discovery procedure. In that context, the Delegation remarked that national patent laws required that an applicant described his invention in a clear and complete manner so that the person skilled in the art would be able to carry out the claimed invention, which meant that the applicant was obliged to disclose all information necessary to fulfill the enablement requirement. However, the Delegation considered that that 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 noted that as the second study on the sufficiency of disclosure (document SCP/22/4) had revealed, patent laws of Member States varied on the

details of the enablement requirement but those disclosure requirements are unrelated to the privilege and the confidentiality of communications between patent advisors and their clients. In relation to the question of how the risk of willfully excluding important information in the application could be addressed, the Delegation stated that during the reading of the application, patent examiners at the IPOs conducted their own search for prior art and determined whether the application could stand as written. In that regard, the Delegation remarked that IPOs did not rely solely on the list of prior art provided by the applicant: for example, willfully deleted information on prior art was not removed from the scope of prior art and could still be searched and considered by an examiner; non-compliance with a disclosure requirement might lead to the invalidation of the patent; and willful exclusion of information might constitute a breach of the Professional Code of Conduct, while in most countries such professional misconduct triggered different sanctions or disciplinary measures. The Delegation recalled that at the twenty-first session of the SCP, Switzerland had proposed that the SCP work on a non-binding soft law as a solution to the cross-border aspect of the patent attorney-client privilege. The Delegation explained that such framework might contain general definitions of key terms such as patent advisor or privileged information and also a minimum standard of the privilege. The Delegation was of the view that that framework might serve as a template for national laws, since it provided a flexible approach that allowed adapting national legislation according to the Member State's legal background and needs. The Delegation reiterated that proposal and encouraged Member States to enter into discussions on the content of a non-binding framework.

197. The Delegation of Singapore expressed its appreciation for the work of the Secretariat. The Delegation stated that in a global economy where applicants filed patent applications in multiple jurisdictions, the treatment of confidential information and the risks of divulging such information were of concern. The Delegation noted that according to the Singapore's Evidence Act, communications between an attorney and his client were in general confidential. The Delegation said that, in addition, the Singapore Patents Act extended that privilege for communications between patent agents and their clients, which meant that any communication with respect to any matter relating to patents between a person and a registered patent agent or an entity qualified as a firm of patent agents was privileged from disclosure in legal proceedings in the same way as a communication between a person and his lawyer, and such protection applied to foreign patent agents as long as they were registered in accordance with the law of Singapore. The Delegation continued that in April 2013, an IP Steering Committee set up by the Ministry of Law had published an IP Hub Master Plan to establish Singapore as a global patent hub in Asia with an IP center and a dispute resolution center. The Delegation was also pleased to host an office of the WIPO Arbitration and Mediation Center since May 2010. In that context, the Delegation stated that Singapore's law provided clarity regarding the confidentiality to IP professionals in their communication with clients in legal proceedings, which increased the confidence level of IP professionals both local and foreign in the Singapore's IP legal system. The Delegation looked forward to contributing to further discussion and sharing of best practices, national experiences and solutions to issues and concerns arising under that topic.

198. The Delegation of the United Kingdom thanked the Delegations that had shared their experiences regarding confidentiality of communications. In the Delegation's view, the handout prepared by the delegation of Japan had provided a relatively simple but extremely useful demonstration of the various questions that could arise in cross-border situations. The Delegation stated that in England and Wales, communications with solicitors and barristers were covered by professional privilege, while in Scotland and Northern Ireland similar laws were in place although the regimes differed slightly. The Delegation noted that recent case law had confirmed that communications with foreign lawyers were entitled to the same legal professional privilege as communications with English lawyers. The Delegation noted that, however, legal professional privilege was not extended by the common law to

communications with people who were not lawyers, such as patent attorneys or accountants. The Delegation explained that nonetheless, Section 280 of the Copyright, Designs and Patents Act 1998 did extend legal privilege to communications with patent attorneys by providing that in England, Wales, Scotland and Northern Ireland, communication documents, material or information related to inventions, designs, technical information or trademarks or as to any matter involving passing off were privileged, where an attorney acted for a client in the same way as if the attorney had been the client's solicitor. The Delegation continued that in order for Section 280 of the Copyright, Designs and Patents Act to apply, the patent attorney should be a registered UK patent attorney on the UK register or a person who was on the European list held by the European Patent Office. The Delegation pointed out that patent attorneys registered anywhere else in the European Economic Area (EEA) could apply to be included on the UK register or could benefit from the European Union legislation concerning mutual recognition of professional qualifications; further, Section 280 also extended to partnerships and corporate bodies of such patent attorneys. The Delegation explained that therefore, in order for communications with the foreign patent attorney who was not a lawyer to get legal professional privilege in the UK, the patent attorney would need to be an EEA attorney who had successfully applied to be registered in the UK or to be on the European list held at the European Patent Office. In summary, the Delegation stated that communications between patent attorneys and their clients were privileged where the patent attorney acted for a client in the same way as if the attorney had been the client's solicitor, but that only applied to patent attorneys registered in the UK or on the European list held at the European Patent Office, and thus did not generally apply to communications with foreign patent attorneys. The Delegation noted that a number of individual countries such as Spain had taken domestic steps to afford privilege to communications with patent attorneys providing a level of privilege in respect of communications between patent attorneys and their clients equivalent to that provided between lawyers and their clients. The Delegation observed that patent professionals and their clients sought certainty with regard to cross-border aspects of the issue.

199. The Delegation of Australia stated that from the establishment of the Commonwealth of Australia in 1901, successive Australian Governments had, in principle, supported privilege of IP professional advice for clients of non-lawyer patent attorneys, just as privilege would apply to clients of lawyers. The Delegation noted that even from those early days, while many patent attorneys in Australia were also solicitors, patent attorneys were not generally required to possess legal qualifications, and at present, it was not a requirement for patent attorneys registered in Australia to be lawyers. The Delegation further noted that privilege in communications with patent attorneys had been provided in the first Commonwealth patent legislation, the Patents Act of 1903: Section 102 of that Act provided that "[e]very patent attorney shall have such privilege as are prescribed", which included that communications between patent attorneys and their clients shall be privileged to the same extent as communications between a solicitor and his client. The Delegation explained that under the 1990 Patents Act, that privilege had been expanded to include privilege in any record or document made for the purposes of such a communication. The Delegation continued that amendments in 1998 to subsection 200(2) of the 1990 Patents Act had been passed to provide that communications between an attorney and his client "in intellectual property matters" would be privileged. The Delegation emphasized that that amendment insured that privilege applied to communications between registered patent attorneys and their clients in intellectual property matters, which meant matters relating to patents, trademarks, designs or related matters. The Delegation pointed out that in 2004, the Honourable Justice Heerey in the Federal Court case of Eli Lilly v. Pfizer Ireland Pharmaceuticals had found that client-attorney privilege was "confined to communications with patent attorneys registered as such in Australia" and did not extend to communications with any patent attorney/agent anywhere else in the world. The Delegation underlined that the Australian Government had recognized that changes to the Act were needed to afford a

client of a non-lawyer patent attorney certainty in relation to confidentiality of intellectual property advice both in Australia and overseas, and furthermore, privilege applicable to clients of non-lawyer patent attorneys should also apply to their communications with overseas non-lawyer patent attorneys. The Delegation noted that the push for legislative reform in Australia had led to the enactment of the Intellectual Property Laws Amendment (Raising the Bar) Act in 2012 and that the provisions relating to privilege had come into effect on April 15, 2013. The Delegation explained that combined subsections 200(2) and (2A) of the Patents Act highlighted that a communication, a record or document made for the dominant purpose of a registered patent attorney providing intellectual property advice to a client was privileged in the same way, and to the same extent, as a communication, record or document made for the dominant purpose of a legal practitioner providing legal advice to a client. The Delegation underlined that reference in subsections 200(2) or (2A) to a registered patent attorney included a reference to an individual authorized to do patents work under a law of another country or region, to the extent to which the individual was authorized to provide advice of the kind provided. In the Delegation's view, that provision recognized that it was not always desirable or practical for applicants to limit their requests for advice to Australian patent attorneys, since in Australia the majority of patent applications came from applicants located outside Australia, and many foreign applicants continued to use patent attorneys in their own country. The Delegation observed that the scope of privilege was limited to the scope of a person's authority to perform the work in their home country or region: if a person was only authorized to do patents but not trademarks work in their home country, they would only receive privilege in Australia for their patents work. The Delegation underlined that while Australian legislative provisions afforded foreign innovators privilege in communications with their own patent attorneys and Australian patent attorneys when seeking protection in Australia, the reverse situation where Australian innovators seek protection overseas was less certain. The Delegation observed that in the absence of similar rights in foreign jurisdictions, Australian clients could not be confident that communications even with their local attorneys in Australia would be protected against disclosure in foreign court proceedings. The Delegation believed that free and frank communication between client and attorney was essential to good, clearly articulated patent applications. In the context of the global patent system, the Delegation believed that high quality professional representation led to well drafted specifications, greater certainty in validity of granted patents, and importantly, an increase in the quality of information disseminated to the public for the purpose of further innovation.

200. The Delegation of Poland thanked the Delegations that had contributed to the discussion with extremely informative and valuable presentations, which had shown how the problem of confidentiality had been dealt with in different jurisdictions. The Delegation stated that in Poland there was a general rule in the industrial property law which provided that in proceedings before the patent office in matters related to the filing of applications and maintenance of the protection of inventions, utility model, industrial designs, trademarks, geographical information and topographical information, parties could be represented by a patent or trademark agent or by a person rendering cross-border services. The Delegation noted that in proceedings before administrative and civil courts, including before the Supreme Court, in cases involving intellectual property matters, parties could be represented by barristers, attorneys at law or patent and trademark agents. The Delegation stated that all those legal representatives were obliged to keep the confidentiality of any information and communications obtained in connection with the performance of professional activities and could not be discharged from their obligation to keep professional secrecy as to the facts they obtained when providing assistance in IP matters. The Delegation explained that in terms of court proceedings, that meant that when being summoned to appear at the court hearing as a witness, legal advisors could invoke professional secrecy laws and refuse to testify and reveal any communication with the client before the court, since the provisions of the civil procedure code granted such a right. As regards persons rendering cross-border

services, the Delegation said that there was a general principle provided in the legal provisions regulating various professions including in the Act on Patent and Trademark Agents. According to that principle, such persons were entitled to perform any duties of barristers and attorneys at law or patent trademark agents if they were qualified to perform such duties in their mother countries, but only within the limits of rights provided in respect of that profession in the laws of their own countries, which meant that foreign advisors in Poland enjoyed confidentiality privilege only to the extent they enjoyed it in their home countries. The Delegation remarked that in order to be able to enjoy those rights, such persons had to meet some formal requirements stipulated by the Polish law, such as submitting a certificate confirming that they were qualified to practice their profession in their country of origin, a document indicating his or her citizenship, and a copy of the civil liability insurance. The Delegation further noted that it was advisable that such persons had communication skills in the Polish language. The Delegation then pointed out that that general rule applied to citizens of the EU Member States, while the principle of reciprocity applied to persons rendering cross-border services that were members of non-EU Member States. The Delegation concluded that although the scale of the confidentiality problem in Poland was not fully known, Polish patent and trademark agents were very much interested in having a regulation on confidentiality of communications between clients and their advisors at the international level.

201. The Delegation of the United States of America thanked the Delegations of Japan and Spain for their informative presentations. The Delegation emphasized that the lack of international standards could present problems for innovators who sought to patent and thus had to obtain counsel in multiple jurisdictions. The Delegation stated that discovery rules in the United States of America tended to be more liberal than in many other jurisdictions. The Delegation noted that the attorney-client privilege in its country was governed by a patchwork of federal common law that was not uniform throughout the United States of America: for example, generally US patent agents in many jurisdictions received the same protection as patent attorneys in federal courts, however, in some jurisdictions within the US, patent agents did not receive the same privilege which created an inconsistency in the system. The Delegation further noted that the client-attorney privilege was not always extended to communications with foreign patent practitioners in US courts: for example, some jurisdictions had a bright line rule denying privilege, while others considered many factors under different tests which might or might not recognize the privilege. The Delegation observed that such a situation could create challenges for stakeholders in enforcing their patent rights internationally, and thus, in order to better assess the situation, in late 2014, the United States Patent and Trademark Office (USPTO) had begun an outreach initiative to obtain views from US stakeholders and to formulate a response to that issue. The Delegation remarked that such an outreach had also been initiated in response to a joint proposal by the AIPPI, AIPLA and FICPI for harmonization of the privilege rules. The Delegation highlighted that, as part of that outreach, the USPTO had conducted major activities, including the hosting of a round table discussion with panelists representing a broad cross-section of intellectual property interests, and the collection of written comments from stakeholders which expressed a range of concerns about the lack of clear privilege protections, and thus supported the adoption of a legislative solution. The Delegation recalled that in April 2015, the US Delegation had reported to Group B+ that the US would continue working on the issue of client-attorney privilege, for instance by exploring the possibility of adopting federal legislation. The Delegation also pointed out that in June 2015, the USPTO had published on its website a report summarizing the feedback received from stakeholders. Further, the USPTO had drafted a model legislative language that could address the US domestic situation with an accompanying description of the policy issues involved, and that draft model language had been shared with stakeholders to determine where consensus existed. The Delegation continued that in August 2015, the US had solicited public comment on the promulgation of a Patent Trial and Appeal Board privilege

rule that would grant privilege to communications with foreign practitioners in Appeal Board proceedings as part of a proposed rule package. The Delegation reiterated that the United States of America planned to continue working with Group B+ on that matter and to provide policy guidance to their stakeholders and to the US Congress as needed on the topic of possible federal legislation. The Delegation however observed that progress in that area depended on the actions of groups outside of the USPTO's control, and that in order to continue to work with the relevant parties, the USPTO needed additional support from those groups. The Delegation remarked that specifically, further progress in that area required actions by both US stakeholders and the Congress. The Delegation stated that public comments on the proposed appeal board rules package were due on November 18, 2015, and that the USPTO was in the process of reviewing those comments in order to prepare a final rule on privilege. The Delegation considered that whether such a rule ultimately went forward would depend not only on factors such as the nature of the comments received, but also on the handling of the appeal board rules package as a whole. The Delegation noted that although the timeline for a final rule package was uncertain, it generally took several months at a minimum for such a rule package to be finalized. The Delegation concluded that once a potential domestic solution to attorney-client privilege issues was develop, the United States of America would be ready to explore possible international approaches.

202. The Delegation of Portugal thanked the Delegations of Spain, Japan and Switzerland for their presentations. The Delegation stated that while there was not a specific legislation relating to the confidentiality of communications between a patent attorney and his client in Portugal, the patent attorneys who were members of the Portuguese Association of Industrial Property Consultants were bound by the rules of the Association and of the relevant international federation. The Delegation noted that the patent attorneys who were also attorneys at law were as well subject to the rules established by their own professional bar, which recognized the obligation of confidentiality in communication with clients. The Delegation observed that although there were no legally prescribed penalties, the duties of confidentiality were generally safeguarded in the national territory. The Delegation remarked that, however, that was not true at the international level, since there were no regulations covering that subject and the differences were found within the various jurisdictions. The Delegation stated that the lack of an international regulation on the issue of confidentiality was disturbing, considering a cross-border character of the information contained in patent documents. In its opinion, non-disclosure rules that had a transverse nature among several countries were required. The Delegation observed that the international IP system would benefit if a common solution were achieved between the different Member States to ensure that confidentiality of patent attorneys' professional advice was not subject to distant rules.

203. The Delegation of India reaffirmed its stand on the issue as taken at the previous sessions of the SCP. The Delegation reiterated that neither the Paris Convention nor the TRIPS Agreement provided for any such privilege. The Delegation considered that harmonizing client-attorney privilege implied harmonizing the exceptions to the disclosure. The Delegation noted that, in the Indian patent system, persons who graduated in science or engineering were qualified to practice as patent agents after passing the Indian Patent Agents examination, even without having a law degree. The Delegation explained that the Indian Evidence Act provided protection for lawyers from discovery proceedings, and that a patent agent, being a person of scientific background, did not fall under such protection. The Delegation observed that, since such disclosure might help the courts in the final determination of substantive issues such as novelty, inventive step, industrial applicability and sufficiency of disclosure, such privilege might be detrimental to the patent system. In the Delegation's view, the issue was of substantive nature and governed by national laws, and thus the work of the Committee on that issue should be discontinued.

204. The Delegation of Romania, speaking on behalf of the CEBS Group, thanked the

Delegations of Japan and Spain for their presentations and the Delegations that had provided an insight into their national experiences. The Delegation reiterated the importance that the CEBS Group attached to the confidentiality of communication between clients and their patent advisors with respect to cross-border aspects. The Delegation noted that it was evident that the variety of regulations on client-attorney privilege or the lack of regulations were detrimental to the interests of patent holders who wanted to market their products in other countries, and therefore, the CEBS Group strongly supported continuing work in the Committee with the aim of developing a non-binding soft law instrument that would protect confidentiality of communications between clients and patent advisors. In that regard, the Delegation proposed that the Secretariat conduct a study that would describe and assess various types of soft law approaches in that area.

205. The Delegation of Greece, speaking on behalf of Group B, expressed the importance that Group B attached to the item regarding confidentiality of communications between clients and patent advisors. The Delegation explained that that issue had an international dimension which should be addressed at the international level, in particular the aspect of recognition of foreign advisor's privilege. In that regard, Group B considered that the SCP should take substantive steps to address the issue in a manner that left enough flexibility for Member States in light of the differences in legal systems among Member States. In that context, Group B supported the view that a soft law approach should continue to be pursued and stated that the sharing session among Member States with regard to how confidentiality applied to different types of patent professionals agreed during the twenty-second session of the SCP contributed to that discussion. Furthermore, Group B noted that different opinions were presented around that issue, and therefore, it might be wise to see the concrete programs and/or difficulties in a more objective and precise manner. As a possible approach for that purpose, Group B proposed two studies to be considered by the Secretariat. The first one was a study based on a questionnaire/survey to Member States including elements such as obstacles to expand the types of professionals covered by client-attorney privilege; differences of the treatment between national and foreign patent advisors including the client-attorney privilege in order to provide reciprocal attorney-client confidentiality privilege and elimination of any obstacles to such difference. The second study would be in relation to court decisions on that subject matter in Member States. The Delegation explained that the collection and analysis of court cases could make more visible what issues needed to be dealt with and how they could be addressed. The Delegation further noted that the issue of confidentiality of communications between clients and patent advisors was also of critical importance from the viewpoint of practitioners. Therefore, Group B supported the continuation of the work of the Committee on that topic in response to the voices from real world, which would ultimately contribute to the creation of an enabling environment for innovation.

206. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States, thanked the Delegations for their presentations. The Delegation reiterated its position taken in previous sessions of the SCP and stated that time was ripe to consider a concrete mechanism to address the recognition of foreign patent advisors' privilege. The Delegation affirmed that, without prejudice to existing national legislation and in order to ensure optimal flexibility, a soft law approach should be considered, aiming at conferring the same protection in Member States to communications between a client and its foreign patent adviser and to communications between a client and its national patent adviser. In the Delegation's view, 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 users of the patent system, irrespective of the level of development of individual WIPO Member States.

207. The Delegation of Congo (Democratic Republic of) congratulated the Chair and

thanked the Secretariat for their technical assistance. The Delegation also thanked those Delegates who had shared their experiences on the topic. The Delegation expressed its concern with the potential loss of the confidential nature of communications between clients and attorneys, because if there was no confidentiality, the information would lose its importance. The Delegation noted that a non-lawyer could not act as a patent attorney and, as other delegations had noted, each country had its particular legislation on that issue. The Delegation suggested that a resolution on making uniform legal requirements in Member States on confidentiality of information between clients and attorneys be adopted during the course of the twenty-third session of the SCP.

208. The Delegation of Iran (Islamic Republic of) thanked those delegations who had shared their views, experiences and information on the issue, and reiterated its position expressed during the previous sessions of the SCP. The Delegation stated that the issue of client-attorney privilege was a matter of procedure that fell outside the scope of application of patent laws and it was not treated similarly within different national laws. The Delegation further noted that that matter fell within the area of private law, procedural law or regulation of professional services and hence fell outside of the mandate of WIPO. Therefore, the Delegation did not support any proposals for norm setting, setting out soft law or continuing substantive work on those issues. The Delegation expressed its support to the statement made by the Delegation of India. The Delegation believed that that issue should be taken out from the SCP agenda, because it was not relevant to the work of the SCP, and therefore, the Delegation could not support any suggestions for future work on that issue.

209. The Delegation of the Republic of Korea supported the statements made by the Delegation of Romania, speaking on behalf of the CEBS Group, and the Delegation of Greece, speaking on behalf of Group B. The Delegation recognized the importance of the confidentiality privilege between clients and their patent attorneys, particularly when it came to cross-border aspects. The Delegation therefore supported to continue the discussion on that topic in the SCP, including the preparation of a comprehensive study by the Secretariat. The Delegation also supported the proposals to explore the possibility of taking a non-binding soft law approach to address those issues.

210. The Delegation of China thanked the Delegations that had shared their experiences on the confidentiality of communication between clients and their patent advisors. The Delegation stated that the information provided had helped them realize once again the value of such confidentiality in ensuring the quality of legal services and safeguarding public interests. However, the Delegation pointed out that the intrinsic differences between national litigation systems should also be properly understood and recognized. The Delegation thought that while it would be useful to carry out investigation, research and cooperation on that matter, no harmonized norms should be developed at the international level, be it binding legal system or non-binding soft law. The Delegation reaffirmed its stance on that issue as taken in previous sessions of the SCP. The Delegation considered that confidentiality of communications between clients and their patent advisors was more of a matter concerning national litigation and procedural law, and thus the SCP was not an appropriate platform to discuss that topic.

211. The Representative of TWN stated that it was important to maintain absolute transparency around the granting of patents and patent litigations, therefore, an opaque layer around the patent specifications should not be allowed. The Representative considered that the confidentiality privilege to patent advisors compromised the transparency requirement in the administration of patents, which included both patent prosecution procedures and litigation of patents. The Representative further noted that the patent specification was a public document and, therefore, any related records that were used for the preparation of the patent specification should also be available to the scrutiny of the

patent office as well as in court in order to find out the truth about the claims made in the specification. The Representative was of the opinion that from a public policy perspective, it might not be a good idea to maintain a high level of confidentiality when it came to the patent application. In the Representative's view, when areas of public interest were concerned, the level of confidentiality should not be heightened. The Representative stated that some Member States had granted or extended those confidentiality privileges due to different interests, such as creating an IP hub in their jurisdictions; however, many other countries might have other interests and needs and thus should be free to take a different policy approach towards the confidentiality issue. The Representative noted that in order to continue discussion on that issue in the SCP, a public policy analysis on how the confidentiality privilege was going to impact the public policy should be carried out. The Representative highlighted that while advocating for that privilege, there were no country examples on how that privilege was impacting the enjoyment of patent rights or negatively impacting the granting of patents. The Representative considered that if there was no link between the disclosure to the patent attorney by the client and the patent disclosure requirement, the communications could be protected, but otherwise, the patent offices or the courts should not be prevented from scrutinizing such information.

212. The Representative of APAA congratulated the Chair for her continued leadership and thanked the Delegations of Japan and Spain for their presentations as well as the other Delegations that had shared information on their practices with regard to confidentiality. The Representative stated that the APAA, which represented patent attorneys in the Asian region, had passed a resolution concerning the issue of attorney-client privilege in 2009. The Representative explained that the resolution had shown recognition to the issue of attorney-client privilege and had called for collecting and sharing information on current and prospective problems throughout the various legal jurisdictions in WIPO Member States. The Representative noted that intellectual property disputes might occur across multiple jurisdictions. APAA, as an association of IP professionals advising their clients on the potential risks related to IP matters, believed that it was necessary to recognize the confidentiality of communications between attorneys and their clients across jurisdictions. The Representative therefore strongly supported taking further steps towards setting minimum international standards for protecting clients' rights against forced disclosure of confidential communications between attorneys and their clients, and also urged the SCP to conduct a comprehensive study for collecting and sharing information on current and prospective problems related to that issue in WIPO Member States.

213. The Representative of AIPPI stated that during a seminar that had been held in WIPO on the issue of confidentiality, the various difficulties that could be encountered particularly with regard to cross-border litigation had been very clearly presented. The Representative noted that the Delegation of Japan had also shown very simply and effectively the difficulties related to patent law and patent rights that needed to be resolved. The Representative considered that the issue of confidentiality was of interest for all developing countries as well as developed countries and thus that topic needed to be maintained on the agenda of the SCP so that discussion could continue in order to find a minimal solution for it.

AGENDA ITEM 9: TRANSFER OF TECHNOLOGY

214. The Chair recalled that during the twenty-second session of the SCP, it had been decided that at its twenty-third session, the Committee would discuss the topic of transfer of technology *vis-à-vis* sufficiency of disclosure based on document SCP/22/4.

215. The Secretariat presented document SCP/22/4, particularly in relation to transfer of technology.

216. The Delegation of Greece, speaking on behalf of Group B, reiterated great importance it attached to the issue of transfer of technology in general. The Delegation emphasized the close relationship between having a healthy intellectual property system to foster innovation, development of improved technology that benefited all and the role of technology transfer. The Delegation stated that in February 2015, as part of the Committee on Development and Intellectual Property (CDIP) project, an Expert Forum on International Technology Transfer had been successfully conducted. In particular, the Delegation recalled that the panel discussion during the Expert Forum had provided useful and informative insights supported by practical experiences of panelists. The Delegation noted that the CDIP was still discussing how it should proceed with its work, taking into account of those thoughts that had come from the Forum, which concerned technology transfer in general. Therefore, Group B expressed its belief that the SCP should not consider future work relating to technology transfer in general. In the Delegation's view, there was only one aspect which could be dealt with by the Committee taking into account the mandate of the SCP, i.e., the issue of voluntary licenses between patent holders and third parties as well as non-assertion statements by patent holders, for example in the field of HIV/AIDS and a variety of technological fields. The Delegation stated that a study on that field exploiting the expertise of the SCP could complement the general discussion at the CDIP, while avoiding duplication of work with other committees such as the CDIP.

217. The Delegation of Nigeria, speaking on behalf of the African Group, reiterated its position that had been taken in the previous SCP sessions. In its opinion, the work in the CDIP should be independent of the work in the SCP, since the CDIP's activities on technology transfer covered different areas. The Delegation proposed that the Committee prepare a study on the relationship between the patent system and international technology transfer. The Delegation expressed its interest in continuing discussion on that agenda item as part of the future work of the Committee.

218. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States, recalled that at the SCP22, it was decided to discuss transfer of technology *vis-à-vis* sufficiency of disclosure, as contained in document SCP/22/4. The Delegation noted that that document consisted of three parts, the enabling disclosure requirement, the support requirement, and the written description requirement, and that the study contained information based on the contributions of 58 Member States and three regional offices. The Delegation further noted that the study expressed that "it is through the disclosure requirement that the patent system facilitates the dissemination of information and access to technological knowledge contained in the patent application. This results in the expansion of public stocks of technical knowledge and an increase in the overall social benefits, for example, inducing the technology transfer and avoiding a duplicative R&D." The Delegation stated that it supported that statement. The Delegation noted that during the 16th session of the CDIP, the evaluation report on the "Project on Intellectual Property and Technology Transfer: Common Challenges – Building Solutions" had been discussed, and that as a follow up, the CDIP had requested the Secretariat to map WIPO's existing activities in the field of technology transfer for consideration at the 17th session of the CDIP. The Delegation considered that that was a valuable exercise in completing the Project, and thus until completion of that Project and a thorough follow-up analysis, the Delegation was not in favor of launching new initiatives within the SCP.

219. The Delegation of Romania, speaking on behalf of the CEBS Group, noted that document SCP/22/4 clearly pointed to the fact that the disclosure of an invention, as prescribed by the patent system, contributed to the dissemination of technical knowledge and induced transfer of technology. The Delegation stressed that, as demonstrated by other studies, other factors (political or economic) might facilitate or constitute barriers to the

transfer of technology. The Delegation believed that quality of patents and a well-functioning PCT system were important elements for the patent system to fulfil its objectives in terms of supporting innovation and transfer of technology. The Delegation further noted that at the same time, when addressing that topic in the SCP, it was necessary to avoid duplication with other WIPO bodies, such as the CDIP. The Delegation stated that for that reason, the Delegation could not support other possible initiatives until the "Project on Intellectual Property and Technology Transfer: Common Challenges – Building Solutions" was finalized.

220. The Delegation of India expressed its support to the statement made by the Delegation of Nigeria on behalf of the African Group. The Delegation stressed that sufficiency of disclosure was at the heart of the matter of the patent law and provided the *quid pro quo* of the patent system. The Delegation recalled that in the fourteenth session of the SCP, the Committee had started discussing the topic of transfer of technology, and had given reference to the role of patent systems in the context of the transfer of technology. The Delegation quoted paragraphs 48 and 49 of document SCP/14/4, which stated that: "One of the characteristics of "knowledge", including technological knowledge, is that it is a public good that is "non-excludable" (people cannot be excluded from freely using a public good) and "non-rival" (it can be used simultaneously by many people). The nature of knowledge as a public good means that, once an invention has been created, it can be freely used by others at no additional cost. This results in situations where an inventor, who must invest to create a new invention, cannot capture the full benefits of the invention through its exploitation (e.g., selling in the market). Free riders can copy or imitate the invention and sell the copied products much more cheaply than the original inventor, because they do not bear the cost of R&D. This would reduce the expected returns of the original inventor, and would result, in theory, in an under-provision of new inventions. The patent system is intended to correct such innovation under-provision by providing innovators with limited exclusive rights to prevent others from exploiting their invention and thereby enabling the innovators to appropriate the returns on their investment. At the same time, the patent system requires innovators to disclose fully their inventions to the public. These fundamental elements of the patent system play an important role in the dissemination of knowledge and the transfer of technology." The Delegation stated that that statement suggested that the knowledge content of the patent specification served as an extremely important tool for transfer of technology. The Delegation noted that as document SCP/22/4 had revealed, under ideal conditions, a patent specification should divulge the technology in an enabling manner, so that a person skilled in the art could work out the invention without undue burden of further innovations. The Delegation however observed that there were instances especially in the health sector where a product could not be produced due to insufficiency of description of the patent specification and therefore, the Delegation wondered to what extent the patent system as a stand-alone system could contribute to the transfer of technology without the aid of accompanying trade secrets. The Delegation reiterated its request that the role of patent systems in the context of transfer of technology should be carefully studied in the background of sufficiency of disclosure.

221. The Delegation of South Africa aligned itself with the statement made by the Delegation of Nigeria on behalf of the African Group. The Delegation thanked the Secretariat for preparing document SCP/22/4 and recalled that the twenty-second session of the SCP had agreed to undertake a study on the sufficiency of disclosure based on that document, since SCP/22/4 had not adequately described that requirement. The Delegation stated that the requirement of sufficiency of disclosure was the bedrock of the IP system. In the Delegation's view, WIPO should continue discussing how the system could be improved, including considering initiatives that could assist against the avoidance of full disclosure with a view to maintaining the system's integrity and to allowing for the patenting of quality inventions which would contribute to the building and dissemination of knowledge, innovation, creativity, and technology as well as to avoiding duplication of R&D for the

benefit of all. The Delegation stated that the requirement of sufficiency of disclosure had the potential to play a key role in national innovation systems. The Delegation continued that that requirement was a crucial component of the technology dissemination and technology transfer function of the patent systems. The Delegation was of the opinion that that requirement was indeed an important flexibility provided by the TRIPS Agreement, which could contribute to the benefit of people across the world, if it was applied optimally and accompanied by appropriate policies and initiatives. The Delegation recognized that the study 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 which stated that "Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in prior art". The Delegation expressed its view that the study on sufficiency of disclosure had explored the patent laws of different countries but did not in itself constituted investigation of how patent law could contribute to technology transfer and more specifically how access could be ensured using flexibilities. The Delegation noted that it was important to note that the availability of laws did not in itself mean understanding of the implementation of the rights and obligations in a manner that encouraged optimum technology transfer. The Delegation expressed its support to the proposal by the Delegation of Nigeria on behalf of the African Group on future work on the issue of transfer of technology.

222. The Delegation of Vietnam expressed its support to the statement made by the Delegation of India.

223. The Delegation of Colombia stated that the topics of transfer of technology and sufficient disclosure in the patent application were in some instances badly interpreted. The Delegation noted that transfer of technology was a procedure to make technology available for commercial exploitation in order to help development. The Delegation observed that there might be many reasons for transferring technology such as forming alliances with other companies who could continue to develop the technology or could take on the manufacturing stage or could put the technology on the market and/or distribute it. The Delegation then remarked that transfer of technology was established through a legal relationship in which the holder of the technology or the holder of the patent rights granted others the rights to exploit that technology. The Delegation highlighted that when a technology was protected by patents, in some cases there was confidential information related to the patented material that was not included in the patent application but was maintained as a commercial secret, for instance, an active compound could be patented but the processes for manufacturing it might be kept as a commercial secret. The Delegation pointed out that in such cases, not disclosing that information was not understood as a lack of sufficient disclosure.

224. The Delegation of China noted that the SCP played an important and positive role in comprehensively 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. The Delegation therefore suggested that the SCP further study the relationship between the patent system and technology transfer, identify possible difficulties faced by developing countries in the process, seek viable solutions, and share experience of different countries on the promotion of technology transfer as well as study possible systems or rules that would be both operable and conducive to technology transfer. The Delegation noted that document SCP/22/4 on the substantive patent law issue of sufficiency of disclosure had pointed out that timely disclosure of patent information enabled the dissemination of patented technologies, avoided duplication of research and improved overall social benefit. While the Delegation agreed to the contents of that document, in its view, further evaluation and discussion on the role of sufficiency of disclosure in technology transfer was needed. The Delegation therefore suggested that the Secretariat continue analyzing the relationship

between sufficient disclosure and technology transfer.

225. The Delegation of Iran (Islamic Republic of) expressed its support to the statements made by the Delegations of India and South Africa supporting the proposal made by the Delegation of Nigeria on behalf of the African Group for future work on the subject of technology transfer.

226. The Delegation of Brazil, speaking on behalf of GRULAC, recalled that GRULAC had consistently expressed its interest in new joint efforts under the agenda item of transfer of technology during the previous SCP sessions. With reference to the proposals made by some delegations, the Delegation requested other delegations to submit their proposals on the topic in writing. The Delegation expressed its support to the proposals made by the African Group and by the Delegation of China.

227. The Representative of TWN expressed its belief that WIPO, as a specialized agency of the United Nations, had a mandate to work on transfer technology. The Representative recalled that the panelists of the seminar on patents and access to medicines, irrespective of their backgrounds, had agreed that the patent system was not working when there was a market failure. The Representative stated that transfer of patented technology was very important and should be facilitated, especially in the area of health. The Representative noted that there were instances of patent rights being used to prevent technology transfer: for example, certain companies that had developed a Hepatitis C drug had offered a license to genetic companies that was perpetual in nature and could prolong the patent monopoly, since there was uncertainty with regard to a pending patent application on the drug that made generic producers to take the license; the Competition Commission of China had imposed a fine on Qualcomm for indulging in anticompetitive practices for the licensing of the company's patented technology; and in India, patent holders like Ericsson had obtained injunctions against certain smartphone manufacturers. The Representative pointed out that although disclosure was an important element for facilitating technology transfer, a standard format for disclosing technology had not yet been created. The Representative understood that different technologies needed different disclosure format, and suggested that disclosure formats should be created for the different types of patent applications in the main five to seven types of technologies such as pharmaceuticals or biotechnology. In the Representative's view, not having a disclosure format could be used by the patent holder to avoid disclosing the invention sufficiently. The Representative stated that it was important to inform patent offices in developing countries about the minimum requirements for patent disclosure, which would facilitate technology transfer. The Representative then noted that, as part of the CDIP project on technology transfer, the Secretariat had carried out studies that had recommended that the patent law flexibilities were also an important way of technology transfer, and therefore, it was important that the Secretariat continue to work on the flexibilities and on how they could facilitate technology transfer. The Representative stated that discussions in the SCP on the topic of transfer of technology should be focused on the relationship between patents and technology transfer instead of technology transfer as a theme.

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

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

229. The Delegation of Brazil, speaking on behalf of GRULAC, recalled the history of the 1979 WIPO Model Law for Developing Countries on Inventions: in 1965, the United

International Bureaux for the Protection of Intellectual Property (BIRPI), the predecessor of WIPO, published a Model Law for Developing Countries on Inventions; about ten years later in 1974, the need was felt for a revision of that Model Law, and the current Model Law was published in 1979. The Delegation states that, with the spirit of providing the Secretariat with a useful tool for capacity building activities, GRULAC countries had proposed, during the last session of the SCP, the beginning of the discussion on the revision of that Model Law (document SCP/22/5). The Delegation explained that the proposal by GRULAC took into consideration the following aspects, among other issues: the availability of funds in the 2014/2015 Program and Budget as well as in the next biennium; consideration of the relevance of main factors of patent law in a comprehensive manner; and legislative and policy assistance in line with the Development Agenda recommendations 13 and 14. The Delegation considered that its proposal offered the opportunity to update a document from the 70s to reflect changes occurred after that period in the patent law area, in particular, the entry of force of the TRIPS Agreement in 1995 and implementation of its provisions in national legislations. In its view, a revised document would be used as the basis for consideration by Member States when updating or reviewing their patent legislations. Based on the comments received during the last session, the Delegation observed that there was consensus on two points, namely, the Model Law was outdated and the revision of the Model Law should not lead to harmonization. Taking those comments into account, the Delegation proposed that the Secretariat prepare a proposal for consideration of Member States on the terms of reference and modalities that such a revision could follow. The Delegation clarified that Member States must be able to intervene and participate in that process. The Delegation recalled that Member States, during the last session, GRULAC had requested that discussions be held in three areas: (i) usefulness of the Model Law for the work of the Secretariat; (ii) the situation of the Model Law *vis à vis* the international patent system; and (iii) information exchange in respect of what Member States would expect in a Model Law from a UN agency such as WIPO. The Delegation suggested that those points should be the parameters for the Committee's discussions.

230. The Delegation of India restated its support to the proposal by GRULAC. It stated that the 1979 WIPO Model Law should be modified in order to make it fully and adequately reflect the developments of the recent past as well as the TRIPS flexibilities. The Delegation expressed its belief that the proposal however should not construed to mean any harmonization of patent laws.

231. The Delegation of Paraguay fully supported the statement made by the Delegation of Brazil on behalf of GRULAC. Observing a support to the GRULAC proposal by most of the regional groups and several individual delegations, the Delegation considered that it was timely to go into some greater detail on two elements of the proposal, namely the terms of reference and modalities. As regards the terms of reference, the Delegation was of the view that some interventions during the last session of the Committee had demonstrated that there had been certain confusion with regard to what the revised Model Law was trying to achieve. The Delegation considered that the Committee should instruct the Secretariat to present, at the next session, the terms of reference to carry out a factual and comprehensive exercise that would address the needs and considerations of Member States. In its opinion, that would enable Member States to have a clearer idea of the way forward. The Delegation noted that, for example, as a first step, it would be appropriate to review all of the provisions of the Model Law with the aim of reviewing whether they were still relevant. In its opinion, a similar exercise could be carried out with the comments and the rules. With regard to the modalities, the Delegation stated that the Committee should charge the Secretariat with proposing flexible and inclusive modalities to take the process forward. The Delegation observe that, during that process, the actors in the process could present their own legislations, regulations and practices on patent matters, and the Secretariat could illustrate the various different technical assistance activities on specific issues, rather than providing

technical assistance activities through confidential and bilateral cooperation. The Delegation stated that the revision of the Model Law and technical assistance provided by WIPO on a bilateral level were not incompatible: on the contrary, both processes should feed into one another, benefiting everyone, particularly small countries with limited resources, such as Paraguay, taking into account the fact that the main objective of development of those patent systems was to promote innovation, creativity, competitively and foreign investment. The Delegation noted that, for the preparation of the terms of reference and modalities, Member States could guide the Secretariat with regard to their various interests. The Delegation further observed that at the last session of the Committee, the relevance of the Model Law in technical assistance activities and parameters for the negotiators of the Uruguay Round in the context of the TRIPS Agreement and a special group of WTO was highlighted. With regard to the risk of harmonizing national patent laws by an instrument of "soft law" such as a model law, the Delegation stated that since the situation in the years of the 70s and 80s was quite different from the current situation, it was very unlikely that countries would simply discard their current laws to adopt provisions of a new Model Law. The Delegation noted that the Model Law would not be of a binding nature, and the process of the revision of the Model Law should be an academic and factual exercise, taking into account the current standards in the international patent system, and should serve as a basis for modifications that each Member State might wish to adopt within its own legal framework. The Delegation further considered that an updated Model Law would enable the Secretariat to build a relevant document in the framework of technical and legislative assistance activities. The Delegation reiterated that the GRULAC proposal was of a procedural nature and was not attempting to start a substantive discussion in the current session on the contents of the Model Law, but on the modalities and terms of reference, taking into account the considerable support from the majority of the membership. Finally, the Delegation stated that it was always ready to work in a constructive way with all delegations to take forward and strengthen the work of the Committee.

232. The Delegation of Romania, speaking on behalf of the CEBS Group, thanked GRULAC for their proposal to revise the 1979 WIPO Model Law for Developing Countries on Inventions. The Delegation reiterated that engaging in such an exercise would trigger harmonization of substantive patent law, yet harmonization was not currently among the objectives of the Committee. The Delegation further stated that since all Member States advocated for a balanced work program that would meet the concerns of all Member States, if the Committee would agree to include work on the Model Law in its agenda, it would need to revisit the current five topics in order to maintain the delicate balance that had been agreed upon. The Delegation therefore considered that it was not worthwhile to engage in such an exercise.

233. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States, reiterated the importance of retaining the delicate balance of different regional priorities in the current work program. In its opinion, including the discussion of the 1979 Model Law in the agenda would take the Committee further away from a balanced work program. The Delegation stated that, although the background information relating to the GRULAC proposal was interesting, the European Union and its Member States were still unclear as to the reason and the background why that revision was sought, as more appropriate means were already available. In that regard, the Delegation highlighted the 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 in the area of patents, which 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, so far, it had not heard any convincing arguments about the need to revise the Model Law in order to further consider the proposal. If taken forward, the Delegation was of the view that a revision would lead to a substantive

harmonization of patent laws. In that case, the Delegation believed that the Committee could use the opportunity and start with harmonization of other aspects of patent law, which could be beneficial to all. On a substantive note, the Delegation reiterated that WIPO should not touch upon interpretation of the TRIPS provisions.

234. The Delegation of India, speaking on behalf of the Asia and Pacific Group, supported the proposal of GRULAC on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions. The Delegation considered that the revision of the Model Law should emphasize legislative and policy options for Member States. In its opinion, the current agenda item was by no means at a lesser level of priority, and should be given equal importance with other substantive agenda items.

235. The Delegation of Trinidad and Tobago supported the proposal made by GRULAC to revise the 1979 WIPO Model Law for Developing Countries on Inventions. The Delegation expressed its belief that such a revision was necessary in order to effectively assist developing countries to bridge a gap that was currently being experienced in the international IP system.

236. The Delegation of Iran (Islamic Republic of) supported the statement made by the Delegation of India on behalf of the Asia and Pacific Group and the proposal submitted by GRULAC. The Delegation considered that a revision of the Model Law should be development-oriented and in line with the Development Agenda recommendations. In its view, the revision should also provide legislative and policy options for developing countries to utilize flexibilities envisaged in the TRIPS Agreement. The Delegation reiterated that the revision of the model provisions would not be translated directly into national laws. It stated that developing countries should adapt the Model Law in accordance with their national requirements, and thus the Model Law provisions in its entirety should not be used in national laws.

237. The Delegation of Greece, speaking on behalf of Group B, took note of the GRULAC proposal. The Delegation stated that Group B could not accept continued discussion on that proposal which created a significant imbalance in the SCP discussions.

238. The Delegation of South Africa supported a revision of the Model Law. The Delegation considered that, in order to assist developing countries, the Model Law should be updated to reflect all the development in the area of patent law over the past few decades, giving consideration on the specific needs of developing countries.

239. The Delegation of the United States of America expressed its support for the statement made by the Delegation of Greece on behalf of Group B. The Delegation stated that it had not heard any convincing arguments for the undertaking of a revision of the Model Law.

240. The Delegation of China stated that a revision of the Model Law could provide developing countries with concrete legal and policy assistance, which fell under the mandate of the SCP and was useful for moving the work of the SCP forward. The Delegation therefore supported the proposal of GRULAC. The Delegation recommended that the Secretariat listen to the views of Member States in a comprehensive and sufficient manner, in particular, collect information on the specific needs of developing countries in terms of the revision of the Model Law. In its view, since it was a model law for developing countries, the needs of developing countries should be given priority and respected. The Delegation looked forward to information reports and work proposals by the Secretariat as the basis for future discussions.

241. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States, fully supported the statement made by the Delegation of Greece on behalf of Group B. The Delegation reiterated that it was not convinced as to the reasons and background of the revision sought, since in its view, more appropriate means were already available.

242. The Representative of TWN stated that the independent review of the WIPO technical assistance had clearly shown that there had been a huge gap between the Development Agenda recommendations and the technical assistance in the area of legislative assistance provided by WIPO. In his view, the best way to resolve that gap was to revise the Model Law, which had been framed in 1979. The Representative considered that the Model Law was not suitable to address development concerns in the post-TRIPS era. He noted that it did not use the flexibilities available in the TRIPS Agreement: for instance, the flexibilities available to determine the scope of patentability was not used and the provisions concerning compulsory licenses were very limited. The Representative was of the view that the Model Law was not suitable to address the present day challenges posed by the patent regime, especially in the context of developing countries' development needs. The Representative further noted that the Model Law went against the spirit of the Development Agenda. Noting its understanding that the Secretariat had been using another version of the model law not in the public domain, the Representative said that it was important to ensure transparency in the technical assistance.

243. The Representative of KEI expressed its support for the statement made by the Delegations of Brazil on behalf of GRULAC and India on behalf of the Asian and Pacific Group as well as by the Representative of TWN.

244. The Chair noted that a number of delegations had supported the revision of the Model Law and had asked the Secretariat to prepare the terms of reference and options for modalities, while a number of other delegations had not supported the proposal and had stated that there were not enough convincing arguments brought by GRULAC to revise the Model Law.

AGENDA ITEM 11: FUTURE WORK

245. The Delegation of Romania, speaking on behalf of the CEBS Group, expressed its strong preference for achieving a balanced program of work that would meet the concerns of all Member States. The Delegation stated that the Group was primarily interested in advancing discussions on the quality of patents, as substantive patent law issues were the core of the agenda. The Delegation noted that, based on the studies that had been undertaken so far and the debates that had taken place, work on concrete steps to increase the quality of patents would be necessary. Furthermore, the Delegation reiterated that the CEBS Group was in favor of launching a questionnaire on the quality of patents based on the proposals made by the Delegations of Canada, the United Kingdom, Denmark and the United States of America. In its view, a compilation of the answers to such a questionnaire would result in a useful document. The Delegation also expressed its support for the proposal made by the Delegation of Spain at the 19th session as well as the latest proposal by the United States of America. In relation to the confidentiality of communications between clients and their patent advisors, the Delegation reiterated its support for a soft law approach as a useful way forward. The Delegation recalled its proposal for a study to be conducted by the Secretariat, which would describe and assess various types of soft law approaches in that area.

246. The Delegation of Brazil, speaking on behalf of GRULAC, expressed its wish that the

Committee would approve, as its future work, 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 the Member States of WIPO. The Delegation further noted that its Group was also interested in new developments under the agenda item of patents and health as well as new joint efforts relating to technology transfer. As regards the 1979 WIPO Model Law, the Delegation stated that its Group was looking forward to at least having a follow-up and exploring ways to move forward, since the Committee had not had a very consensual outcome from the discussion under the relevant agenda item. In that regard, the Delegation stated that it was ready to constructively engage in finding a future work related to a revision of the Model Law. In addition, the Delegation noted that its Group was waiting to receive the written proposals that had been put forward by other delegations so that the Group could analyze them.

247. The Delegation of the United States of America expressed its willingness to continue work of the SCP under the five agenda topics that had been agreed upon. Specifically, the Delegation suggested that its proposal in document SCP/23/4 be included in the future work program. The Delegation also recalled the previous proposals that it had made within the topic of quality of patents, namely, documents SCP/20/11 Rev., SCP/19/4 and SCP/17/10. In addition, the Delegation referred to its proposal concerning patents and health (document SCP/17/11).

248. The Delegation of Mexico stated that it was interested in continuation of the sharing session on inventive step that allowed sharing of experiences among experts of the various regions. The Delegation suggested that the Committee go into greater depth of such interesting discussion on patents and that similar work be carried out with respect to another document prepared by the Secretariat on sufficient disclosure.

249. The Delegation of Greece, speaking on behalf of Group B, stated that, as a preliminary comment, Group B would like to see the work of the SCP to be carried out on the five agenda items as it had been already agreed. The Delegation reiterated the importance of a balanced work program for the SCP discussions and recalled a number of proposals made by the members of Group B.

250. The Delegation of Chile stated that the Committee could continue to work on the five topics that were on its agenda in a balanced way. The Delegation considered that as regards the exceptions and limitations, the Secretariat could collect more information on experiences and case studies on the effectiveness of exceptions and limitations, also from industry, civil society and trade organizations. With regard to the topic of quality of patents, the Delegation considered that exchange of experiences regarding different models and forms of work sharing between patent offices would be useful. On patents and health, the Delegation stated that, since the seminar had been very interesting, a similar activity, such as sharing of experiences on patents and health, could be envisaged.

251. The Delegation of Spain expressed its greatest interest in the topic of quality of patents within the agenda of the Committee. The Delegation therefore suggested two activities for future work. First, the Delegation suggested that the Committee carry out additional work related to inventive step. In its view, inventive step was an essential element of substantive patent law that was the main purpose of the Committee. The Delegation explained that the work should preferably go into greater depth on the issue already raised in document SCP/22/3, for example, inclusion of a greater number of jurisprudence and examples and special emphasis in the assessment of inventive step in areas of special difficulty. The Delegation further noted that a similar activity could be carried out with respect to sufficiency of disclosure, and that it would also be interesting to continue the exchange of experiences

with respect to assessment of inventive step and sufficiency of disclosure. As regards the second program of work, the Delegation suggested that the Committee study one aspect which was more procedural, namely, reutilization of work products in accordance with the proposal of the United States of America, and particularly with respect to benefits and problems associated with the publication of search strategies.

252. The Delegation of Paraguay supported the Committee having a number of topics that were balanced. The Delegation stated that the topics of most interest for it were the issues on exceptions and limitations to patent rights, patents and health, transfer of technology and work sharing, which were the topics that had already been on the agenda of the Committee. With regard to the argument put forward by certain delegations concerning the balance being disturbed by the discussions on the proposal by GRULAC, the Delegation expressed its view that the inclusion of the Model Law as an individual topic would not affect the balance of the agenda. The Delegation observed that since the Committee had already finished discussions on the five agenda topics for the 23rd session of the SCP, the Committee could add other topics which were of interest to other delegations or regional groups without disturbing the discussions on the five topics.

253. The Delegation of Iran (Islamic Republic of) stated that it supported continuation of discussions on exceptions and limitations to patent rights, patents and health, transfer of technology and a revision of the 1979 WIPO Model Law. On the item of patents and health, the Delegation suggested that the Secretariat commission a study by independent experts, selected in consultation with SCP members, examining the constraints faced by developing and least developed countries in making full use of patent flexibilities for public health purposes both in the pre-grant and post-grant stage. On technology transfer, the Delegation suggested that a detailed study on the relationship between patent systems and transfer of technology be undertaken by independent experts. In addition, the Delegation stated that it was difficult to go along with the item of confidentiality of communications between clients and their patent advisors as well as with the proposal on work sharing.

254. The Delegation of the Russian Federation thanked all delegations for their productive way of work. As regards quality of patents, in particular inventive step, the Delegation noted great interests of Member States in discussing substantive issues of patent law. The Delegation observed that inventive step was one of the most complicated requirements assessed in the examination that led to quality of patents. The Delegation therefore suggested that the Committee request the Secretariat to provide one or two examples or models which could be understood by experts from various technical fields, for instance, simple examples such as a toothbrush or pencil, so that Member States could have a step-by-step approach for assessment of the inventive step. In its opinion, such examples could be brought together in a small compendium of examples. The Delegation further noted that on the basis of those examples and document SCP/22/3, the Committee could study the methodologies and follow the steps of inventive step assessment utilized in various offices. In addition, the Delegation referred to paragraph 121 of document SCP/22/3, and proposed that the Secretariat study the issue of additional information and evidence, such as additional documents with additional technical information, submitted after the filing date (or priority date) and how such additional information affected the assessment of inventive step. The Delegation also stated that it wished to continue work on sufficiency of disclosure. With respect to future work on exceptions and limitations, the Delegation noted that many delegations had shown their interest in exceptions and limitations, and in its opinion, practical information on that subject was particularly interesting. The Delegation therefore suggested that the Secretariat study, on the basis of information provided by Member States, on barriers to use exceptions and limitations, for example, compulsory licensing or government use. The Delegation expressed its interest in improving the legislative framework with regard to exceptions and limitations.

255. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States, emphasized that in discussing future work, a balanced program should be reached. In its view, the current five agenda items reflected different priorities, and therefore it was of the utmost importance to maintain a balance. In reference to quality of patents, the Delegation reiterated that a work program should be established based on the proposals made by the Delegations of Canada and the United Kingdom (document SCP/17/8), the Delegation of Denmark (document SCP/17/7), the Delegation of the United States of America (document SCP/17/10), and by the Delegation of Spain as endorsed by all other Member States of the European Union (document SCP/19/5 Rev.). The Delegation stated that it remained in favor of launching a questionnaire containing the elements of all the proposals by the Delegations of Canada and the United Kingdom, Denmark and the United States of America. In relation to quality of patents, the Delegation stressed that it was committed to discussions on key aspects of substantive patent law, which had to be reflected in the future work program. As regards opposition systems, the Delegation was of the view that the elaboration of a compilation of models of opposition systems and other administrative revocation and invalidation mechanisms, in a non-exhaustive manner, should be considered. On work-sharing programs, the Delegation considered that a dedicated page on the WIPO website for work sharing activities would improve awareness of existing initiatives and enable patent offices to collaborate more effectively. In addition, the Delegation stated its support for the proposal by the United States of America (document SCP/23/4), and noted with satisfaction the overwhelming cross-regional support it had received. Furthermore, the Delegation supported conferences on the margins of the SCP sessions, during which experiences on work sharing programs could be discussed and ways to improve the usefulness of those programs to IP offices could be explored. The Delegation observed that a study by the Secretariat into how different laws and practices limit the potential for work-sharing and what voluntary measures could be put in place to address any problems at the international level, could identify areas where initiatives could be undertaken to improve the efficiency of the patent system. Given the optional nature of the schemes endeavored, the Delegation was of the opinion that any efforts to improve the quality and efficiency of the patent system should not be hindered. In relation to confidentiality of communications between clients and their patent advisors, the Delegation stated that time was ripe to consider a concrete mechanism to address the recognition of foreign patent advisors privilege.

256. The Delegation of China expressed its hope that the Committee would push forward the work of the SCP in a sustained and balanced manner. He Delegation noted that extensive and in-depth information sharing and experience exchange conducted at SCP at that stage enabled Member States to have a better understanding of the issues and learn from one another with regard to useful legal and practical exercises. The Delegation looked forward to more comprehensive studies and discussions on such issues as exceptions and limitations to patent rights, patents and health and transfer of technology in the future. The Delegation observed that many suggestions had also been made on the way forward with regard to those topics: for example, on exceptions and limitations, carry out case studies and collect information on the experience of different countries; on patents and health, conduct in-depth studies on solutions involving the disclosure of INN by taking into account the flexibilities offered by international treaties; on technology transfer, look at difficulties faced by developing countries and possible incentives with regard to technology transfer. The Delegation believed that they were valuable suggestions for the future work of the SCP, and looked forward to more progress to be made in the discussion of each topic.

257. The Delegation of Nigeria, speaking on behalf of the African Group, stated that for patents and health, the African Group would like to see a commissioning of a study by independent experts to be selected in consultation with Member States, examining the

constraints raised by developing and least developed countries in making full use of the patent related flexibilities for public health purposes in both pre-grant and post-grant stage. The Delegation further suggested that an information exchange session on national experiences related to the use of health related flexibilities for promoting public health objectives, or the lack thereof, or the challenges thereof, be held. As regards transfer of technology, the Delegation suggested that a detailed study by independent experts on the relationship between patent systems and the transfer of technology be prepared. The Delegation further stated that the Secretariat should prepare an updated study on what components of the insufficiency of disclosure could limit transfer of technology to developing countries.

258. The Delegation of the United Kingdom expressed its appreciation to the experts who had shared their knowledge to contribute to the collective understanding, particularly on client-patent advisor privilege, and supported further work in that area. With regard to patents and health, the Delegation thanked the panel members who had contributed to the Seminar. The Delegation further stated that it welcomed further updates in the future regarding the development of the Patentscope in connection with chemical patent search using INN, which in its view, was the right direction to go in. Noting the widespread cross-regional support for the proposal for the work sharing outlined in document SCP/23/4, the Delegation shared the view that further work in that area could lead to increased quality of granted patents. With regard to quality more generally, the Delegation would welcome an agreement to launch the questionnaire on quality of patents proposed in document SCP/18/9, which took account of previous proposals in documents SCP/17/7, 17/8 and 17/10. The Delegation stressed the importance of striking a balance in the agenda of the SCP as a multilateral forum. For the moment, The Delegation recommended the Committee continue with agreed five agenda items.

259. The Delegation of India expressed its wish to include the following studies in the future work of the Committee: (i) study to correlate relations between enabling disclosure and transfer of technology, which should include to what extent the patent system as a stand-alone system could contribute to transfer of technology without the aid of accompanying trade secrets. The role of patent systems in the context of transfer of technology should be carefully studied in connection with sufficiency of disclosure; (ii) revisit document SCP/21/9 concerning the feasibility of disclosure of INN in patent applications, specifically where INN were known to applicants; (iii) study on Markush claims. The study should be conducted on cost and benefit of patenting inventions using Markush claims, and could broadly be divided into, for example, issues related to patent law such as inventive step, sufficiency of disclosure and industrial applicability, the scope of such claims in the context of generic versus specific disclosure, cost of search and examination, and contributions of such claims to development of essential medicines. The Delegation further expressed its support for the studies proposed in the proposal of Brazil (document SCP14/7 and SCP19/6), and suggested that the Secretariat continue developing working documents for potential flexibilities and exceptions and limitations which would be useful for development concerns. In addition, the Delegation stated that it support the proposal of GRULAC on the revision of the Model Law.

260. The Delegation of Switzerland proposed to continue with the work towards a soft law approach with respect to attorney-client privilege. In particular, it suggested to the Committee the compilation by the Secretariat of Member States' opinions on the points that should be regulated in a soft law on the client-attorney privilege. With respect to exceptions and limitations, recalling that only nine contributions had been received for the preparation of document SCP/23/3, the Delegation considered that more case studies should be collected by extending a deadline for Member States to contribute to the subject. In its view, that would be useful for the Committee to better understand how exceptions and limitations

contribute to the needs of developing countries.

261. The Delegation of Greece, speaking on behalf of Group B, reiterated that the CDIP was an appropriate forum to discuss general aspects of transfer of technology.

262. The Delegation of Colombia observed that it would appear to be rather difficult to depart from the five agenda items that had been agreed by the Committee in 2010. The Delegation stated that among the various agenda items, it supported the most practical one, which was quality of patents. The Delegation observed that quality of patents, to some extent, could be included under the other four agenda items without necessarily detracting from their importance. In its view, examining the situation as the Committee had done during the 23rd session of the SCP, for example, with respect to inventive step, had been one of the areas that had best received by Member States. The Delegation therefore supported the statement made by the Delegation of Spain with respect to continued discussions on inventive step, which was the most important requirement when examining patent applications. The Delegation also expressed its support for the proposal by the United States of America on work sharing, which in its view would lead to greater transparency in examination work and facilitate the work of all patent offices.

263. The Delegation of Greece, speaking on behalf of Group B, expressed its opinion that it would be very difficult to depart from the five issues that had been agreed by the Committee. The Delegation stated that with the issue under agenda item 10, the SCP agenda was not balanced, and expressed its view that the work of the Committee should go on with the five agreed agenda items.

264. The Delegation of Pakistan expressed its belief that substantive discussions on technology transfer and patents and health were essential for a balanced work program. The Delegation therefore expressed its support for the proposal by the African Group concerning new studies on those two issues. In addition, the Delegation supported the request made by GRULAC for a revision of the Model Law.

265. The Delegation of the Republic of Korea stated that the Committee should take a balanced approach and share useful information on various topics, reflecting different views of Member States. The Delegation noted that the key interest of the Republic of Korea was further work on quality of patents. Believing that the study on work sharing would be beneficial for all Member States, the Delegation strongly supported the proposal on work sharing by the Republic of Korea, the United Kingdom and the United States of America (document SCP/20/11 Rev.) and the proposal by the United States of America (document SCP/23/4). In addition, the Delegation supported further discussion on confidentiality of advice by patent advisors based on a soft law approach, and further information sharing on exceptions and limitations to patent rights, patents and health and transfer of technology.

266. The Delegation of South Africa supported work of all the issues in the Committee, since all of them were equally important. The Delegation put emphasis on the proposals that had been submitted by the Africa Group on transfer of technology and patents and health.

267. The Delegation of Nigeria, speaking on behalf of the African Group, recalled the proposal that had been put forward in 2011 by the African Group and the Development Agenda Group on patents and health, and suggested that the elements contained in that proposal form part of future work of the SCP.

268. The Delegation of Switzerland emphasized that it supported future work on the five agenda items. With respect to patents and health, the Delegation expressed its support for the proposal by the United States of America (document SCP/17/11).

269. Following the consultations with the regional group coordinators, the Chair submitted her proposal regarding the future work of the Committee. The Chair thanked all regional groups for their intensive efforts. The Chair expressed her hope that a good result for everyone had been reached through the informal consultations, although it might not be the best solution for some delegations. The Chair stated that she submitted her proposal to the Committee with best intention and good will to continue the work of the Committee. She explained that the proposal submitted to the plenary was the fourth version of her draft, which represented the balance as much as possible in order to fulfill the wishes of all delegations. The Chair noted that while not everyone was happy with her proposal, at least the Committee could continue its work, which was of utmost importance. The Chair observed that the multilateralism was a very difficult exercise.

270. The Delegation of Brazil, speaking on behalf of GRULAC, thanked the Chair for her efforts. The Delegation, referring to item (4)(ii) of the future work concerning the confidentiality of advice by patent advisors, stated that although the last part of that item had been difficult for GRULAC to accept, in a constructive spirit, the Group had been willing to accept it. However, in order to avoid prejudging results of the compilation referred to in that item, the Delegation suggested that, after the word “including”, the word “possible” be inserted. The Delegation explained that its suggestion would not bring any change in substance.

271. The Delegation of the United Kingdom, in responding to the suggestion by the Delegation of Brazil, stated that it was clear that the current language meant that information would be supplied if limitations or difficulties in cross-border issues were encountered. The Delegation expressed its hope that its clarification helped the Delegation of Brazil move toward acceptance of the Chair’s proposal.

272. The Delegation of Brazil stated that if it was the same meaning, it could accept inserting the words “if encountered” as suggested by the Delegation of the United Kingdom.

273. The Delegation of the United Kingdom stated that it did not wish to reopen the text, and that the clarification should be put on record.

274. The Delegation of Brazil stated that it did not understand why the exact language clarified by the Delegation of the United Kingdom could not be included in the text.

275. The Chair stated that, if the Committee did not wish to reopen the discussion, it would be wise to put the clarification on record and keep the text as it was.

276. The Delegation of Greece, speaking on behalf of Group B, stated that it did not wish to reopen any item, as the text had been fully negotiated. In its view, the text could not satisfy everybody, including its Group. While the Delegation noted that the future work program was limited to the five agreed items, it expressed its concern that the summary by the Chair suggested future discussions on a topic which fell outside those five items. The Delegation understood that the content of the summary by the Chair was at the discretion of the Chair. However, the Delegation stressed that the Model Law was not a recognized and agreed agenda item and should not form part of the agenda for the next session of the SCP. It emphasized the importance of a balanced agenda to the functioning of the Committee as a primary multilateral forum for patent law discussions. The Delegation stated that discussing issues outside of the five agenda items undermined the agreement by the Committee that set the said five agenda items with an effort to reflect concerns from all regions.

277. The Delegation of India, speaking on behalf of the Asia and Pacific Group, noted that

all delegations had been witness and partners in the negotiation process of future work and had tried their best, and that the regional group coordinators who had put forward their different positions had arrived at a common minimum denominator that was reflected in the Chair's proposal. The Delegation stated that its Group did not have a common position, as some members had some concerns which would be raised individually. The Delegation stated that, if their concerns were met, the Committee would be able to arrive to consensus on future work.

278. The Delegation of Nigeria, speaking on behalf of the African Group, expressed its appreciation to the Chair, regional group coordinators, Member States and the Secretariat for their hard work and engagement, while the Delegation would have preferred a better outcome to the end of the session. It stated that the African Group recognized the instrumental role of the work of the SCP in facilitating participation in, and the use of, the international patent system in such a manner that stroke a fair balance in the use of patents for social, technological and economic development, while taking into account the different levels of development of Member States and their sovereign interests. The Delegation therefore noted that it was not encouraging that the SCP could not be more ambitious in its future work on matters that were of immense concern to diverse membership, especially in the areas of health, social sustainability, non-discriminatory practices, access to information and knowledge, and a fair chance at economic growth and development through patent flexibilities and the teaching function of the patent system. In its view, if the SCP had been created as a forum to discuss issues, facilitate coordination, and provide guidance concerning the progressive development of patent law, Member States should demonstrate willingness to adopt a balanced prioritization of inter-related issued in order to achieve the objective of not only the SCP but also the international IP framework. The Delegation considered that the differences in priority should not be a hindrance to working on issues that clearly met the merits of serving the public good for which the commitment should be unwavering. The Delegation noted that, for the African Group, the priority had been given to the topic of patents and health, and it had also invested on the topics of transfer of technology and exceptions and limitations, quality of patents, including opposition systems. The Delegation explained that that was why for future work of the Committee, the African Group's proposals had encompassed interlinked issues that facilitated use of the patent system to address several pressing public policy objectives, including health, access, fostering of innovation and technology transfer. In its opinion, those subject matters were interlinked and were complimentary in order to serve the objective of ensuring integrity in the patent system and its flexibilities as well as promoting a balance between patent protection and social benefits. The Delegation observed that the joint African Group and Development Agenda Group proposal contained in document SCP/16/7 and SCP/16/7 Corr. had clearly addressed consistent and increasingly disproportionate challenges for access and use of the patent system, all of which sustained an asymmetric balance in the current patent landscape. The Delegation noted that its updated proposal to be submitted in advance of the 24th session of the SCP would remain invested in the original concerns contained in the referenced documents, while also contextualizing the urgency, constraints and need to act in the interest of unquestionable challenges to fairer use of the international patent system by developing and least developed countries. The African Group welcomed the half-day seminar on patents and health related issues, which had illustrated some challenges to the use of patent-related flexibilities for public health purposes for developing and least developed countries. Although it had not been exhaustive, the Delegation believed that the session had been informative on practices, gaps and practical ways forward. The Delegation reiterated that disclosure was the bedrock of the patent system. Therefore, in its opinion, practices within the patent systems that provided opportunities to avoid full disclosure of all necessary information to ensure integrity, high quality and full dissemination of knowledge in exchange of exclusive patent rights were a departure from the intentional *quid pro quo* nature of the patent system and the international IP structure. The African

Group wished to put on record that it supported the proposal of GRULAC on the revision of 1979 Model Law for Developing Countries on Inventions, and expressed its willingness to exchange views, and more importantly, determine result-oriented activities on that agenda. The Delegation expressed its belief that the African Group had demonstrated immense flexibility toward reaching a workable future work at the 23rd session of the SCP. The Delegation expressed its regret that such flexibility could not be fully reciprocated towards issues of critical concern for humanity. The Delegation therefore urged renewed commitment to adopting a work program that facilitated the capacity of developing and least developed countries to effectively use flexibilities in the international patent system to address public policy priorities related to public health and socio-economic objectives. Notwithstanding its concerns, the Delegation stated that its Group remained optimistic that the substantive issue of global policy concerns would be addressed with the merit, good faith, flexibility and political will they deserved. The Delegation expressed its willingness to continue supporting the Chair's efforts to advance the work of the SCP.

279. The Delegation of Iran (Islamic Republic of) reiterated that it could not go along with work sharing, which was a bilateral or trilateral issue. It stated that without having a precise definition of the concept of patent quality, work sharing would not be workable between national offices. In its view, work sharing was a matter of procedure which fell outside the mandate of the SCP as a substantive committee. The Delegation therefore requested the deletion of item (2)(ii) regarding work sharing. The Delegation further noted that it could not go along with the future work regarding the confidentiality of communications between clients and their patent advisors, and requested that the words "with respect to cross-border aspects […] in cross-border issues" be removed. Furthermore, the Delegation requested that the Committee hold informal consultations with each regional group plus two or three, since some regions had difficulty in reaching a unified position. In its opinion, it was difficult for countries to raise their concerns and positions in the plenary.

280. The Delegation of Romania, speaking on behalf of the CEBS Group, thanked the Chair for her excellent work and tireless efforts. The Delegation stated that the CEBS Group could accept the Chair's text. The Delegation observed that since it was very much in the human nature to seek for better and for more, it could understand the intervention of the Delegation of Iran (Islamic Republic of) from that perspective. However, the Delegation noted that while everyone had its priorities and its preferences, each Member State was a part of a community, and had a duty to listen and to be open to the others' concerns. The Delegation requested the Delegation of Iran (Islamic Republic of) to reconsider its position, taking into account the fact that the majority of regional groups expressing their positions were ready to accept the text that had been discussed for so many hours in so much detail. The Delegation proposed to adjourn the meeting for such a consideration to take place.

281. The Chair adjourned the meeting.

282. The Chair reconvened the meeting, and asked whether there was consensus on the Chair's proposal.

283. The Delegation of Iran (Islamic Republic of) thanked the Chair for her patience and efforts and extended its sympathy to members and observers of the SCP as well as the Secretariat for staying late in the room. The Delegation stated that it was regrettable that the Committee was not able to arrive at consensus on future work. It noted that the Delegation had shown maximum flexibility. The Delegation recalled that it had proposed the language from the first day of the session: many developing countries, including the Delegation, had raised their concern on work sharing and confidentiality of communication between client and patent attorneys. The Delegation noted that it could not go along with those topics, and had requested the regional group coordinator of the Asia and Pacific Group to convey that

message to the Chair. The Delegation requested the Committee to respect and accommodate concerns and interest of all members, as WIPO was consensus-based. In its view, the rules of procedures of WIPO showed two ways: either consensus or vote. The Delegation further requested that the Secretariat be neutral and impartial. While thanking the Chair, the Delegation stated that it was regrettable to bring some ideas to some proposals which would obviously be not accepted. The Delegation concluded that it could not join the consensus.

284. The Delegation of Greece, speaking on behalf of Group B, stated that Group B supported the work of the SCP and was able to accept the delicate balance reached in the Chair's proposal. The Delegation expressed its deep disappointed that one delegation was unable to go along with the consensus. Noting great importance it attached to the work of the SCP, the Delegation hoped that at the twenty-fourth session of the SCP, all delegations would come to the Committee prepared to engage in discussions under the existing five agenda items. The Delegation thanked the Chair for her intense efforts to help the Committee moving towards a common perspective on future SCP work.

285. The Delegation of Romania, speaking on behalf of the CEBS Group, reiterated its support to the Chair's text on the future work. The Delegation considered that it provided complex sets of activities, in which everyone should find something of its interest. The Delegation therefore stated that it was dissatisfied with the fact that the Chair's proposal could not be a consensual text. It expressed its hope that on a next occasion, the Committee would be able to find more constructiveness from the side of delegations.

286. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States, thanked the Chair for her efforts in identifying a compromised solution in order to achieve consensus on future work. The Delegation also thanked the Secretariat for its support and all delegations for their presentations. The Delegation stated that it was very disappointed that no consensus could be reached on future work. The Delegation noted that the European Union and its Member States, in an effort to take the work of the Committee forward and in the spirit of compromise that should be the hallmark of the work of the Committee, could have accepted the proposed work plan on future work. In its opinion, although the proposed work program contained elements with which the Delegation was uncomfortable with, the overall package on future work represented a reflection of regional interests that had been heard during the session. The Delegation deeply regretted that no consensus could have been reached.

287. The Delegation of Pakistan joined other delegations in appreciating the Chair's efforts. The Delegation stated that it was deeply disappointed at the fact that the Committee could not achieve a consensus. However, the Delegation observed that there was hard diversion of views on very fundamental issues right from the beginning, and urged Member States to be flexible and cooperative, taking into account all Member States' interest in an equitable manner in the future. The Delegation expressed its hope that a better atmosphere in the Committee would prevail in the future.

288. The Chair raised a question as to whether the Delegation of Iran (Islamic Republic of) intended to break the consensus of the meeting.

289. The Delegation of India stated that, as a regional coordinator of the Asia and Pacific Group, it had been conveying its concerns that there were members in its Group which would not be able to go along with the proposal. The Delegation considered that isolating or mentioning a particular member at that stage would not set a positive precedence for the future, since there were situations where individual countries had their strong concerns and due respect should be given to them. While there were members who had their strong

positions and had put them forward, the Delegation expressed its hope that the Committee would find a way to bridge the gap at the next session.

290. The Delegation of Pakistan supported the statement made by the Delegation of India on behalf of the Asia and Pacific Group. The Delegation considered that every Member State had a right to its position. The Delegation noted that while it was disappointed by the outcome, in order to have a more cordial atmosphere, it was important that the Committee did not isolate or single out a member.

291. The Chair shared the concerns raised by some delegations. In view of the great number of delegations joining the consensus, the Chair sought clarification from the Delegation of Iran (Islamic Republic of) whether it could dissociate with the consensus and record that fact in the report.

292. The Delegation of Iran (Islamic Republic of) stated that it could not understand the point raised by the Chair. The Delegation noted that it should follow national interest and concerns. The Delegation asked the Chair to be neutral and declare that there was no consensus. It considered that it was not a good practice in international organizations to single out one country.

293. The Delegation of Greece requested that the discussions be reflected in the record. The Delegation expressed its personal view that what had happened was disrespect.

294. The Chair stated that, since there is no agreement, the only activity foreseen for the next SCP was what had been agreed at the 22nd session that the Secretariat would improve the web page on work sharing and collaborative activities. Failing agreement otherwise, the Chair suggested the following: the Committee would carry on discussions at its next session on the basis of the agenda of the 23rd session (document SCP/23/1); Member States might submit proposal on the work of the Committee prior to its next session. The Chair expressed her gratitude to interpreters who had volunteered to stay until the late hour.

295. The Delegation of Brazil, speaking on behalf of GRULAC, thanked the Chair's effort for finding a common ground for different positions, and expressed its appreciation to the Secretariat and interpreters. With respect to the work of the Committee in the next session, the Delegation appreciated the way the matter of the Model Law was reflected in the Chair's summary. The Delegation recalled that its proposal was supported by four regional groups representing a substantial proportion of the membership. In its view, that was a clear evidence of the need to further discussing that issue. The Delegation looked forward to continue debating with all delegations next year, hopefully with new ideas on how to move forward with that matter.

296. The Delegation of Nigeria, speaking on behalf of the African Group, thanked the Chair for her efforts and commitment, and extended its thanks to the Secretariat, interpreters, regional group coordinators and all delegations. The Delegation stated that it had have hoped to have an agreement on the future work and regretted that the Committee could not have consensus. Being aware of the practice that the committees agreed by consensus or vote, the Delegation considered that it would not really help the future conversations on future work if the Committee singled out a particular delegation. Therefore, in its view, it might be more positive to agree that the Committee did not have consensus. The Delegation expressed its hope that the SCP could work further to reach that consensus very quickly and continue the important work.

297. The Delegation of Romania, speaking on behalf of the CEBS Group, expressed its gratitude to the Chair for having assumed the exercise, the leadership of the Committee, for her able guidance and for her hard work as well as her commitment to the advancement of

the work of the Committee. The Delegation also thanked the Secretariat for its valuable support before and throughout the session, and expressed its appreciation to interpreters. The Delegation was pleased that the 23rd session of the SCP had provided Member States with the opportunities to listen to very interesting and useful presentations which had contributed to a better understanding on the issues on its agenda. The Delegation wished that it could have repeated such experience at the next session, and regretted that it would not be the case since the Committee could not have consensus on the future work. The Delegation reiterated the interest and importance the CEBS Group attached to the work of the SCP and its confidence in future agreements.

298. The Delegation of China thanked the Chair, the Secretariat and the regional group coordinators for the work during the informal consultations. The Delegation expressed its regret that the Committee had not reached an agreement on future work. It stressed great importance the Delegation attached to the SCP. The Delegation noted that there were so many Member States at WIPO with different stages of development and with different national interest. While the Delegation attached importance to different interest of various countries, the Delegation expressed its wish that more constructive spirit would be demonstrated at the next session so that the SCP could advance its work.

299. The Delegation of Greece, speaking on behalf of Group B, thanked the Chair for her intense efforts to help the Committee to pursue a common perspective on the future SCP work. The Delegation stated that it had enjoyed the presentations and the work that had been carried out by the Committee during the 23rd session. The Delegation therefore expressed its disappointment that the Committee would not see any elaboration on its work at the next session. The Delegation reiterated great importance it attributed to the work of the SCP, and noted its disappointment that it had not been able to reach consensus in short of one delegation. The Delegation expressed its hope that at SCP/24, all delegations could come to the Committee prepared to engage in discussions under the existing five agenda items.

300. The Delegation of India, speaking on behalf of the Asia and Pacific Group, expressed its appreciation to the Chair for her leadership. The Delegation also thanked the Secretariat and interpreters as well as the regional group coordinators who worked hard. The Delegation emphasized that WIPO was a consensus driven organization. In its opinion, consensus meant almost everyone and everyone had to agree on a particular thing. It considered that each country's voice should be heard and their concerns be taken care of. The Delegation hoped that healthy precedence would continue, and at the next SCP session, Member States would come back with fresh mind and would take into consideration the serious concerns raised by other members. The Delegation stated that a preparatory effort should be made before putting proposals, and that those proposals should not be strong in such a way that they would not create consensus. The Delegation noted great importance the Group attached to the work of the Committee, and expected healthy practice of WIPO which allowed all Member States go ahead together.

301. The Delegation of Pakistan extended its sincere appreciation for the effort by the Chair and for the hard work of the Secretariat and interpreters. Since Member States seemed to agree to disagree at the 23rd session, the Delegation expressed its hope that the lessons learnt would provide the Committee with a better opportunity to engage in a more productive and conductive spirit for the next session.

302. The Delegation of Iran (Islamic Republic of) thanked the Chair for her patience and the Secretariat and interpreters for their hard work. The Delegation reiterated that it attached great importance to the SCP work, and expressed its hope that at the next session, concerns of all countries would be respected and also accommodated by other sides. The

Delegation stated that a lot of proposals and suggestions made by developing countries had not been accepted by other sides. The Delegation hoped that a good spirit would prevail in the next session, respecting each other and not treating each other with threat which would harm the Organization.

303. The Delegation of Switzerland thanked the Secretariat, the Chair in particular, interpreters and all delegates for their hard work. The Delegation expressed its deep disappointed about the fact that the Committee did not have a work program and that it was based on the fact that it was one Member State which did not agree to it. The Delegation observed that other groups had made so much effort to convince Member States to agree to it. The Delegation noted that the future work program had reflected some points that the Delegation could agree and some points that it could not agree: nevertheless, everybody had made the effort. The Delegation expressed its hope that the Committee would continue in a better spirit in the future, and stated that it attached great importance to the Committee. The Delegation expressed its wish that the Committee continue with good outcome and fruitful and constructive work.

304. The Delegation of the United Kingdom expressed its appreciation to the Chair, the Secretariat and interpreters. While expressing its disappointment about the impasse, the Delegation stated its hope that the report of the session would reflect that all delegations hoped to engage in discussion constructively in the twenty-fourth session of the SCP.

AGENDA ITEM 12: SUMMARY BY THE CHAIR

305. The Chair introduced the Summary by the Chair (document SCP/23/5).

306. The Summary by the Chair was noted.

307. 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

308. The Chair closed the session.

309. *In accordance with the procedure previously adopted by the Committee (see paragraph 308 above), Committee members and observers are invited to comment on this draft report, which is being made available on the SCP Electronic Forum. The Committee*

will be invited to adopt the report at its next session.

[Annex follows]

LISTE DES PARTICIPANTS/LIST OF PARTICIPANTS

I. MEMBRES/MEMBERS

AFGHANISTAN

Nazirahmad FOSHANJI, Third Secretary, Permanent Mission, Geneva

AFRIQUE DU SUD/SOUTH AFRICA

Elena Mihail ZDROVKOVA (Ms.), Senior Manager, Patent and Designs, Trade and Industry, Companies and Intellectual Property Commission (CIPC), Pretoria

Pragashnie ADURTHY (Ms.), First Secretary, Permanent Mission, Geneva

ALGÉRIE/ALGERIA

Fayssal ALLEK, premier secrétaire, Mission permanente, Bellevue

ALLEMAGNE/GERMANY

Irene PAKUSCHER (Ms.), Patent Law, Federal Ministry of Justice and Consumer Protection, Berlin

Lena PASCHOLD (Ms.), German Patent and Trade Mark Office, Munich

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