

Standing Committee on the Law of Patents

Twenty-Second Session
Geneva, July 27 to 31, 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-second session in Geneva from July 27 to 31, 2015.
2. The following States members of WIPO and/or the Paris Union were represented: Afghanistan, Algeria, Angola, Argentina, Australia, Austria, Belarus, Brazil, Burundi, Cambodia, Cameroon, Canada, Chile, China, Colombia, Côte d’Ivoire, Czech Republic, Denmark, Djibouti, Ecuador, Egypt, El Salvador, Estonia, Finland, France, Gabon, Germany, Ghana, Greece, Guatemala, Honduras, Hungary, India, Indonesia, Iran (Islamic Republic of), Ireland, Italy, Japan, Kyrgyzstan, Lithuania, Luxembourg, Malaysia, Mexico, Monaco, Montenegro, Nigeria, Norway, Oman, Pakistan, Panama, Paraguay, Peru, Philippines, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Saudi Arabia, Senegal, Singapore, South Africa, Spain, Slovakia, Sri Lanka, Sweden, Switzerland, Trinidad and Tobago, Ukraine, United Kingdom, United Republic of Tanzania, United States of America, Uruguay, Yemen and Zimbabwe (75).
3. 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 Patent Organisation (EPO), the European Union (EU), the General Secretariat of the Andean Community, the Patent Office of the Cooperation Council for the Arab States of the Gulf (GCC Patent Office), the South Centre (SC), the World Health Organization (WHO) and the World Trade Organization (WTO) (10).

4. Representatives of the following non-governmental organizations took part in the meeting in an observer capacity: All-China Patent Agents Association (ACPAA), American Intellectual Property Law Association (AIPLA), Asian Patent Attorneys Association (APAA), CropLife International, European Law Students' Association (ELSA International), Free Software Foundation Europe (FSF Europe), Innovation Insights, Institute of Professional Representatives before the European Patent Office (EPI), Intellectual Property Owners Association (IPO), International Association for the Protection of Intellectual Property (AIPPI), International Centre for Trade and Sustainable Development (ICTSD), International Chamber of Commerce (ICC), International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Japan Intellectual Property Association (JIPA), Japan Patent Attorneys Association (JPAA), Knowledge Ecology International, Inc. (KEI), Médecins Sans Frontières (MSF), Non-Commercial Foundation for Development of the Center for Elaboration and Commercialization of New Technologies (Skolkovo Foundation) and Third World Network Berhad (TWN) (19).
5. A list of participants is contained in the Annex to this report.
6. The following documents prepared by the Secretariat had been submitted to the SCP prior to the session: "Draft Report" (SCP/21/12 Prov. 2); "Draft Agenda" (SCP/22/1 Prov. 2); "Report on The International Patent System: Certain Aspects of National/Regional Patent Laws" (SCP/22/2); "Study on Inventive Step" (SCP/22/3); "Study on Sufficiency of Disclosure" (SCP/22/4) and "Proposal by the Group of Latin American and Caribbean Countries (GRULAC)" (SCP/22/5).
7. In addition, the following documents prepared by the Secretariat were also considered by the Committee: "Proposal from Brazil" (SCP/14/7); "Proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group" (SCP/16/7); "Corrigendum: Proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group" (SCP/16/7 Corr.); "Proposal by the Delegation of Denmark" (SCP/17/7); "Revised Proposal from the Delegations of Canada and the United Kingdom" (SCP/17/8); "Proposal by the Delegation of the United States of America" (SCP/17/10); "Patents and Health: Proposal by the Delegation of the United States of America" (SCP/17/11); "Questionnaire on Quality of Patents: Proposal by the Delegations of Canada and the United Kingdom" (SCP/18/9); "Proposal by the Delegation of the United States of America regarding efficiencies of the patent system" (SCP/19/4); "Proposal by the Delegation of Brazil regarding exceptions and limitations to patent rights" (SCP/19/6); and "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.)
8. The Secretariat noted the interventions made and recorded them on tape. This report summarizes the discussions reflecting all the observations made.

GENERAL DISCUSSION

AGENDA ITEM 1: OPENING OF THE SESSION

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

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

10. The SCP unanimously elected for one year Mrs. Bucura Ionescu (Romania) as Chair and Mrs. Nahanny Canal Reyes (Mexico) as Vice-Chair.

AGENDA ITEM 3: ADOPTION OF THE AGENDA

11. The Chair introduced the revised draft agenda (document SCP/22/1 Prov. 2) based on the five items previously discussed by the SCP, for adoption.

12. The Delegation of Nigeria, speaking on behalf of the African Group, thanked the Chair for her proposal, and expressed its support for the revised agenda.

13. The Delegation of Japan, speaking on behalf of Group B, stated that the original draft agenda would have better reflected the current situation of the discussions and that it could not see the necessity to change the original draft, since only two substantive items had to be discussed during the twenty-second session of the Committee, namely, the study on inventive step and the study on sufficiency of disclosure, due to no agreement on future work in the previous session of the SCP. The Delegation stressed the technical nature of the Committee, and encouraged the Committee to start technical discussion, leaving aside procedural aspects. The Delegation, however, expressed its flexibility to accept the proposed amended agenda at a later stage. The Delegation expressed its hope that the flexibility showed in relation to the acceptance of the agenda by Group B would be reciprocated at a later stage.

14. The Delegation of Pakistan, speaking on behalf of the Asia and Pacific Group, welcomed the Chair's proposal as striking the right balance, and therefore as an acceptable agenda.

15. The Delegation of China expressed its gratitude to the Chair and the Secretariat for their effort as well as the regional group coordinators for their flexibility, and supported the revised draft agenda.

16. The Delegation of Romania, speaking on behalf of the Central European and Baltic States (CEBS), thanked the Chair for her work concerning the revised draft agenda and expressed its readiness in following the proposed document. The Delegation pointed out that also the original draft agenda would have been a practical way to move forward.

17. The Delegation of Brazil, speaking on behalf of the Group of Latin American and Caribbean Countries (GRULAC), supported the Chair's proposal.

18. The Delegation of Belarus, speaking on behalf of the Caucasian, Central Asia and Eastern European Countries (CACEEC), supported the statement made by the Delegation of Romania on behalf of the CEBS Group.

19. The SCP adopted the revised draft agenda (document SCP/22/1 Prov. 2).

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

20. The Committee adopted the draft report of its twenty-first session (document SCP/21/12 Prov. 2).

AGENDA ITEM 5: REPORT ON THE INTERNATIONAL PATENT SYSTEM

21. Discussions were based on document SCP/22/2.

22. The Secretariat noted that since the twenty-first session of the SCP, information concerning certain aspects of national/regional patent laws had been received from the following Member States/Regional Offices: Australia, Belarus, the Dominican Republic, El Salvador, Georgia, Japan, Madagascar, Poland, Portugal, Republic of Korea, Serbia, Tajikistan and ARIPO.

23. The Delegation of Belarus thanked the Secretariat for updating the information on some aspects of the law of patents in relation to Belarus. The Delegation provided some technical comments concerning the information available on the website of the SCP. Further, the Delegation requested to replace the word “information” by “any information” with respect to the texts concerning prior art, novelty and inventive step, in order to make the texts clearer and in line with the law of the Republic of Belarus.

24. The Delegation of El Salvador congratulated the Chair and the Vice-Chair for their election. Concerning the Report on the International Patent System, the Delegation pointed out that while El Salvador had not modified its legislation since 2006, it had requested the amendment of the wording of certain aspects of the report, namely those related to the grace period and exceptions and limitations. The Delegation thanked the Secretariat for having included the requested amendments and for keeping updated the information on national legislation on patents in the various Member States.

25. The Delegation of Australia congratulated the Chair for her appointment. The Delegation took the opportunity to update Member States about the recent developments of the Australian legislation. The Delegation stated that under the recently passed Intellectual Property Law Amendment Act of 2015, the revised Patent Act would enable countries to source generic versions of patented pharmaceuticals from Australia in accordance with the TRIPS Protocol interim waiver and the TRIPS Protocol when it would come into effect. The Delegation specified that those amendments would commence on the 25th of August, 2015, and that under the new scheme, Australian laboratories would be able to apply to the Federal Court for a compulsory license to manufacture generic versions of patented medicines and export those medicines to developing countries that were experiencing serious public health issues. The Delegation further stated that adequate compensation for the patent holder would be negotiated to ensure that they would not be disadvantaged by the arrangements. The Delegation believed that those amendments would advance the human right to health for everyone, including children in developing countries, by assisting the treatment of serious health problems such as HIV, malaria and tuberculosis. The Delegation explained that the scheme was designed to be as easy to use as possible and was open to all developing countries, provided that they met specified criteria.

26. The Delegation of Chile congratulated the Chair and the Vice-Chair and thanked the Secretariat for the documents. The Delegation observed that there were some elements of the Chilean patent law that still had to be included in the Report and that they would contact the Secretariat. The Delegation stated that Chile was in the process of amending and reforming its patent law and that in the future, it would present the new amendments.

27. The Delegation of the Russian Federation congratulated the Chair and Vice-Chair for their election and wished them a successful work. The Delegation thanked the Secretariat for the work carried out in the previous sessions of the Committee. The Delegation noted that amendments had been made to the Russian legislation on patents which had become applicable since January 1st, 2015. Without entering into the details of all the changes, the

Delegation particularly stated that the publication of the search and examination results had been introduced in order to allow third parties to provide their opinions about the patentability of the invention. In addition, the Delegation mentioned a change concerning the procedure of extending the term of patent protection of the inventions related to medicines and agro-chemicals.

28. The Delegation of Poland congratulated the Chair for her election and wished her all the success in her excellent work. The Delegation noted that they had submitted some information concerning the national regulation of the grace period within the Polish legislation in order to clarify its national system. The Delegation explained that in the Industrial Property Law of Poland, the grace period concept as such was not explicitly indicated as it was in other countries. However, the Delegation specified that there were two provisions of law which covered the issue to some extent. In particular, the Delegation stated that the first of those provisions provided the conditions under which the priority to obtain a patent was determined in Poland, while the second provision was about the criteria of novelty. The Delegation explained that the effect of those two provisions, when read together, was that disclosure should not have been taken into account in determining novelty, if the disclosure had occurred within six months before the filing date at an official recognized international exhibition in Poland or elsewhere in the world. Consequently, the Delegation stated that in Poland the kind of disclosure which did not destroy novelty had to be linked to the concept of priority. The Delegation thanked the Secretariat for introducing those changes with respect to the Polish legislation.

29. The Delegation of Portugal congratulated the Chair for her election and thanked the Secretariat for the update of the SCP electronic forum website. The Delegation stated that it had taken the opportunity to introduce some amendments to the text concerning grace period, exclusion from patentable subject-matters and exceptions and limitations to patent rights, in accordance with the English translation of the Portuguese Industrial Property Code.

30. The Delegation of Romania, speaking in its national capacity, expressed the wish to share with the Committee some recent modifications to the Romanian patent law. The Delegation stated that the law had been amended in 2014, following the adoption of the Law No. 83/2014 on employees' inventions, which had excluded regulations related to employees' inventions from the content of the patent law and had provided for some significant modifications in that respect. The Delegation noted that the most important modifications concerned the mechanism to allocate intellectual property rights for the employees' inventions, namely with respect to the right of employees to receive a fair remuneration as a consequence of their inventions and the right of employers with regard to inventions in the case of which they brought a significant material contribution. The Delegation pointed out that the main considerations for adopting a separate law on employees' inventions were on the one hand the belief that the change would contribute to their better evaluation and to stimulate the business environment and, on the other hand, the idea that the industry and research community would benefit from better quality of patents and the inventors would be encouraged to create patentable solutions by receiving significant rewards. The Delegation concluded that the aim of that new law was to stimulate the employees who were performing a creative work and the business environment. The Delegation stated that more detailed information would be sent to the Secretariat in due time.

31. The Delegation of Japan joined the previous speakers in congratulating the Chair for her election and thanked the Secretariat for its extensive work in preparing the meeting. The Delegation expressed its wish to speak about the recent revision of the Japanese patent law, although they were not made to the seven items published on the SCP electronic forum website. As regards the revision of its employee invention system, the Delegation explained

that in Japan, research and development activities conducted by business organizations had been a driving force behind innovations. The Delegation therefore deemed essential to clarify adequate incentives for any employee inventions, aiming to encourage inventions. In order to achieve that goal, the Japan Patent Office (JPO) had reviewed and revised its employee invention system. In particular, the Delegation explained that the outline of the revision involved the following three points: first, when employers had decided that the right to obtain patent rights for any employee inventions would be granted to the employers based on any contract, any employment regulations, or any other rules, then such rights were to belong to the employers, from the outset, in order to resolve any instability of rights pertaining to patents, that is, to resolve to whom rights pertaining to patents belong. Secondly, when the right to obtain patents for any employee inventions was given to the employers, the employees who invented the inventions had the right to receive financial compensation equivalent to reasonable values for their inventions and other economic benefits. Finally, in order to encourage inventions, the Minister of Economy, Trade and Industry would formulate guidelines that would specify the procedures for calculating the appropriate financial compensation and any other economic benefits for employee inventions, based on listening to opinions from the Industrial Structure Council. Concerning the revision of domestic laws for Japan's accession to the Patent Law Treaty (PLT), the Delegation noted that in order for Japan to accede to the PLT that was designed to harmonize and streamline procedures for domestic applications, which varied country by country, the JPO had revised the related regulations under the Patent Act of Japan. The Delegation stated that for example, applicants, even when they were unable to submit Japanese translations of foreign language documents within the deadline, would still be able to submit translations during a specified period of time after the deadline expired; in other words, the Commissioner of the JPO would notify them to that effect and allow them to submit translations within a specific deadline. The Delegation observed that the revisions to the Trademark Act were also made to enable Japan to accede to the Singapore Treaty on the Law of Trademarks. In addition, the Delegation noted that on April 1, 2015, the JPO had started accepting requests for oppositions under its new patent opposition system.

32. The Delegation of the Republic of Korea extended its congratulations for their election to the Chair and the Vice-Chair. The Delegation expressed its wish to share with the Committee the recent amendment of its patent legislation in relation to the grace period. The Delegation explained that those amendments had been adopted in order to relax the declaration requirements for pre-filing disclosure. The Delegation noted that while some Member States allowed applicants to use the grace period without overburdening them, some other countries required mandatory declaration of pre-filing disclosure at the time of filing in order to facilitate monitoring by third parties and administration by patent offices. The Delegation clarified that before such amendments, its country had also required applicants to declare at the time of filing any pre-filing disclosure they had made. The Delegation pointed out that according to the amended Korean Patent Act, it was possible for applicants, after having paid the requested fees, to declare their disclosures at any time during the period leading up to the registration or grant, even if they had failed to declare it during the filing phase. The Delegation explained that the goal of the amendment was to increase certainty for third parties and enhance convenience for the applicants. The Delegation specified that third parties could still check pre-filing disclosures related to registered patents and that applicants were given the chance to fix the mistake of failing to declare such disclosure at the moment of filing the patent application. The Delegation believed that the new amendments would be beneficial especially for applicants unfamiliar with the patent system, such as small entities not assisted by a patent attorney.

GENERAL DECLARATIONS

33. The Delegation of Belarus, speaking on behalf of CACEEC, expressed its wish to congratulate the Chair and Vice-Chair for their election and thanked the Secretariat for the work carried out on the documents for the twenty-second session of the Committee. The Delegation stated that CACEEC had always attached a great importance to the work of the Committee since they considered it an important forum for discussing all issues related to patent law. The Delegation pointed out that all issues under the program of the Committee were important. The Delegation expressed its hope that discussions at the Committee would allow to come up with a more balanced, effective patent system, both at the national and international levels. The Delegation noted that discussions during the meeting on inventive step and sufficiency of disclosure should be practical in nature and should consist of an exchange of information and experiences to improve the quality of patents. The Delegation expressed its appreciation for the efforts of the Committee to resolve issues related to patents and health, the transfer of technology and the preservation of confidentiality of advice by patent advisors. The Delegation endorsed the search for an optimal way to use the patent system and solve social problems, and expressed its willingness to participate in a constructive way to the discussion on all items under the agenda.

34. The Delegation of Pakistan, speaking on behalf of the Asia and Pacific Group, congratulated the Chair and Vice-Chair for their election and expressed their appreciation for the hard work of the Secretariat in preparing for the meeting. The Delegation expressed its commitment to continue constructive and balanced discussions on all topics on the agenda. The Delegation considered the work of the Committee critical in balancing the right of patent owners and public interest, particularly in the area of public health, technology transfer and patent-related flexibilities. The Delegation noted that it was essential to find the right balance between patent rights and the right to health, taking into account the differences in the social, economic and technological development of Member States, as well as the TRIPS flexibilities, the respect for intellectual property laws and the needs of all Member States. The Delegation noted that such approach would not only allow governments, especially in under resourced countries, to maintain the necessary policy space to face health needs, but also to promote further innovation. The Delegation expressed its hope to see productive discussions on all proposals in that regard. The Delegation considered that the discussion and exchange of best practices and national experiences in the twenty-second 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 and interests of all members. The Delegation further specified that Members of the Asia and Pacific Group would intervene in their national capacity on specific agenda items.

35. The Delegation of Romania, speaking on behalf of the CEBS Group, congratulated the Chair and Vice-Chair for their election and expressed its hope to advance the work of the Committee in an efficient and pragmatic manner. The Delegation thanked the Secretariat for its important contribution to the preparation of the session, and especially for the two comprehensive studies on the inventive step and the sufficiency of disclosure. The Delegation shared the understanding that the pillars of the patent system were the criteria for patentability, which remained at that stage circumscribed to national or regional visions and specificities. The Delegation believed that if the WIPO's relevancy in that area was to be maintained in the current globalized knowledge-based economy, it would be necessary to concentrate on addressing challenges faced by users of the patent system at the international level. The Delegation therefore welcomed the opportunity to discuss in a more focused way the topic of quality of patents, including opposition systems. The Delegation considered that the two studies prepared by the Secretariat provided the Committee with the basis of work that would be of benefit to all users of the patent system. In the same vein, the

Delegation reiterated its support for the proposal to launch a questionnaire on quality of patents as presented by the Delegations of Canada, the United Kingdom, Denmark and the United States of America. The Delegation believed that there was scope for making progress on other issues: among those, the topic of confidentiality of communications between patent advisors and their clients was considered of great interest for the CEBS Group. In that context the Delegation recalled that the seminar organized by WIPO during the previous SCP session had conveyed a clear message on the necessity to find solutions for cross-border aspects for the benefit of both holders and users of intellectual property rights. The Delegation expressed the opinion that also the topic of work sharing deserved further consideration with a view to strengthening and facilitating international cooperation. The Delegation took note of the proposal by GRULAC to revise the 1979 WIPO Model Law for Developing Countries on Inventions. The Delegation hold the view that before engaging in such significant endeavors, there was need to better understand the impact of the possible inclusion of the proposal in the program of future work. The Delegation strongly advocated for a balanced work program that would meet the concerns of all Member States. To conclude, the Delegation reiterated its commitment to engage constructively in the debates of the Committee in order to have a fruitful session.

36. The Delegation of Japan, speaking on behalf of Group B, expressed its wish to congratulate the Chair for her election and believed that the Committee would advance its work under her wise guidance. The Delegation also congratulated the Vice-Chair for her election and thanked the Secretariat for the hard work in preparing the session. The Delegation stated that Group B strongly believed that the SCP, as an only multilateral forum in the field of patents, had a responsibility to provide a venue for technical discussion on issues of substantive patent law in a manner responding to the evolving real world. Referring to the two studies on inventive step and sufficiency of disclosure under the agenda item of quality of patents, one of which had been proposed by Group B and the other proposed by other groups, the Delegation pointed out that, at the current session of the SCP, there were the only two items for substantive discussion because of disagreement on the future work in the previous session of the Committee. At the same time, the Delegation considered that those two subject-matters were very core parts of the substantive patentability requirements and were at the heart of the patent system. The Delegation believed that in order to properly understand what a patent was and how patents should be, it was critical to collect a deep understanding of those core patentability requirements and deemed that the studies prepared by the Secretariat were very good bases for the discussion to deepen participants' understanding in that regard. From that perspective, the Delegation expressed its wish of being engaged in the technical and substantive discussion on the studies under the agenda item on quality of patents. The Delegation stressed the importance of continuing that kind of substantive and technical work in order to let the SCP continue to be a central multilateral forum, which gathered experts and contributed to the development of the patent system. The Delegation further expressed the willingness of Group B to engage constructively in the discussion on the future work of the SCP. The Delegation stated that with respect to quality of patents, including opposition systems, Group B expected the Committee to build further work upon the basis established within the current session, in light of substantive contribution to the real world of patents. The Delegation underlined that international work sharing and collaboration was one of the critical issues. It expected that an agreement would be reached by the SCP with some concrete work for the future, which could substantially contribute to that perspective. In relation to the topic of confidentiality of communications between clients and their patent advisors, the Delegation stressed the importance of cross-border aspects on that issue. The Delegation believed that predictability was one of the important elements for enabling business environment. The Delegation expressed its wish to further discuss how the Committee could respond to such demand from the real business world. The Delegation expressed its willingness to also engage in discussion on other topics, from the perspective of future work and assured the

engagement of Group B in the work of the Committee with a constructive spirit in finding a way to move forward.

37. The Delegation of Brazil, speaking on behalf of GRULAC, congratulated the Chair for her election and expressed its belief that under her guidance, the Committee would achieve good results. The Delegation observed that the Committee had a short but interesting agenda, in particular, under agenda item 6 there were five issues under consideration, as well as two studies relating to substantive examination, i.e., sufficiency of disclosure and inventive step. The Delegation considered that it was important for member States to learn from each other's experience and practice under those two topics. While acknowledging similar practices in some countries, the Delegation was of the view that the Committee was invited to recognize that intellectual property policies and legislation should address national economic and scientific issues as well as development concerns. The Delegation noted that the first study entitled "study on inventive step", acknowledged different practices in every country, characterizing various approaches taken by IP Offices. The Delegation observed that, whether it was called non-obviousness or inventive step, the topic had a key role in national innovation systems and for that reason, it was considered as a valued flexibility provided by the TRIPS Agreement. The Delegation considered that the second study, entitled "sufficiency of disclosure", consolidated factual information provided by IP Offices on how Member States had implemented the sufficiency of disclosure requirement. The Delegation believed sufficiency of disclosure a crucial component of the patent system for its function of technology dissemination and therefore technology transfer from developed to developing countries. The Delegation stated that, concerning the current work of the Committee, GRULAC attached great importance to exceptions and limitations to patent rights. The Delegation recalled that, as a result of discussions held during the previous session of the Committee, it had requested the Secretariat to prepare an analysis of those exceptions and limitations that had proven effective to address development concerns. The Delegation further noted that, based on such analysis, it had expressed the wish to propose the development of a non-exhaustive manual on that topic as a reference to Member States of WIPO. Furthermore, the Delegation expressed the interest of the GRULAC in new joint efforts related to the discussion of topics of patents and health and technology transfer. Regarding the agenda item 7 and other issues, the Delegation recalled the statement made on behalf of GRULAC during the previous session of the SCP on the need for complete revision of the 1979 WIPO Model Law for Developing Countries on Inventions, and stated that GRULAC had presented a proposal having the aim of starting discussion on the revision of such Model Law. In particular, the Delegation pointed out that the revision of such Model Law should take into account international legal landmarks such as the WTO agreements and the WIPO Development Agenda Recommendations. The Delegation urged all delegates to take advantage of the few days before the discussion to go through the Model Law and recognize that it was outdated and did not serve anymore the intended purpose.

38. The Delegation of China congratulated the Chair and Vice-Chair for their election and thanked the Secretariat for its hard work. The Delegation stated that it attached great importance to the work of the SCP, which was an important platform for discussions on the international patent system. The Delegation hoped that the Committee could play a greater role in encouraging innovation and promoting economic, social and technological development. The Delegation observed that different national situations and development levels meant different interests. In the Delegation's view, that required all parties to show more flexibility and cooperative spirit so as to cover as far as possible the interests of all parties. The Delegation believed that improving capacity building of all offices to enable meaningful work sharing, enhancing applicants' level and capacity of their understanding of the international patent systems and enhancing their ability to better prepare patent applications would be conducive to improving the overall quality of patents. The Delegation considered that at the same time the use of flexibilities available in the patent system to

promote technological transfer would be conducive to better realization of the social value of the patent system. To conclude, the Delegation expressed its wish to progress discussions within the Committee during its twenty-second session, under its able chairmanship.

39. The Delegation of Nigeria, speaking on behalf of the African Group, expressed its congratulations to the Chair and Vice-Chair for their election and expressed its confidence in their ability to steer the work of the Committee. The Delegation thanked the Secretariat for its hard work and preparation for the meeting. The Delegation stated that the African Group recognized the instrumental role of the SCP in building knowledge, understanding and application of various patent-related norms that facilitated participation in and an effective use of the international patent system. The Delegation believed that those inherently included enabling factors, encapsulated in the Development Agenda Recommendations, with the objective of enhancing patent-related uses for social, technological and economic development. The Delegation expressed the wish of the African Group to continue to look forward to active engagement within the SCP on the identified issues that supported the objectives of the African region, giving regard to the different levels of development of WIPO Member States. The Delegation expressed its wish that there would be constructive exchanges on the issues before the Committee, and in particular, in enhancing discussion on activities in the area of exceptions and limitations to patent rights, patent and public health, and technology transfer. On quality of patents, including opposition systems, the Delegation requested the Secretariat to provide further work on opposition systems in discussing the topic of quality of patents. The Delegation believed that the two studies under discussion during the first day of the Committee, on inventive step and sufficiency of disclosure, though non-exhaustive, provided a helpful knowledge resource on national practices in those fields. The Delegation thanked the Secretariat for its hard work in providing such studies. The Delegation looked forward to the presentation by GRULAC on holding constructive discussions on their proposal for the revision of the 1979 WIPO Model Law for Developing Countries on Inventions. The Delegation reserved its right to make further interventions on its national capacity.

40. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States, congratulated the Chair and the Vice-Chair for their election and expressed their willingness to take an active part in the discussion of the Committee under their stewardship. The Delegation observed that the previous SCP session had held a successful and interesting discussion regarding Member States experiences on international work sharing and collaboration. The Delegation believed that progress had also been achieved in the area of confidentiality of communications between clients and their patent advisors, where a fruitful seminar had been held. The Delegation noted that the program of the week contained two studies, one on inventive step contained in document SCP/22/3, and one on sufficiency of disclosure contained in document SCP/22/4. The Delegation thanked the Secretariat for its work in preparing those studies and looked forward to the discussion on those topics. The Delegation recalled that the work program contained five topics for discussion, namely: quality of patents, including opposition systems; client patent attorney privilege; exceptions and limitations to patent rights; transfer of technology; and patents and public health. The Delegation regretted that the intensive discussions held on the future work program during the previous session of the SCP had not resulted in a future work program acceptable to all. In relation to the discussion on future work, the Delegation pointed out that since the current work program contained a delicate balance of different priorities, it was of the utmost importance to retain such a balance. The Delegation stated that the EU and its Member States attached considerable importance to advancing the work on the 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, as well as by the Delegation of Spain and the Member States of the European Union. The Delegation stated that it was in favor of launching a questionnaire containing the

elements of all the proposals. The Delegation expressed its belief that further work in that area could be beneficial to all WIPO Members. The Delegation considered that the sharing session on work sharing during the previous session of the SCP fruitful and interesting. The Delegation recalled that they had already formulated several ideas on how to take that work forward, such as creating a dedicated webpage on the WIPO website, and organizing conferences and preparing studies. The Delegation considered that by investing time on the topic of international cooperation, the Committee could contribute to a more efficient, effective and higher quality patent system. The Delegation expressed its wish to make progress also on other topics, in particular, the client patent attorney privilege, as convergence of differing provisions in that area would be of benefit to users of the patent system. Turning to document SCP/22/5 containing a proposal from GRULAC to revise the 1979 WIPO Model Law for Developing Countries on Inventions, the Delegation observed that such proposal would likely imply a very substantial amount of time that the SCP needed to dedicate. Additionally, the Delegation was of the opinion that several items of the current work program, such as exceptions and limitations, overlapped with such proposal. The Delegation believed that, as a consequence, a new balance would need to be found in relation to the topics under discussion. Furthermore, the Delegation considered that the proposal was unclear in relation to important points such as oversight and execution of the exercise. On the substance, the Delegation emphasized that a revision of the Model Law should not touch upon the interpretation of the TRIPS provisions. In the Delegation's view, there was need of more clarity on such key issues in order to properly consider the implications of such proposal. The Delegation reiterated their commitment to discussing key aspects of substantive patent law with the aim of international patent law harmonization. The Delegation expressed their dedication to the work of the Committee and looked forward to a constructive session.

41. The Delegation of India congratulated the Chair and Vice-Chair for their election and complimented the Secretariat for having prepared the documents for the discussion in the current session of the SCP. The Delegation believed that the development of the patent system and the use of patent rights should operate in a balanced and objective manner, which should meet the goal of providing the protection for the moral and material interests of the inventors, and at the same time, should assist developmental aspects of the society as well. The Delegation also believed that a patent was also a social product that had a social function. 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 of the Committee. The Delegation reaffirmed its views expressed in the previous SCP meeting, in particular, on the issues related to exceptions and limitations to patent rights, quality of patents, including opposition systems, patents and health, client-attorney privileges and transfer of technology. With regard to quality of patents, the Delegation considered that the quality of examination needed to improve substantially in conformity with the policy objective of a country so that huge social cost of granting patents to insignificant improvement would not be created. In its view, granting patents on insignificant improvement only led to litigation and create barriers for the dissemination of knowledge and transfer of technology. Taking note of documents SCP/22/3 and 4, the Delegation expressed its wish to make detailed comments on those documents during the discussions on the documents. As agreed by the Committee, the Delegation believed that those studies should be based on the information provided by Member States, and should be a collection of factual information, and allowed Member States to come up with analysis or recommendations, if any. Further with respect to other related documents, the Delegation reiterated its views expressed in the previous SCP meeting. The Delegation believed that sharing of work of other patent offices was not the remedy for improving the quality of patents and also, it could not be considered to be a solution for addressing the backlog. Rather, in the Delegation's view, the sharing of work of other offices could have weakened

the examination process and capability of patent offices in developing countries. Thus, it was Delegation's 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. The Delegation, therefore, believed that the work sharing should not become an area for norm-setting in future. On the issue of exceptions and limitations, the Delegation reaffirmed its support to the work program as proposed by Brazil (SCP/14/7 and SCP/19/6) and reiterated that the proposed study might focus upon the use of some exceptions and limitations, such as compulsory licensing, parallel imports, government uses, Bolar exceptions, etc., which were extremely important from the point of view of accessibility and affordability of medicines in developing countries and least developed countries (LDCs). On the issue of patents and health, in order to meet the requirement of public health with respect to patented drugs and to provide the lifesaving drugs on affordable price in developing countries and least developed countries, the Delegation believed that there was a need not only to study the TRIPS flexibilities and effective implementation or utilization of compulsory licensing provisions under patent law, but also to study the impact of grant of compulsory licenses and consequential impact on availability and prices of patented drugs. Further, the Delegation reaffirmed its support to the studies proposed by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group (SCP/16/7) on patents and health. The Delegation further reaffirmed its views expressed in the previous SCP meeting on the issue related to document SCP/21/9 concerning feasibility study on the disclosure of International Nonproprietary Names (INN) in patent applications and/or patents and on the issue of a study related to Markush formulae and 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 client-attorney privileges, the Delegation reiterated that since the issue was of substantive nature and should be governed by national laws, the discussion on that topic discontinued in the Committee. On the issue of transfer of technology, the Delegation believed that the protection and enforcement of patent rights should promote technological innovation and transfer of technology (achievable by patent specifications independent of any know-hows) in the country where the rights were protected, thereby providing the mutual advantage to producers as well as to users of technological knowledge. In order to create balance of rights and obligations, the Delegation considered that the protection and enforcement of patent rights *vis-à-vis* technological content of patent specifications should be conducive to the socioeconomic developments of the country. In the Delegation's view, the document SCP/22/4 concerning a study on the sufficiency of disclosure should also be considered under the transfer of technology, as it was much related to the issue of transfer of technology. Finally, the Delegation expressed satisfaction on the progress made by the SCP in bringing out reasonable studies, giving a clear picture on the existing situation across countries on the subjects under consideration. The Delegation extended its full cooperation and expressed its readiness to participate constructively in the Committee's discussions.

42. The Delegation of Iran (Islamic Republic of) joined the other delegations in congratulating the Chair and Vice-Chair for their election and thanked the Secretariat for its hard work in preparing for the current session of the SCP. The Delegation associated itself with the statement made by the Delegation of Pakistan on behalf of the Asian and Pacific Group. The Delegation attached great importance to the work of the SCP for substantive discussion and advancing norm-setting. The Delegation believed that the Committee should have set out a balanced work program, which provided the opportunity for fruitful exchange of views on a wide range of topics related to patents, such as, exceptions and limitations to patent rights, quality of patents, including opposition systems, patents and health and transfer of technology. The Delegation therefore considered that all agenda items should be treated equally by the Committee. The Delegation was of the view that the deliberation 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 to explore the ways to better adapt the patent system to meet the needs of their national development. In that context, the Delegation believed that the international harmonization of patent laws without giving due account to the differences in the levels of social, economic and technological development would not benefit all Member States. Regarding the subject of technology transfer, the Delegation expressed its wish to see a comprehensive work program, in which the incentives and impediments of a patent system to transfer of technology would be analyzed. The Delegation considered that a sufficient consideration should also be given to patent law flexibilities and their possible role in promotion of transfer of technology. 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. In the absence of such definition, the Delegation was of the opinion that the proposals could not be fully comprehend by other delegations. Therefore, in the Delegation's view, it would be useful to first try to agree on a common definition and the scope of such term. The Delegation further considered that it would be important to study and to evaluate the role of the requirement of sufficiency of disclosure in the quality of patents. The Delegation also supported further discussion on opposition systems and preparing a compilation of models on opposition and administrative revocation systems. The Delegation was of the opinion that the issue of patent and health, including having access to essential medicines with affordable price, was an important issue for developing countries including Iran. The Delegation's expectation from the inclusion of that item in the work of the Committee was to recognize the practical ways to respond to the challenges caused by the patent system in the field of health. The Delegation believed that the full use of flexibilities accorded under international agreements and their ineffectiveness were other issues, which should be addressed in the SCP.

43. The Delegation of the Republic of Korea congratulated the Chair and Vice-Chair for their election and thanked the Secretariat for its hard work in making the necessary preparation for the current session of the Committee. The Delegation supported the statement made by the Delegation of Pakistan on behalf of the Asia and Pacific Group. The Delegation recognized that the SCP had always been a forum for Member States to engage in substantive, fruitful discussions on technical issues pertaining to patent law and international cooperation. Moreover, the Delegation noted that throughout the last few years, the SCP had provided Member States with the opportunity for sharing beneficial experiences and insights on important issues. The Delegation considered the discussion within the Committee had been extremely beneficial in enhancing the capacities of Member States in taking advantage of the patent system to the greatest possible extent. The Delegation expressed its complete devotion to the balanced development and usage of the patent system in order to effectively recognize and protect the creative and intellectual authorship of inventors. The Delegation endorsed to furthering global interest in promoting social inventions that would ultimately enhance the life of people all around the world, for example by affording them a higher degree of comfort and self-determination. The Delegation expressed its hope that discussion at the Committee would prove to be enlightening and productive for everyone involved, and that each issue would be carefully regarded in light of the greater good.

44. The Representative of TWN observed that the current session of the SCP had taken place after the 20th year anniversary of the TRIPS Agreement. In the Representative's view, during the last twenty years, there had been plenty of evidence to show that TRIPS Agreement had failed to fulfill its promises, especially in the context of addressing the development and challenges of developing countries. The Representative was of the opinion that almost universal protection of product patent regime failed to deliver on both innovation on and access to medicines and that there was no substantial increase in the

R&D outcomes with regard to health products to meet the unmet health care needs of developing countries. Similarly, the Representative believed that the patent monopoly was blocking access to affordable medicines and incapacitated both developing and developed countries to fulfill their obligation on the right to health. The Representative considered that the exorbitant prices of hepatitis C oral anti-viral drugs were a case in point. Against that background, the Representative recalled the main findings contained in a declaration titled “Declaration on Patent Protection: Regulatory Sovereignty under TRIPS” by Max Planck Institute for Innovation and Competition on the occasion of the 20th anniversary of the TRIPS Agreement. The Representative quoted the document by saying that first, the “historically unprecedented numbers of patents filings and grants” created problems such as backlogs at patent offices, patent thickets, market entry barriers and increased litigation that ultimately generated impediments to research and commercialization. The Representative recalled that the result was raising costs of monitoring patents and legal uncertainty, limiting the economic freedom of market participants, which in turn affected consumer welfare and distorted competition. The Representative further quoted a part of the study according to which, “the overall social benefits of innovation were reduced while an imbalance emerges between those able to cope with the resulting insecurities and related costs, such as multinational enterprises with their own patent departments, and those who cannot, such as small and medium sized enterprises or individual inventors”. Second, the Representative was of the opinion that the new technologies such as biotechnology, business methods and computer science as well as standard setting, strategic patenting and non-practicing entities, all affected the functioning of the patent system as a regulatory institution. Third, the Representative stated that the role of patents in corporate management had undergone a change from a defensive means to protect research and development outcomes to strategic assets to influence the conditions of competition. As a fourth point, the Representative considered that the industrialized countries had tilted the balance in the patent regime towards right holders by reducing the burden for the patent applicants such as expanded scope of patentability, lower eligibility standards and reduced fees, as well as extending the rights of patent owners such as longer term of patents, stricter sanctions and strengthened ways for private and public enforcement. Against that background, the Representative called upon both the Member States and the Secretariat to shed the notion that a patent was the necessary tool to stimulate technological invention and commercialization, and instead to work towards curbing the abuse of patent monopoly. The Representative believed that the discussion on the two studies on inventive step and sufficiency of disclosure requirements was an important opportunity to curb the abuse of patent monopoly. The Representative looked forward to a constructive engagement in the coming days, and expressed her hope that Member States would take the right decisions to address the development challenges posed by patents.

45. The Representative of MSF expressed its regret that there was no agreement on the future work program in the previous Committee and expressed its wish to anticipate substantive progress to be made before the SCP, especially on the issues of patents and public health, including the proposal submitted by the African Group on public health and patents. The Representative reminded the Committee that 2014 and 2015 had witnessed a number of increased public health challenges at a global scale, facing many Member States of the Committee. The Representative highlighted a number of examples, for instance, the Ebola crisis last year had further demonstrated the failure of the patent-centric innovation system in biopharmaceutical sectors. The Representative mentioned, as another example, that hepatitis C had become a challenge to both developed and developing countries, while the medicines were priced out of reach of many. In addition, the Representative noted that the newly revised World Health Organization (WHO) Model List of Essential Medicines had included new medicines treating hepatitis C, cancer and drug-resistant tuberculosis. In her opinion, all of those new medicines remained under heavy patent thickets and presented concerns for many Member States in getting access. The Representative called on the

Committee and the Member States to keep connecting patent discussion with social reality, not to discuss normative issues in isolation from prominent social impacts such as those related to health, to recognize the increasing public health challenges facing many Member States and to make concrete progress on the proposal of public health and patents. In addition, the Representative considered that the Committee could mainstream public health considerations in other substantive discussions. For instance, in the discussion of inventive steps, the Representative suggested that national provisions on inventiveness that had proven to promote public health such as Section 3(d) of India's Patent Act be discussed. The Representative further suggested that the Committee continue working on the issue of mandatory disclosure of INN, which had not been concluded in the previous session. The Representative believed that disclosure of INN remained crucial for public health agencies and non-governmental organizations to effectively monitor public health-sensitive patents at an early stage. In the Representative's view, the requirement of INN disclosure would direct more rational filing behaviors of the applicants and prevent abuse of the patent system.

46. The Representative of CIPA congratulated the Chair and Vice-Chair for their election and expressed his gratitude to the Secretariat for its hard work in preparing for the meeting. The Representative believed that all users of the patent system needed proper protection of cross-border confidentiality communication between clients and their patent advisors, regardless of what was or was not agreed on other substantive issues before the SCP. The Representative considered vital to the whole community that the Committee would sort that issue out.

47. The Representative of Innovation Insights congratulated the Chair and Vice-Chair for their election. Being a new observer to the SCP, the Representative explained that Innovation Insights was a cross-sectoral industry group dedicated to sharing information about innovation and technology diffusion, and specified that its aim was to be a source of information to policy makers and other interested parties. The Representative stated that its members were large and small innovative businesses in sectors such as semiconductors, software, green technologies and medical technologies. The Representative expressed their availability to discuss, on the basis of their first-hand experiences, any topic related to IP management and development and scaling of new technologies, and indicated their eagerness to work with the Committee.

48. The Representative of Innovation Insights, speaking on behalf of IPO, ICC and itself, observed that the agenda of the SCP contained several practical topics related to the functioning of the patent system, such as quality of patents. The Representative stated that businesses wanted quality patents, whether their own patents or those of other actors. The Representative considered that patents that would not hold up if challenged, created uncertainty, wasted resources and could undermine investments and innovation. In her view, patent quality was a priority topic for all stakeholders. In relation to the topic of work sharing and efficiency of the patent system, the Representative noted that work sharing arrangements were multiplying. For instance, the Representative noted that the IP Offices of Brazil and the United States of America had announced a new collaboration during the previous month and that at the beginning of the year, Egypt and Japan had launched a new Patent Prosecution Highway (PPH). In the Representative's view such arrangements could reduce pendency and enhance patent quality, even if their impact depended on how they were set up and operated. The Representative considered that for that reason, information exchange about work sharing was a valuable part of the SCP work. With regard to technology transfer, the Representative stated that their members had a wealth of experience with the development of cutting-edge technology solution around the world, and in particular with the management of patents to support and advance those processes. The Representative expressed their wish that they contribute to advance the work of the Committee in such an important area.

AGENDA ITEM 6: FIVE ISSUES UNDER CONSIDERATION

(I) QUALITY OF PATENTS, INCLUDING OPPOSITION SYSTEMS

- Study on inventive step

49. Discussions were based on document SCP/22/3.

50. The Secretariat presented the document.

51. The Delegation of Japan, speaking on behalf of Group B, thanked the Secretariat for preparing the study on inventive step contained in document SCP/22/3 and for the informative presentation of that document. The Delegation noted that the inventive step requirement was a core part of substantive patentability requirement and that exclusive rights should be awarded only to the invention whose contribution to society deserved it. The Delegation stated that, in that regard, an exchange of practices and information among experts on that issue was what had been expected from the SCP. The Delegation stated that further deepening of the understanding on the office practices relating to inventive step could lead to fundamental basis upon which international work sharing and collaboration could be built. The Delegation noted that understanding of the methodologies employed for evaluating inventive step was critical for the use of examination results by the other offices. The Delegation further stated that recognizing the fact that many offices employed the so-called “problem-solution approach”, further evaluation by Member States of that methodology would be fruitful. Further, referring to the paragraphs of the study relating to obviousness, the Delegation noted that that was the most interesting and, at the same time, the most difficult part of evaluation of the inventive step. For the same reason which the Delegation had mentioned in the context of methodologies employed for evaluating inventive step, the Delegation considered that it was useful to know what indicators were adopted by offices to clarify the concept of obviousness.

52. The Delegation of Romania, speaking on behalf of the CEBS Group, thanked the Secretariat for the study on inventive step which was submitted to that session and presented extensively at the previous day of the session. The Delegation expressed its belief that discussing that study as well as the study on sufficiency of disclosure would help the Committee make progress on the topic of quality of patents. With regard to the study on inventive step, the Delegation stated that it appreciated the information provided on the most important elements of the evaluation of the inventive step, namely, the definition of the person skilled in the art, methodologies employed for evaluating an inventive step, and the level of the inventive step. The Delegation also found it useful the historical approach to the introduction of the requirement of inventive step as that allowed to better understand the importance of correctly evaluating an inventive step for granting high quality patents. At the same time, the Delegation wished to highlight its interest in further exploring the advantages and disadvantages of the methods used in evaluating an inventive step.

53. The Delegation of India wished to reiterate its stand that the study on inventive step, contained in document SCP/22/3, must not be construed as a tool for harmonization of the concept of inventive step. Further, the Delegation stated that one of the flexibilities left by the TRIPS Agreement was that it did not define the term “inventive step”. In that context, the Delegation recalled paragraph 4 of the Doha Declaration on TRIPS Agreement and Public Health, which in its concluding line declared the right of WTO members that: “In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose”. The Delegation stated that Article 8 of the TRIPS Agreement mandated that the WTO members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and

nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures were consistent with the provisions of the Agreement. Further, the Delegation referred to the statement by the Committee on Economic, Social and Cultural Rights, of November 26, 2001, on Article 15.1(c) of the International Covenant on Economic, Social and Cultural Rights which reminded that: "Ultimately, intellectual property is a social product and has a social function". Therefore, the Delegation stressed that, in its opinion, 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. Further, regarding general description and history of the inventive step, the Delegation agreed that the inclusion of such a requirement in the patentability criteria was based on the premise that the patent protection should not be given to anything that a person with ordinary skill could deduce as an obvious consequence of what was already known to the public. Regarding the definition of a person skilled in the art (PSIA) and methodologies employed for evaluating the inventive step, the Delegation noted that the study, thankfully, indicated to the fact that the exact level and subtle nuances of the PSIA's creative or reasoning capacity in each jurisdiction were not always easy to grasp. The Delegation continued that, in fact, the level of the skilled person may be one of the most important policy issues for inhibiting the entry of frivolous inventions. The Delegation stated that, whereas, in many jurisdictions, that man was presumed to be devoid of any inventive skill, the Supreme Court of the United States of America had refused to treat him as an automaton and endowed him with a certain modicum of inventive activity, which had been denied in other jurisdictions. The Delegation quoted the Supreme Court's statement that: "A person of ordinary skill is also a person of ordinary creativity, not an automaton". In the opinion of the Supreme Court, "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious [...]". The Delegation further stated that in the light of teaching of KSR, therefore, it was not difficult to understand the decision of the Intellectual Property Appellate Board (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, also, if the intention of inventive step and sufficiency of disclosure in the patent law was understood, the ground of IPAB decision in distinguishing the skilled person in those two different and yet interrelated context could be understood very clearly. The inventive step had developed as an additional layer of novelty and therefore, lowering the level of the skilled person would be detrimental to the growth of industry as even the frivolous inventions would even get exclusivity. In the context of sufficiency of disclosure, however, the skilled person should be able to translate the specification into the technical reality without undue burden of experimentation. The Delegation further stated that the skilled person in the context of sufficiency of disclosure needed to be educated about the state of art from the teachings of the specification in the interest of transfer of technology. It noted that the decision of the IPAB had relied on the decision of the KSR (in Sankalp Rehabilitation, Order No. 250/2012) as well as on the decision of the Delhi High Court in ROCHE vs. CIPLA [CS (OS) No. 89/2008 and C.C. 52/2008] while issuing its opinion in Alloys Wobbens (Order No. 123/2013) which had been cited in the study. However, for the sake of clarity, the Delegation wished to mention that Biswanath Prasad Radhey Shyam vs. Hindustan Metal Industries (cited as AIR 1982 SC 1444) laid the foundation of the jurisprudence related to inventive step in India. In particular, the Delegation noted that paragraphs 25 and 26 were seminal for formulating the concept of inventive step in ROCHE judgment as well as in all other judgments (including those of IPAB) in India: "*The expression 'does not involve any inventive step' used in Section 26(1)(a) of the Act and its*

equivalent word 'obvious', have acquired special significance in the terminology of Patent Law. The 'obviousness' has to be strictly and objectively judged. For this determination several forms of the question have been suggested. The one suggested by Salmond L. J. in *Rado vs. John Tye & Son Ltd.* is apposite. It is: whether the alleged discovery lies so much out of the Track of what was known before as not naturally to suggest itself to a person thinking on the subject, it must not be the obvious or natural suggestion of what was previously known." (Paragraph 25). "Another test of whether a document is a publication which would negative existence of novelty or an 'inventive step' is suggested, as under: 'Had the document been placed in the hands of a competent craftsman (or engineer as distinguished from a mere artisan), endowed with the common general knowledge at the 'priority date', who was faced with the problem solved by the patentee but without knowledge of the patented invention, would he have said, 'this gives me what I want?' (Encyclopaedia Britannica; *ibid*). To put it in another form: 'Was it for practical purposes obvious to a skilled worker, in the field concerned, in the state of knowledge existing at the date of the patent to be found in the literature then available to him, that he would or should make the invention the subject of the claim concerned?' [Halsbury, 3rdEdn, Vol. 29, p. 42 referred to by *Vimadlal J. of Bombay High Court in Farbwirke Hoechst & B. Corporation v. Unichem Laboratories*] (paragraph 26). The Delegation further stated that regarding the level of inventiveness (obviousness), the study admittedly stated that the title of that section was misleading and it mainly focused upon the secondary indices, but did not discuss anything about said "level". Regarding the alleged "level", the Delegation stated that the observation of the Executive Office of the President of the United States of America was very pertinent, which observed that: "Setting an appropriate bar for novelty and non-obviousness is particularly important in a new field; if the bar is not set high (something difficult to do in a new field), firms may well find themselves inadvertently infringing patents, both because of the sheer number of patents and because commercial need is driving many inventors to create similar inventions near-simultaneously (Lemley and Melamed 2013)" [Patent Assertion and U.S. Innovation, Executive Office of the President, June 2013]. The Delegation continued that in the KSR, the Supreme Court of the United States of America stated that: "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 stated that in *Biogene vs. Medev*, 1997 RPC, the House of Lords cautioned against loosely granted monopolies that: "It is inevitable in a young science, like electricity in the early nineteenth century or flying at the turn of the last century or recombinant DNA technology in the 1970s, that dramatically new things will be done for the first time. The technical contribution made in such cases deserves to be recognized. But care is needed not to stifle further research and healthy competition by allowing the first person who has found a way of achieving an obviously desirable goal to monopolize every other way of doing so [...]". Noting further that above stated reports and decisions pointed to the question of level of standards for determining the most fundamental aspects of the patentability, the Delegation wished to reiterate that the TRIPS Agreement allowed the Member States to determine that level and apply it in the domestic legislations so that an appropriate balance that took into account the interest of the inventor *vis-à-vis* the interest of the society be achieved.

54. The Delegation of Belarus thanked the Secretariat for the comparative study on the inventive step and highly appreciated the quality of the accomplished work. The Delegation stated that the study gave an overview of the approaches taken at the national level in determining that relatively difficult criteria of patentability. In the opinion of the Delegation, the information provided in the study was systematic and comprehensive. The Delegation

also expressed its appreciation for the informative presentation made by the Secretariat on the subject. Further, the Delegation stated that it was obvious that the criterion of “inventive step” was a prerequisite for the quality and strength of the future patent, which in turn was important for further technological development and ensuring a balance of interests in society. In that regard, the Delegation further noted that in the national legislation, efforts were being made to ensure the implementation of the highest standards in this area and that they would continue to improve the national legislation and methodologies used by its Office to determine the inventive step criterion, including, on the basis the study prepared by the Secretariat and the results of its deliberations of the Committee on the issue. The Delegation stated that the exchange of experiences and views undoubtedly would contribute to that work. In conclusion, the Delegation sought clarification and comments as to the possibilities of using the results of the study with regard to the future work of the Committee.

55. The Delegation of Mexico thanked the Secretariat for the excellent work in relation to two documents, namely inventive step and sufficiency of disclosure. As far as Mexico’s view with regard to the inventive step criterion, the Delegation agreed with the opinions that it was an important factor in determining the quality of a patent. Specifically, the Delegation stated that, the Mexican legislation described the profile of a person skilled in the art as a technician who had expertise and knowledge in the area of the invention concerned. The Delegation noted that, pursuant to its legislation, the methodology used for determining an inventive step was the problem-solution approach. The Delegation further stated that in the Mexican Institute of Industrial Property (IMPI), the exchange of experiences with other patent offices, getting to know other systems and carrying out cooperation activities were very important. In its view, they enabled to have a better overall picture and therefore to take better decisions in implementing the national patent legislation. The Delegation noted that, in particular, IMPI had been working with other patent offices, for example, the Spanish office and the European Patent Office, in preparing guidelines for examination, particularly related to assessing inventive step of polymers and other inventions in the areas of biotechnology, which had resulted in a document of tremendous usefulness and support to some patent offices in Latin America. The Delegation reiterated its readiness to participate in all discussions related to patents because of the major importance it had in the system of industrial property.

56. The Delegation of the United States of America thanked the Secretariat for preparing document SCP/22/3, which provided a good overview of the similarities and differences of how inventive step, also referred to as obviousness, was evaluated in patent offices around the globe. The Delegation stated that, as had been pointed out by several delegations, the evaluation of obviousness or inventive step of a claimed invention was very important to the quality of issued patents. In the United States, the evaluation of obviousness by the USPTO and by the courts was crucial in determining whether an applicant could be granted a patent, and in deciding if a patent was valid, respectively. The Delegation noted a great deal of case law developed by the courts to determine whether an invention was obvious and on the definition of the person skilled in the art (PSIA). The Delegation further stated that the inquiry into whether an invention was non-obvious and thus potentially patentable was codified in Section 103 of the United States Code, which stated that “A patent for a claimed invention may not be obtained [...] if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” The Delegation continued that, in other words, an invention that was not exactly described by the prior art, but nevertheless would have been obvious to a person of ordinary skill in the art at the time of the invention, was not patentable. The Delegation explained that obviousness was a question of law based on underlying factual inquiries. The framework for the objective analysis of obviousness had been enunciated by the Supreme Court of the United States of America in *Graham v. John*

Deere Co. in 1966. It included the following factual inquiries: (i) determination of the scope and content of the prior art; (ii) ascertaining the differences between the claimed invention and the prior art; and (iii) resolving the level of ordinary skill in the pertinent art. Once the Graham factual inquiries were resolved, the examiners must determine whether the claimed invention would have been obvious to one of ordinary skill in the art. The Delegation further stated that in *KSR International Co. v. Teleflex Inc.*, the Supreme Court had reaffirmed the Graham factual inquiries, but also had set forth a flexible approach to determining whether claims were obvious, that replaced the previously applied rigid standard. The Delegation noted that, under the previous approach, i.e., the “teaching-suggestion-motivation” or “TSM”, an express reason to modify the prior art had been required in order to permit the combination of multiple prior art references so that they would describe all the elements of a claim. The KSR approach, on the other hand, only required a reasoned explanation that avoided conclusory generalizations to justify combining multiple art references. The Delegation clarified that the TSM analysis might still be used as one of a number of rationales that might support a conclusion of obviousness. With respect to document SCP/22/3 and its summary, the Delegation stated that those two documents contained information that was very useful for both applicants and offices. Observing that the information provided a picture of the differences and similarities between offices on how the determination of obviousness/inventive step was carried out, the Delegation noted that that would be of great interest to patent offices, and should provide useful information to applicants filing in multiple jurisdictions. The Delegation considered that to make the documents more useful to the public and IP professionals, it was necessary to make the access to the documents easier by, for example, making the documents available in an electronic format. In particular, the Delegation suggested that the Secretariat make available the information obtained for those studies on the WIPO website as a table, a spreadsheet or other appropriate format, with links which would allow for easy access to the information relating to a country or patent office simply by selecting a few links. The information made available on that website could include the definition of a person skilled in the art used by the various offices, and the methodology used by the offices to determine obviousness or inventive step and other suitable points. The Delegation continued that, for example, information described in the study by the Secretariat could be linked to the country or office name, and further links could be provided to statutes, examination guidelines, case law and other official documentation. Similarities in the approaches taken by different offices in determining whether claims were obvious or involved inventive step, and particular areas of divergence in approaches, if any, should be pointed out. The Delegation further stated that it was clear from the study that the topic was complex. In its view, other elements of obviousness or inventive step should similarly be explored by the Secretariat, to complement the work presented in document SCP/22/3. In this regard, the Delegation suggested that the Secretariat update the study described in document SCP/22/3 by including information on how the various offices determine the conditions under which it was proper to combine prior art references to decide whether claims were non-obvious or have inventive step, and the manner in which secondary considerations (such as commercial success and supplemental data) were considered and applied by examiners during examination. The update would include information on whether offices consider the content of previously filed applications in evaluating both the novelty and non-obviousness or only the novelty of claims in later-filed applications. The Delegation continued by stating that the determination of obviousness and inventive step was intimately related to the selection of the prior art which was used by the examiner in reaching a patentability decision. In its view, even when the same law was applied, different conclusions could be reached by examiners if the prior art they considered was different. Therefore, the Delegation noted that, differences in how the prior art was defined by the offices had a great effect on the results of the analysis of obviousness or inventive step, and must be considered in a complete study of the topic. To take into account that aspect of inventive step, the Delegation proposed that the Secretariat update the study with information that would reflect the practice of the various offices with respect to

selecting prior art. The Delegation stated that, for example, the update should consider the practice of offices in determining whether the prior art would meet publication requirements, whether it was available to the public, whether it must be available locally or anywhere in the world, and whether it must be in written form. The update should also address how offices handle prior art patent applications that were filed before, but published after, the filing of the claims being examined. The Delegation further suggested that the information contained in those updates to the study also should be included in the WIPO website, as described above. The Delegation concluded by stating that such updates to the study would produce a more complete and useful picture of the state of obviousness and inventive step determinations in offices around the world.

57. The Delegation of Portugal expressed its appreciation to the Secretariat for the preparation of a study on inventive step. The Delegation stated that the Portuguese examiners employed a problem-solution approach as a methodology for assessing the inventive step requirement. In addition, the Delegation stated that in accordance with the Portuguese Industrial Property Code, an invention should be considered as involving an inventive step with regard to the state-of-the-art if it was not obvious to a person skilled in the art. The Delegation noted that the study was very important because it allowed sharing of information among Member States, providing a stronger knowledge and understanding of the inventive step requirement, which, in its opinion, was important for the improvement of the quality of the patents system in each Member State.

58. The Delegation of Japan thanked the Secretariat for its extensive work in preparing the document and for the presentation. The Delegation informed the Committee that the Japan Patent Office (JPO) was revising its Patent Examination Guidelines, so that a basic idea of the guidelines would be suitable globally, and that the description in guidelines would be succinct and obvious. The Delegation stated that with regard to “reasoning” that was applied to set forth reasons for denying the presence of an inventive step of the claimed invention, while the reasoning might be conducted from various and broad viewpoints, a systematic explanation of each viewpoint and procedures for such reasoning were not clearly indicated in the current examination guidelines. The Delegation explained that the outline of the revision was as follows: first, examiners divide various factors for reasoning into two types: one was factors that worked against an inventive step, and the other one was factors that supported an inventive step. The examples of factors that worked against an inventive step were: (i) motivation for applying the secondary prior art to the primary prior art; (ii) design modification, etc. from the primary prior art; and (iii) mere aggregation of prior art. The examples of factors that supported an inventive step were: (i) advantageous effects over the prior art; and (ii) obstructive factors. Second, the examiners would determine whether or not they could set forth the reasoning by taking into consideration all the factors, including factors that supported an inventive step, as well as the factors that worked against an inventive step. The Delegation stated that, furthermore, in the JPO’s examination guidelines dealing with inventive step, there were no clear reminders directly advising examiners to be careful to avoid impermissible hindsight in examining inventive step. In this regard, the Delegation noted that, in the examination guidelines of other offices, such as of the United States of America, China, the Republic of Korea, and the EPO, such reminders to prevent hindsight were clearly stated. In order for examiners at the JPO to make appropriate decisions on inventive step, the Delegation noted that the following point would be introduced in its examination guidelines, so that examiners were careful not to be confused by such hindsight: when it seemed that a person skilled in the art could have easily arrived at the claimed inventions, and when making decisions about approving cited inventions, examiners were often influenced by the claimed inventions. Quoting the current examination guidelines of the JPO which stated: “The fact of gaining commercial success or the equivalent can be considered as a useful fact in determining the existence of an inventive step.”, the Delegation stated that in the examination guidelines of patent offices of,

for example, the United States of America, China, the Republic of Korea, the EPO as well as the PCT International Search and Preliminary Examination Guidelines, the so-called secondary indication other than commercial success could also be considered in determining the existence of an inventive step. Based on that, the Delegation explained that the following indicator, which was the secondary indication included in the examination guidelines of other offices mentioned above, would be added in its guidelines: “the claimed invention solved a long felt need”.

59. The Delegation of Chile thanked the Secretariat for preparing the study on inventive step contained in document SCP/22/3. The Delegation stated that the information contained in the document describing national practices was an important input to the SCP discussions, especially since at the international level, there were flexibilities as regards the definition of inventive step. The Delegation stated that, in the case of Chile, an invention was considered to be inventive if, for a person skilled in the art, the invention was obvious and could not be derived in an evident manner from the prior art. According to the guidelines used by INAPI, the analysis conducted to determine the inventive step was based on two essential concepts: (i) the person skilled in the art; and (ii) the obviousness of the invention. The Delegation stated that the analysis of the inventive step carried out by national offices was an essential element in guaranteeing the grant of patents that, on the one hand, fulfilled the essential patentability requirements, and on the other hand, provided a benefit to society. For the Delegation, the balance between the grant of patents and the benefit that patents provided to society was one of the fundamental elements to ensure an efficient patent system.

60. The Delegation of Brazil thanked the Secretariat for preparing document SCP/22/3 which acknowledged the different practices and approaches taken by the IP offices in evaluating the inventive step criterion. Noting that the topic had a key role in national innovation systems, the Delegation stressed that it was a valid flexibility provided under the TRIPS Agreement. The Delegation expressed its surprise by the use of some terms in the study such as “in many jurisdictions” or “most countries”. In that regard, the Delegation referred to the mandate given to the study that it would be based on the information provided by Member States, and would be a collection of factual information without analysis and recommendation. With reference to the proposals made by some delegations, the Delegation requested other delegations to submit their proposals on the topic in writing.

61. The Delegation of France thanked the Secretariat for the quality of the study presented for the twenty-second session of the SCP and expressed its wish to share information as to its national practice regarding the inventive step. The Delegation stated that, in France, the concept of inventive step was governed by Article L.611-14 of the Intellectual Property Code. According to that article, “an invention shall be considered to involve an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art [...]”. The Delegation stated that a similar definition was provided in the EPC. An opinion on the novelty and inventive step of each patent application was provided in a written opinion on patentability accompanying a preliminary search report. The patent examination guidelines of the National Institute of Industrial Property (INPI) provided information on the assessment of inventive step. However, a lack of inventive step did not lead to a rejection by the patent office; as it was a matter for the courts. The Delegation stated that, French courts were thus called upon to rule on nullity actions against national patents or European patents that designated France. In order to find out whether a claimed invention involved an inventive step or not, a judge had to ask himself if a person skilled in the art would have managed to arrive, in an obvious manner, at a result corresponding to the terms of the claim on the filing date, considering the state of the art on that date. Three criteria needed to be taken into account in order to appreciate the inventive step of an application, namely, the state of the art, a person skilled in the art and non-obviousness. The Delegation further noted that the

French legislation did not provide a definition of a person skilled in the art. However, French case law had provided clarifications on what was meant by “a person skilled in the art”. In particular, the Delegation explained that the person skilled in the art was a person skilled in the technical field that was linked to the invention. According to the doctrine and case law in France, the person skilled in the art needed to be defined in precise terms and was a person skilled in the technical field in which the problem was posed and in which the invention sought to solve. The Delegation stated that the Court of Cassation had affirmed on several occasions that a person skilled in the art was a person who possessed normal knowledge of the technique in question and was capable, with the aid of his professional knowledge alone, of understanding a solution to the problem which the invention sought to solve. The Delegation continued that, in other words, they were dealing with a specialist who had average qualifications and who possessed normal knowledge of the field that was concerned by the technical problem that the invention proposed to solve. The Delegation further noted that the French legislation did not provide a methodology to assess inventive step or any threshold. Most of the time, the courts adopted a “problem and solution” approach which comprised three stages: (i) identification of the closest prior art of the examined invention, (ii) formulation of the technical problem that was to be solved in order to arrive at the invention starting from the closest prior art, and (iii) obviousness of the solution that the invention brought to the problem for a person skilled in the art. The Delegation continued that the certain secondary indications of non-obviousness could enhance assessment of the criterion of inventive step, in particular, the French courts had recognized that overcoming prejudice was an indication in favor of inventive step if that prejudice was technical in nature and went beyond the technical habits of a person skilled in the art. In addition, judges could also take into account the amount of time required to carry out an invention, if a significant amount of time elapsed between the moment a problem was posed and the time it took to carry out the invention in order to solve that problem. As regards the examples of other indications or criteria, the Delegation referred to INPI guidelines on the examination of patent applications, which were available on the website of INPI.

62. The Delegation of the Russian Federation expressed its gratitude to the Secretariat for the high quality of the study on inventive step and an interesting presentation on the document. The Delegation was of the view that the study was of great importance for understanding the requirement and enhancing the quality of patents. In particular, the Delegation stated that the information describing the approaches taken by the national IP offices would allow examiners to better evaluate the examination results of the other offices and thus would be important to improve work-sharing collaboration. In relation to its national practice on the subject matter, the Delegation stated that a person skilled in the art meant a hypothetical individual who had a general knowledge of, access to and experience in the field in a an obvious or usual way. That type of person was chosen as a yardstick for evaluating the inventive step criterion. The delegation explained that examiners in the patent office of the Russian Federation were free to apply any appropriate method of examination, including the problem-solution approach.

63. The Delegation of Spain thanked the Member States that had provided information on their national law regarding the inventive step requirement, basis on which the study had been prepared by the Secretariat. Noting that the study was of a high quality, the Delegation stated that it would contribute to improved understanding of that essential patentability criterion whose evaluation was highly complex and which was one of the key elements to ensure that the patent system worked correctly. The Delegation continued that that study and the study on the sufficiency of disclosure showed that the Committee should not be afraid of conducting studies on substantive patent law. The Delegation noted that, in the current phase of the Committee's work, the harmonization of substantive patent law was not an objective, but improving knowledge of patent law through studies and enabling sovereign states to take the decisions they deemed appropriate when drafting legislation or

examination guidelines. The Delegation found it interesting that the majority of legislations agreed on the definition of inventive step, and that the true challenge lied in the proper assessment of inventive step requirement. The Delegation considered especially noteworthy the section devoted to the level of the inventive step where many similarities as well as different nuances existing in the different legislations and practices were found. In that regard, the Delegation stated that what could be concluded from the study was that even though the word “harmonization” was in some way considered taboo in the SCP, the reality was that there were much more similarities than differences at the global level in relation to the inventive step requirement. However, the Delegation further noted that there were many cases where the assessment of inventive step yielded different results. Therefore, in the view of the Delegation, it would be interesting to investigate that issue through the assessment of the practical aspect once the theoretical part had been addressed in the study. In particular, the Delegation stated that it would be very interesting for the Member States in future sessions to exchange experiences between representatives of countries belonging to different regional groups, for example, five or six patent examiners, where real cases could be analyzed and the discussion on the various approaches as regards the assessment of inventive step could take place. The Delegation expressed its hope that the study on inventive step would be the first phase of a series of works related to the inventive step requirement within the Committee. The Delegation stated that the inventive step was closely related to the state of the art and in that sense, it would be appropriate to begin works in relation to the state of the art. In particular, the Delegation suggested the SCP to study the documents that were taken into account in assessing the condition of patentability, for example, prior art documents used to evaluate novelty and inventive step as well as disclosures that were excluded from the prior art during the so-called grace period. The Delegation stated that the comprehensive information on its legislation and evaluation of inventive step in the Spanish Patent and Trademark Office as well as related case law were available in the SCP electronic forum.

64. The Delegation of China thanked the Secretariat for the very clear study on inventive step and very good presentation on the topic. The Delegation stated that the evaluation of inventive step was a very crucial issue, hard to master. In particular, the Delegation considered that too loose application of the requirement would cause undue monopoly of technology, whereas too strict application of the requirement might undermine the enthusiasm of innovators. The Delegation noted that it was therefore necessary to establish the reasonable criterion in light of actual needs. The Delegation further stressed the need for countries to exchange experiences in that regard. In its view, in order to facilitate the exchanges and sharing of information, it was desirable to include in the agenda of quality the advancement of implementation projects featuring capacity building which would include building of platforms, improvement of personnel capacity, and enhancement of communication. For that reason, the Delegation suggested that Member States continue to exchange information on the content of capacity building of the patent offices which, for instance, could include patent databases, utilization of IT facilities such as patent search and examination tools, provision of technical assistance to developing countries, strengthened training and exchanges of search and examination staff, and construction of quality management and control systems in patent offices. The Delegation also recommended the Committee to collect and consolidate information on patent systems in the Member States, including the specific practices in inventiveness, and improve the readability and accessibility of the documents to help applicants improve their capacity on drafting patent applications and responding to office actions so as to improve the quality of patents in general. The Delegation expressed its belief that requirements for patent quality should be adapted to the economic and social development realities of countries, and should promote the economic and social development of countries. Given that countries had uneven development levels and encountered different problems, the Delegation considered that they should be allowed to have different understanding and interpretation of patent quality. In its opinion,

discussions on such issues as inventiveness should not be prompted to the harmonization of substantive patent law, neither should it lead to an automatic acceptance of examination results by other countries, nor should it prejudice the autonomy and flexibility of Member States to process patent applications and patents according to the applicable laws.

65. The Representative of ICC congratulated the Chair and stated that ICC represented small and large businesses in all sectors in over 130 countries. From its perspective as a broad-based membership organization representing not only intellectual property rights holders, but also third parties affected by others' intellectual property rights, ICC wished to share its observations on the inventive step criterion for the SCP's consideration. The Representative stated that inventive step or non-obviousness was one of the core criteria for patentability, together with novelty and industrial application. To fulfill that criterion, as demonstrated in the Secretariat's study and presentation, the invention must not have been obvious to a person skilled in the relevant technical field at the date of the patent application, taking into account the state of the art before that date. The Representative further noted that the use of criteria extraneous to those basic rules for the determination of inventive step would create uncertainty and lack of predictability both at the national and the international level, especially when patent applications were filed in several jurisdictions. The Representative continued that, for example, assessment of inventive step should not depend on subjective determinations of whether an invention is "radical", "incremental" or otherwise. Neither the legal requirements for inventive step nor any other basic criteria make any distinction between different levels of invention. Any claim should be judged against the same basic principle, namely "what would one ordinarily skilled in the specific field have done on the relevant day?". The Representative stated that, as another example, while the requirement of ordinary skill clearly depended on the specific field of technology, the principles of evaluation of inventive step should not be sector-dependent; the same basic rules should be applied irrespective of the field of the invention. The Representative stated that more information, including case studies illustrating those points, was contained in the ICC paper on the inventive step criterion available outside the room.

66. The Representative of the Eurasian Patent Organization (EAPO) congratulated the Chair on her election and thanked the Secretariat for the excellent preparation of the study on inventive step contained in document SCP/22/3. The Representative endorsed the proposal of the United States of America concerning the need to make information more accessible on the website, as well as the proposal by Spain, suggesting a study on practical application of the criterion based on cases, for example, cases regarding the patent applications belonging to the same patent family settled in various jurisdictions.

67. The Representative of TWN stated that inventive step was one of the three basic criteria for patentability and that a high threshold level of patentability criteria was important to prevent the abuse of patent monopoly. The Representative stated that patents should not serve as a tool to protect monopoly but serve its purpose, i.e., promoting R&D and technological advancement. Therefore, the inventive step tests and methodologies should focus on the technological advancement. The Representative continued that, over the years, the patent offices, especially in the industrialized countries, had brought down the patentability criteria, particularly the inventive step, to a lower level to increase the quantity of patents at the cost of quality of patents. The Representative stated that one of the important steps to curb the granting of patents with low threshold level patentability criteria was to increase the threshold level of the inventive step criterion. The Representative noted that under the TRIPS Agreement, there was enough flexibility to determine the threshold level of the inventive step. In its view, the first phase towards that end was to define and conceptualize the person skilled in the art as a person "highly skilled" in the art instead of "ordinary skilled" in the art. The Representative called upon the Member States to move away from a low level of inventive step threshold to a high level and stop patenting of trivial

inventions, for example, of known pharmaceutical substance. The Representative stated that the study on inventive step did not, unfortunately, deal with the flexibility available to Member States in determining the threshold level of inventive step requirement. Further, the study revealed that technological advancement was not the sole criterion for evaluating the inventive step. According to the observation of the Representative, some of the criteria on evaluating the level of inventiveness mentioned in the study clearly would result in low level of inventive step threshold. The Representative stated that, for instance, some patent offices recognized a particular commercial success as a criterion to satisfy the inventive step. In her view, that clearly showed that technological advancement was not the sole criteria for judging inventive step and would result in granting of patents on trivial inventions. Therefore, the Representative noted that it would be important to analyze the implications of various methods of evaluating inventive step and the level of inventive step on its potential to eliminate trivial inventions. Calling upon Member States to set a higher threshold level for assessing the inventive step, the Representative suggested that Member States should carry out an independent assessment of effectiveness of existing methods of assessing inventive step in preventing patenting of trivial inventions. She also called upon developing countries not to follow the existing methodologies of assessment of inventive step employed in developed countries as well as the Secretariat not to advocate such methodologies without carrying out the above assessment. The Representative further expressed her concerns on free trade agreements (FTAs) such as the Trans-Pacific Partnership Free Trade Agreement (TPP) which took away the policy space for setting a high threshold level for inventive step. According to her view, a high level inventive step often had the potential to save peoples' lives. In her opinion, patent offices could safeguard the public interest from the abuse of patent monopoly by denying patents on known substances: for example, a Hepatitis C medicine, sofosbuvir, was rejected in Egypt on the grounds of lack of inventiveness.

68. The Representative of MSF wished to echo most of the comments made by the Representative of TWN, especially in terms of encouraging developing countries to adopt high thresholds in evaluating inventive step criterion especially with regards to pharmaceuticals. The Representative also echoed the need and importance of assessing some of the proposed provisions under FTAs which might have harmful impact on public health. The Representative further expressed her hope that the Secretariat would continue providing precise facts, information and case laws, and at the same time leave sufficient flexibilities for countries to determinate their national law. In addition, she expected that the Secretariat would also look at some of the existing studies done by other UN agencies in focusing the discussion of inventiveness into a concrete context of the impact on public health and access to medicines. The Representative stated that, for instance, there were studies done in 2006 and 2007 by WHO and UNDP respectively, which had provided concrete recommendations to developing countries on how to adopt patentability criteria including those on inventive steps, to facilitate the public health needs. In her opinion, those learning should be captured by the Committee, which could provide concrete guidance for Member States to adopt criteria of inventiveness that could support the needs of public health. Finally, the Representative wished to make a comment on the methodology in the study related to the use of case law. She observed that, for instance, the first part of the study had cited a number of case laws mostly from jurisdictions of the United States of America and Europe, however, in the later part of the study, especially concerning the exemplary provisions, no further examples had been given. In her view, for instance, the reason of lack of inventiveness on claims merely presenting small improvement of known substance could be easily linked to some of the case law examples from India, where a number of rejections on pharmaceutical patents had been made, in particular, on the basis of reasoning that, in accordance with its national law, no invention should be patented merely because of changes of known substance without demonstrating unexpected outcome.

69. The Representative of JPAA recalled that the issue of inventive step had been discussed at the SCP during the discussion of the Draft Substantive Patent Law Treaty (SPLT). Therefore, JPAA fully supported the discussion of the issue at the SCP. From the view point of the Representative, since different levels and concepts of inventive step or obviousness between countries was not user friendly, JPAA would appreciate some kind of harmonization on the issue. In addition, the Representative stated that the study on the inventive step produced by the Secretariat as well as related discussions would contribute to the quality of patents.

70. The Representative of AIPPI congratulated the Chair on her election as well as the Secretariat for the preparation of the studies. The Representative stated that AIPPI was an association created more than one hundred years ago (in 1897) which had almost 9000 members representing more than 100 countries; its members came from private practice, industries, research organizations and academics. Among the countries, there were both developed and developing countries. The Representative noted that such diversity among the members and the countries enabled AIPPI to prepare various resolutions which represented a balanced position between industrialized countries and the developing countries. The Representative therefore considered that such diversity was important for the quality of its work. Further, the Representative stated that in the past, AIPPI had studied the very complex question of inventive step. The study by the Secretariat on that subject properly stressed that complexity not just in defining the person skilled in the art, but also, e.g., in the assessment of obviousness. The Representative stated that the AIPPI had adopted resolutions on the subject matter that it would send to the Secretariat.

- Study on sufficiency of disclosure

71. Discussions were based on document SCP/22/4.

72. The Secretariat presented the document.

73. The Delegation of Japan, speaking on behalf of Group B, thanked the Secretariat for preparing the study on the sufficiency of disclosure, contained in document SCP/22/3 and the informative presentation. The Delegation also thanked the Delegation of India for bringing that interesting item to the discussion at the SCP. The Delegation stated that the sufficiency of disclosure was one of the core requirements of patentability. The Delegation further stated that technical information related to an invention shall be disclosed in a patent application in a manner that it could be conducted by the person skilled in the art based on that information. The Delegation continued that the inventive step and the sufficiency of disclosure requirements dealt with two different but at the same time critical aspects of the patent system, which in total could justify the exclusive rights to the invention. Thus, proper understanding of those concepts could lead to a deeper understanding on the rationale of the patent system. Referring to the three elements of the sufficiency of disclosure, namely, (i) the enabling disclosure requirement; (ii) the support requirement; and (iii) the written description requirement, the Delegation noted that they defined the technical information that formed the fundamental basis of a patent document and provided a technical contribution to the society in return for the exclusive rights. The Delegation further stated that the evaluation of the enablement requirement could be a complex task for patented examiners in the process of substantive examination, in particular, in the area where it was difficult to know how to make and how to use the invention simply from the structure of the invention, such as biotechnology. Additionally, the Delegation stated that proper examination of the enablement requirement was a responsibility of examiners to the third parties, because the third parties would accept the exclusive right of the patentees in return for enough disclosure of technical information from which they could also benefit in their research and development activities. In its view, understanding how those requirements were evaluated was equivalent

to understanding how the quality of the technical information in the patent document was ensured. In that regard, it was very interesting to the Delegation to hear from experts how their offices actually evaluated the enabling disclosure requirement, as supplementary information to the study prepared by the Secretariat. In conclusion, the Delegation expressed its expectation that discussions based on the study including exchange of practices could pave the way to continuous technical discussion on the substantive law at the SCP.

74. The Delegation of Romania, speaking on behalf of the CEBS Group, thanked the Secretariat for a study on the sufficiency of disclosure and related presentation. The Delegation stated that, the discussions on the three elements, namely, the enabling disclosure requirement, the support requirement and the written description requirement, would enhance the Committee's understanding of the patent system and raise greater awareness on the benefit of harmonizing patent practices. The Delegation observed from the study that on some aspects, e.g., in relation to the substantive elements of the enabling disclosure and the support requirements, a great amount of similarities of the laws and office practices was observed, while on some other aspects, namely, the manner and order of drafting the description, differences from one country to another might be found. The Delegation expressed its belief that an exchange of views on those issues might provide interesting conclusions to be built upon at the later stage.

75. The Delegation of Chile thanked the Secretariat for the study on the sufficiency of disclosure. The Delegation stated that the sufficiency of disclosure allowed patent offices to put in the hands of society an important tool for the development of new inventions and created an environment to allow future innovation. According to the Chilean practice, the patent law established that any patent application should include a description of the invention which would fully and clearly disclose to the public what was to be protected and how to reproduce it. Thus, the Delegation continued, the patent system encouraged the disclosure and dissemination of technological information and access to the knowledge contained in patent applications. Therefore, the sufficient disclosure requirement implemented the principle that a patent must describe the technology sought to be patented and its application in practice in order to promote technological progress and development of technology, as a counterpart to the grant of the exclusive rights. The Delegation further stated that, accordingly, the disclosure made in the application must enable one skilled in the relevant art to reproduce the invention without any inventive effort of such a person of ordinary skill. It considered that the requirement should be evaluated on a case-by-case basis by a person skilled in the art, who must be able to understand what was described in the application as a whole. The Delegation noted that an application as a whole should be considered in evaluating the sufficiency of disclosure requirement, i.e., including the description, claims and drawings or figures, if any. In addition, the Delegation stated that the description should include "what was known" in order to create a context for the invention and placing it within the technical field to which the invention belonged. The Delegation further stated that the invention should be disclosed in a manner that it showed the technical problem that it resolved and all the characteristics that were necessary to define the invention as well as all the modalities included in the claims, since they would not cover those features that fell outside the technical characteristics disclosed in the description of the invention.

76. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States, thanked the Secretariat for the two studies being presented under the agenda item "Quality of Patents". The Delegation wished to reiterate its support for advancing work on quality of patents. Referring to document SCP/22/3, the Delegation stated that the study addressed core elements in the patent system, such as the definition of the person skilled in the art, and methodologies employed for evaluating an inventive step

and obviousness. The study contained input from a broad range of WIPO's membership. The Delegation emphasized the importance of further examining the inventive step concept as well as methodologies employed for evaluating that requirement in Member States according to the proposal made by the Delegation of Spain and endorsed by all other Member States of the European Union, contained in document SCP/19/5 Rev. Turning to document SCP/22/4 on sufficiency of disclosure, the Delegation noted that the study consisted of three parts, namely, the enabling disclosure requirement, the support requirement, and the written description requirement, looked forward to discussions on the topic. Regarding the other documents under that agenda item, the Delegation stated that a work program should be established in relation to quality of patents based on the proposals made by the Delegations of Canada and the United Kingdom (document SCP/17/8), by the Delegation of Denmark (document SCP/17/7), by the Delegation of the United States of America (document SPC/17/10), and by the Delegation of Spain, as endorsed by all other Member States of the European Union (SCP/19/5 Rev). The Delegation also remained in favor of launching a questionnaire containing the elements of all proposals made by the Delegations of Canada and the United Kingdom, Denmark and the United States of America. As regards opposition systems, the Delegation suggested a compilation of the models of opposition systems and other administrative revocation and invalidations mechanism in a non-exhaustive manner. On work sharing programs, the Delegation stated that a dedicated WIPO webpage for work sharing activities would improve awareness of existing initiatives and enable patent offices to collaborate more effectively. In its view, conferences on the margin of the SCP sessions would allow for the exchange of experiences on work sharing programs and explore ways to improve the usefulness of the programs to IP offices, users of the IP system and the general public. The Delegation noted that a study by the Secretariat on how different laws and practices limit the potential for work sharing and what voluntary measures that 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. The Delegation stated that, given the optional nature of such endeavors, any efforts to improve the quality and efficiency of the patent system should not be hindered.

77. The Delegation of Switzerland congratulated the Chair on her election and thanked the Secretariat for the excellent work on the study of sufficiency of disclosure and the presentation. In its opinion, the study provided comprehensive information and material on the subject for further considerations and discussions at the SCP. The Delegation stated that it had been emphasized several times that the disclosure of an invention along with inventive step belonged to the fundamental requirements for the grant of a patent. With respect to the substantive conditions of the enabling disclosure, as was demonstrated in the study, the Swiss practice was similar to that of other countries. The Delegation stated that, in Switzerland, the requirement for the enabling disclosure would be met when, at the time of the filing, the specification had disclosed the invention in a manner sufficiently clear and complete so that the person skilled in the art could carry it out without unreasonable effort, using common general knowledge and the literature cited in the application. The Delegation pointed out one particular feature of the Swiss practice. It stated that at the national level, Switzerland had a significant number of small innovators that applied for patents. The national patent system adopted a small inventor friendly approach which included various supporting measures, for example, applicants were not obliged to be represented by a patent attorney before the IP office. With respect to the disclosure requirements, all submitted documents at the time of the filing were considered. It was possible to disclose the invention not only in the description or in the drawing, but also in the claims. The Delegation stated that, in general, according to other legislations, the patent abstract served the sole purpose of providing the technical information, however, in its experience, an inexperienced applicant without competent representation by a patent attorney sometimes included part of the disclosure in the abstract. In Switzerland, such a deficiency did not lead to a non-compliance with the disclosure requirement, but it could be corrected during the

substantive examination. The Delegation stated that that was based on an understanding that the patent system should be available to everybody, despite an increasing complexity of the technology and protection requirements. It noted that such an approach had supported not only research intensive sectors but also SMEs and individual inventors in order to capture the whole spectrum of the societal innovation capacity.

78. The Delegation of the Republic of Korea thanked the Secretariat for the preparation of the studies on the sufficiency of disclosure and inventive step and the related presentations. The Delegation was of the view that the studies would help to improve the patent quality. The Delegation shared its recent efforts to increase the quality of patents. The Republic of Korea had been activity implementing multilateral and bilateral work sharing programs, including the Collaborative Search Program (CSP), PPH and PCT. The Delegation stated that the CSP was a pilot program with the office of the United States of America. The pilot program was based on the concept commonly known as CoBOA which stood for Collaboration Before Office Action. The Delegation informed the Committee that that program would be launched as of September 1, 2015. The offices of those two countries would conduct two independent searches and share the results before the first office action. The process would be combined with accelerated examination for the procedural efficiency and convenience of users. It would provide applicants with high quality search results, which would be consistent across the offices, in a timely manner. The Delegation was of the view that, under the CoBOA, applicants would be able to determine their next step in the patent prosecution with more certainty. Further, the Delegation referred to the PPH and stated that it was one of the most famous and widely used work sharing programs. The Delegation noted that, in the Republic of Korea, the registration rate and first action allowance rate for applications filed through the PPH program had been higher than those for ordinary patent applications. In addition, the delegation explained that the first office action pendency and completion pendency for patent examination had significantly reduced. The Delegation noted that KIPO was conducting an internal PPH study to analyze the formal PPH cases to enhance the quality of examination in the PPH framework. In addition, the Delegation stated that KIPO had proposed a collaborative process between the International Search Authorities (ISAs) and Receiving Offices (ROs) in the PCT system. Based on that proposal, the PCT Working Group had decided to revise the PCT rule to transmit earlier search results from ROs to ISAs. In addition, the Delegation stated that KIPO had been conducting other sharing programs, such as Joint Prior Art Search and Examination, with the offices of Japan and China, and the PCT Collaborative Search and Examination program with the offices of the United States of America and EPO. Based on the positive results of the previous work sharing programs, the Delegation expressed its belief that those programs had increased the efficiency of the patent system by reducing the duplicative work and improved quality of examination.

79. The Delegation of Belarus thanked the Secretariat for a very interesting study on the sufficiency of disclosure and the related presentation, prepared and presented in a professional manner. The Delegation stated that the study could serve as a good basis for further work. The Delegation agreed with views of other delegations that the issue of sufficiency of disclosure was very important for ensuring the quality of patents, and for ensuring a balance of interests in society. With regard to its national experience, the Delegation pointed out that under its legislation, the applicant must provide a written description of the invention disclosing it fully enough for its implementation. The examination guidelines provided methodology to be followed by examiners in the examination as regards the compliance with that requirement as well as examples in various fields of technology. The Delegation suggested that one of the possible options for future work on that topic could be a study of mechanisms preventing the grant of patents for inventions that did not meet the requirement of sufficiency of disclosure, including a study of objections filed on that basis during the opposition period.

80. The Delegation of India thanked the Member States for providing the information on the sufficiency of disclosure and the Secretariat for compiling that information in the document. The Delegation stated that India had formulated a multipronged strategy to develop an intellectual property regime in the country to promote creativity (Intellectual Property initiative to drive "Make in India"). In that regard, several measures had been taken to create a strong and vibrant IP regime in India, such as transparency, quality of issued patents, capacity building and certain concession to the small entities. The Delegation further stated that India firmly believed that the quality of patents was very important for the development of any patent system. It considered that the patent specification played a major role in the patent prosecution, opposition, revocation, infringement, technology transfer and public health. According to the Indian Patents Act, the applicant shall fully and particularly describe the invention and best method of performing the invention at the time of filing the application. The Delegation observed that the document covered many areas on the sufficiency of disclosure under the enabling disclosure, the support requirement, and the written description requirement. In that regard, the Delegation explained that the High Court of Mumbai in AIR1969Bom255, paragraph 14, had commented that insufficiency of description had had two branches: (i) the complete specification must describe an embodiment of the invention claimed in each of the claims and that the description must be sufficient to enable those in the industry concerned to carry it into effect "without their making further inventions"; and (ii) that the description must be fair, i.e., it must not be unnecessarily difficult to follow. The Delegation disagreed with disclosure of a single method of preparing a compound in the description as a support, where the application claimed substantial number of compounds. The Delegation further disagreed with the amendment to the specification after the filing date based on the further study in the laboratory or clinical trial results, because it was later acquired knowledge. The Delegation stated that, although the study focused on the fundamental issues of the different patent systems with respect to the sufficiency, it was still deficient in answering the problems of the correspondence of the claimed inventions and sufficiency of the description with respect to the Markush claims. Therefore, the Delegation proposed that a special study be prepared to survey problems of the Markush type of claims which was invariably found in most of the pharmaceutical and biotechnological patent applications. The Delegation explained that claims encompassing innumerable compounds using a single Markush formula hardly found support for those compounds in the description, posing several problems during examination. Particularly, the Delegation stated, a meaningful search for such claims could not be conducted for assessing novelty and inventive step, and it was difficult to assess the unity of invention. According to the experience of India, the reasons for the said study were: (i) the Markush claim was a platform for protecting multiple inventions in a single application and paving way to many further selection patent applications; (ii) most of the time, it was difficult for a person skilled in the art to reach the invention without undue burden; and (iii) the number of examples required, particularly in the context of broad Markush formulas, was yet a matter of debate. The Delegation noted that the questions to be asked were: (i) was there enabling disclosure provided for all the molecules claimed in the application?; (ii) were all the compounds prepared by the applicant before the date of filing?; (iii) could the skilled man prepare all compounds without undue burden?; and (iv) were all the compounds useful to the society? Reiterating the need for such study, the Delegation suggested that the Secretariat conduct a survey for ascertaining common sufficiency requirement for Markush claims among Member States before concluding discussions on the issues regarding sufficiency of disclosure. The Delegation expressed its hope that most of the Member States would agree with the Indian Delegation, as they might also be facing the similar problems in processing patent applications claimed in the Markush type of claims. The Delegation further underlined that the Markush claims should be supported by the enabling disclosure. In addition, the Delegation stated that one of its major concerns was to prevent the grant of patents to trivial inventions. In its opinion, the burden on the prosecution could be facilitated by introducing INN in the specification for known molecules filed as a modified

form. The Delegation reiterated its stand that further study on the mandatory disclosure of INN in the specification could facilitate quality of patents.

81. The Delegation of France noted that, in accordance with the French Intellectual Property Code, a patent application must disclose the invention in a manner sufficiently clear and complete for it to be performed by a person skilled in the art. The Delegation stated that the sufficiency of disclosure was evaluated in relation to a person skilled in the art. The person skilled in the art who acted as a reference for the evaluation of sufficiency of disclosure was the same person who was selected to assess inventive step. The latter should be able to carry out the invention with the aid of the description and the drawings that he could find in the patent application, and by virtue of his basic general knowledge. The Delegation further stated that insufficiency of disclosure was one of the grounds for nullity of a granted patent. As provided in the Intellectual Property Code, a patent shall be revoked by a decision of a court, if it did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The Delegation noted that, according to case law, disclosure was insufficient if it did not allow a person skilled in the state of the art to carry out the subject matter of the invention or to arrive at the expected result using his professional knowledge alone and by carrying out simple operations that did not involve excessive difficulty. However, the French jurisprudence recognized that when evaluating the sufficiency of disclosure, it was necessary to take into account not only essential technical information mentioned in the text of the patent application but also the secondary information which could be deduced therefrom and which a person skilled in the art could find himself when reading prior art documents.

82. The Delegation of the United States of America thanked the Secretariat for preparing the document on the sufficiency of disclosure, which provided an excellent overview of the similarities and differences of how offices evaluated whether the disclosure in a patent application was sufficient. The Delegation stated that the disclosure provided by the applicant was a fundamental part of the public's end of the bargain struck by the patent system, which required a full enabling disclosure of the claimed technology in exchange for the patentee receiving the exclusive rights conferred by a patent. The disclosure allowed the public to learn about the most recent technical developments and to freely use the technical teachings after the expiration of the patent. If an invention was not sufficiently disclosed, the public would not derive the benefits intended by the patent system. Further, the Delegation stated that if an invention was not sufficiently disclosed, under the law of the United States of America, a patent might not be granted. The two inquiries into whether an invention was sufficiently described and enabled were both codified in Section 112(a), Title 35, of the United States Code, which stated: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention." The Delegation explained that the purpose of the enablement requirement was to ensure that the specification sufficiently described an invention in such terms and details that one skilled in the art could make and use the claimed invention without having to carry out "undue" experimentation, and such that the invention was communicated to the interested public in a meaningful way. The Delegation noted that the written description requirement was a separate and distinct requirement from enablement requirement. In explaining the objective of the written description requirement, the Delegation quoted Chapter 2163(l) of the Manual of Patent Examining Procedure of the USPTO which stated that the "objective of that requirement was "to clearly convey the information that an applicant has invented the subject matter which is claimed. [...] Another objective is to put the public in possession of what the applicant claims as the invention." The Delegation further stated that, in its country, the sufficiency of both the written description and enablement was determined based on the

extensive body of case law. The Delegation stated that, for example, factors used to determine whether a claim was enabled were: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. The Delegation noted that none of those factors was determinative, but all were taken into account when such determination was made. The Delegation explained that the analysis of whether an application fulfilled the written description requirement called for a determination of the scope of each claim and an analysis of whether there was sufficient information in the specification to inform a skilled artisan that applicant had been in possession of the claimed invention as a whole at the time the application had been filed. Turning to document SCP/22/4 and its summary, the Delegation stated that those documents addressed some of the important questions that would arise when evaluating the requirements for enablement, claim support and written description. The Delegation continued by stating that the information provided in those documents was very useful to both offices and the users, and therefore it suggested making them even more useful and accessible to the public and to interested offices by providing them in an electronic format. In particular, the Delegation proposed that the Secretariat make available the information obtained for the studies on the WIPO website as a table, a spreadsheet, or other appropriate format, with links which would allow for easy access to the information relating to a country or patent office simply by selecting a few links. The information made available on that website could include the detailed requirements that applicants had to meet to provide an enabling disclosure, to provide sufficient support of the claims and to meet the written description requirement in the various offices. The Delegation further stated that the relevant information could be linked to the country or office name, and further links could be provided to statutes, examination guidelines, case law and other official documentation. Similarities and areas of divergence in the approaches taken by various offices in determining compliance with the requirements for a sufficient disclosure and for claim support should be highlighted.

83. The Delegation of Japan thanked the Secretariat for its extensive work in preparing the document regarding the sufficiency of disclosure. The Delegation informed the Committee about the enablement requirement as provided under the national law of Japan. In particular, the Delegation stated that for an invention of a product, the description should be stated so as to enable a person skilled in the art to use the product. In order to meet that requirement, the way of using the product should be concretely stated, except where the product could be used by a person skilled in the art without such explicit statement based on the statements of the description and drawings, as well as the common general knowledge as of the filing date. The Delegation explained that, for example, in the case of an invention of a chemical compound, it was necessary to state more than one specific use with technical significance, in order to show that the chemical compound concerned could be used. The Delegation further stated that the description of embodiments of the claimed invention should be stated in terms of examples if they were needed in order to explain the invention in such a way that a person skilled in the art could carry out the invention. In cases where it was possible to explain the invention so as to enable a person skilled in the art to carry out the invention based on the statements of the description and drawings, as well as the common general knowledge as of the filing date, no examples were necessary. The Delegation continued that, in the case of inventions in technical fields where it was generally difficult to infer how to make and use a product on the basis of its structure, for example, chemical compounds, normally, one or more representative examples which would enable a person skilled in the art to carry out the invention were necessary. The Delegation noted that, the reasons for refusal could not be overcome, even when the applicant submitted a certificate of experimental results after filing an application so as to make up for any deficiency. The Delegation further informed the Committee that the Japan Patent Office

(JPO) was in the process of revising its Patent Examination Guidelines. In particular, the point to be clarified in the revised Examination Guidelines was that the enablement requirement and the support requirement were different in their purposes and also in determination thereof and, moreover, that a violation of one of the two requirements did not mean a violation of the other. The Delegation stated that the purpose of the enablement requirement was to prevent a patent from being granted for an invention which could not be carried out by the person skilled in the art even when taking into consideration the statement in the description. The Delegation explained that, under the patent system, an exclusive right was given for an invention to a person who disclosed the invention as a compensation for the disclosure. What was determined was whether or not the claimed invention could be carried out by the person skilled in the art on the basis of the statement in the description. The Delegation stated that, on the other hand, the purpose of the support requirement was to prevent a patent right from being granted for an invention which was not made available to the public. Claiming an invention which was not stated in the description would incur granting a patent for an undisclosed invention. The Delegation stated that, to avoid such a consequence, it needed to be determined whether a claimed invention was supported by the description. Taking into account the above, the examiner shall determine whether or not the description and the claims would satisfy each requirement. Further, the Delegation provided examples of violation of support requirement. In particular, the Delegation stated that the first example was the case where the matter neither stated nor implied in the description was stated in the claim. The second example was the case where the content disclosed in the description could neither be expanded nor generalized to the scope of the claimed invention, even in light of the common general knowledge as of filing. The third example was the case where the solution for the problem to be solved by the invention was stated in the description, but not reflected in the claims, in which case a patent was being claimed beyond the scope stated in the description.

84. The Delegation of China thanked the Secretariat for the preparation of the study on the sufficiency of disclosure. In its view, the content of the document was very informative and detailed. Further, in relation to the national practice on the matter, the Delegation stated that according to Article 26.3 of the Patent Law of China, the description should set forth the invention or utility model in a manner sufficiency clear and complete so as to enable a person skilled in the relevant field of technology to carry it out. When necessary, drawings were required. The Guidelines for Patent Examination provided further details regarding the requirement. The Delegation stated that, although the study provided detailed information regarding the sufficiency of disclosure requirement, the Delegation was hoping that Member States could continue providing information or examples on the topic to facilitate a deep discussion and exchanges of views on the matter within the Committee.

85. The Delegation of the Russian Federation commended the work of the Secretariat on the preparation of document SCP/22/4 and presentation made on that document. The Delegation stated that the application of the criterion of the sufficiency of disclosure would increase the quality of patents. The Delegation noted that, however, the requirements related to the application should be sufficient and, at the same time, should not represent an insurmountable barrier for the applicant. Therefore, the question of what scope of the disclosure was necessary and sufficient was an important issue to provide the transfer of technology and to support innovative activities. The Delegation further informed the Committee that the requirement of the sufficiency of disclosure had been introduced in the legislation of the Russian Federation as a criterion for granting legal protection to inventions. The Delegation stated that to evaluate the compliance with the requirement of sufficiency of disclosure, all parts of the application, namely, the description, claims and drawings, if any, submitted on the date of filing, should be taken into account. Further, Article 1375 of the Code contained general provisions concerning the content of application documents: (a) the description must disclose the essence of the invention in sufficient detail for its

implementation by a person skilled in the art; and (b) the claim must clearly state the essence of the invention and be fully supported by the description. Drawings, according to the current legislation, formed part of the application documents necessary for the understanding of the essence of the invention. With regard to the formal requirements regarding the content of the application, the Delegation stated that such requirements complied with the requirements of the Patent Law Treaty.

86. The Delegation of India referred to other related documents under the agenda item “Quality of Patents, including Opposition Procedures”, in particular, documents SCP/17/7, 8 and 10, SCP/18/9, SCP/19/4 and SCP/20/11 Rev. In particular, the Delegation reiterated its views expressed in the previous session of the SCP and were of the view that the work sharing was not the remedy for improving the quality of patents and could not be considered to be a solution for addressing backlogs. The Delegation stated that, rather the work sharing could weaken the examination process and capability of patent offices in developing countries. Thus, in the opinion of the Delegation, steps should be taken to build capacity among patent offices of the developing countries for enabling them to perform their quasi-judicial functions, according to their national laws, in the best manner possible. The Delegation, therefore, expressed its belief that work sharing should not become an area for norm setting in future. Further, the Delegation expressed its appreciation to the Secretariat for the study on the sufficiency of disclosure, contained in document SCP/22/4, as well as its compliment to the Delegation of Japan for giving the credit to Indian Delegation for that study. However, in its opinion, the study might be further enhanced to investigate the role of the sufficiency requirement in the context of the transfer of technology as had been stated by the Delegation in its opening statement.

87. The Delegation of Ecuador thanked the Secretariat for the preparation and the presentation of document SCP/22/4. In Ecuador, the relevant provision was contained in the national legislation as well as in the regional legislation referred to as the Andean Community Decision No. 486 establishing the Common Industrial Property Regime (“Decision 486”). In particular, Article 28 of the Decision 486 stated that the description should disclose the invention in a manner sufficiently clear and complete to be understood and for a person skilled in the corresponding technical field to be able to execute it. The Delegation further stated that the description of an invention should state the title of the invention and include the following information: (i) the technological sector to which the invention relates or applies; (ii) the previous technology known to the applicant that may be useful for understanding and examining the invention, and references to earlier documents and publications relating to that technology; (iii) a description of the invention in terms enabling understanding of the technical problem and the solution provided by the invention, with an explanation of the differences and possible advantages in relation to the earlier technology; (iv) an account of the drawings, if any have been filed; (v) a description of the best method known to the applicant of executing the invention or putting it into practice, with the use of examples and references to the drawings, where applicable; and (vi) how the invention is susceptible of industrial application, if this is not clear from the description or the nature of the invention.

88. The Delegation of Nigeria thanked the Secretariat for producing two studies as decided at the previous session of the SCP. Noting the territorial nature of the patent system, the Delegation stated that the requirement of the inventive step and the sufficiency of disclosure requirement belonged to an area where Member States had sufficient space for making policies aligning with their development or national priorities. Regarding the proposals from some Member States on inventive step, the Delegation considered that the SCP should also look at the revocation of patents due to failing to meet that requirement. Further, the Delegation supported the statement made by the Delegation of India, and reiterated that the patent system was a *quid pro quo* system, meaning that the exclusive

rights were given in exchange of disclosure of information relating to a patented invention in a sufficiently clear manner to enable its implementation by the person skilled in the art. The Delegation further noted that an important aspect of the patent system was disclosure of teaching that led to transfer of technology. In addition, the Delegation stated that the issue of disclosure of the origin of genetic resources could play a role in the discussion on the sufficiency of disclosure.

89. The Representative of TWN stated that the disclosure was a fundamental justification for granting a patent monopoly: in other words, disclosure was part of the contract that society agreed for monopoly in return for the disclosure of the invention. The Representative noted that, in recognition of that principle, patent legislation of most WIPO Member States required such disclosure. Further, she stated that under many national patent laws, the sufficiency of disclosure was a ground for pre-grant and post-grant opposition. The Representative observed that while there was broad recognition of the disclosure requirement, its practical implementation was far from satisfactory. She noted that there were no clear guidelines for disclosure of invention in the specific areas of technology, and that there was a need to improve the disclosure standards so as to enable a person skilled in the art to replicate the invention. In that connection, she relied on Member States to develop detailed disclosure requirements in each technological field. In her view, patent disclosure standards could ensure implementation of high level of patentability criteria, especially inventive step and novelty. The Representative therefore considered that it would eliminate the chances of granting patents with trivial claims or so-called “evergreening patents”. Noting that disclosure of not only the claimed invention but also related information around the claimed invention was required in order to facilitate a proper examination of patents, the Representative referred to the discussion on INN. Further, the Representative stated that the study on the sufficiency of disclosure as well as the study on inventive step, unfortunately, focused mainly on the jurisprudence and practice in developed countries and did not provide information in relation to developing countries. For instance, she stated, the study ignored the issue of disclosure of geographical region of biomaterials in case of inventions related to biomaterials. In conclusion, the Representative called upon Member States to continue the work on the issue of sufficiency of disclosure and its link to patentability criteria and opposition systems.

90. The Representative of AIPPI, based on a proposal by the delegation of Spain, suggested that workshops or seminars on the inventive step and the sufficiency of disclosure requirements be organized. The Representative explained that such workshops or seminars would present the advantage of giving concrete examples applying the principles developed in two studies prepared by the Secretariat, and would be of benefit for the delegations showing them how those principles were applied in the daily practice. The Representative noted that AIPPI was ready to assist the Secretariat in the preparation of the said workshops or seminars, and could provide speakers.

- Related documents

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

92. The Delegation of Spain welcomed the studies undertaken by the Secretariat on two key aspects of substantive patent law such as inventive step and sufficiency of disclosure. The Delegation expressed its commitment to continue engaging in the discussions on crucial issues of substantive patent law. In the Delegation’s view, that was the main mandate of the Committee and was of importance to all Member States regardless of their level of development, since, as had been seen within the framework of the studies on inventive step and the sufficiency of disclosure, the correct application of the patentability requirements

allowed that patents were only granted to those inventions that deserved to be protected. In that regard and without prejudice of any further works on the issue of inventive step; especially with respect to analysis of practical cases by experts from the different regional groups as was proposed during the previous day of the session by the Delegation of Spain; the Delegation made a second proposal for a study of the state of the art. The Delegation noted that it understood the dynamics of the SCP and knew that it was difficult that a proposal was accepted straightaway after being presented, since Member States needed time to evaluate it. Nonetheless, the Delegation asked Member States to consider its proposal for the study of the state of the art for the future work of the Committee. The Delegation then presented its proposal for the study of the state of the art, including the so-called "grace period". The Delegation noted that ever since the sixteenth session of the SCP, the topic "Quality of Patents, including Opposition Systems" had remained on the agenda of the Committee and that the first proposal relating to that topic was submitted by the Delegations of Canada and the United Kingdom (SCP/16/5). The Delegation then expressed its intention to submit a proposal under the sub-item entitled "Process improvement" contained in document SCP/17/8, more specifically in paragraph 17 thereof and with the objective of being complementary to the work-stream on inventive step. The Delegation observed that in order to be able to assess novelty and inventive step, it was previously necessary to define the state of the art and that the definition of the state of the art was not homogeneous in all WIPO's Member States, due mainly but not only to the existence of the grace period. The Delegation explained that the grace period excluded from the state of the art some disclosures of the invention made during a period of time before the priority or filing date. The Delegation further noted that documents filed before the filing or priority date and published on or after that date were treated differently in the various Member States. In the Delegation's view, it would be desirable that all Member States could gain access to information about the different types of grace period, their advantages and disadvantages and about how the patent documents filed before the filing/priority date and published at a later stage were treated. Therefore, if a state was to carry out a legislative change, it could take into account the different options available. In order to improve knowledge concerning the grace period among the Member States, the Spanish Patent and Trademark office (OEPM) proposed that the Secretariat carry out a study, taking into account the information received from Member States, about the different elements that make up the state of the art and particularly, but not only, the grace period, among others: a) disclosures excluded from the state of the art (breach of confidence, experiments, disclosures by the inventor/applicant/ exhibitions); duration of the period (6 months, 12 months, or other duration); from when the period was calculated (priority date or filing date); whether a declaration should be required (consequences of non-compliance); up to what moment prior user rights could arise and under what conditions (up to the filing date or the date of disclosure, whether they could be derived from the applicant); and whether documents filed before the filing/priority date were published on that date or at a later stage and how they were taken into account for the assessment of novelty and/or inventive step.

93. The Delegation of Romania, speaking on behalf of the CEBS Group, stated that the CEBS Group was in favor of the launch of a questionnaire on the quality of patents based on the proposals made by the Delegations of Canada, United Kingdom, Denmark and the United States of America. The CEBS Group was of the view that a compilation of the answers would result in a useful document for all the delegations. With regard to work sharing programs, the Delegation believed that that topic deserved further consideration with a view to strengthening and facilitating international cooperation and obtaining high quality patents. The CEBS Group supported the proposal of a study to be prepared by the Secretariat on how different laws and practices limit the potential for work sharing. As an alternative, the CEBS Group would be interested in the elaboration of a handbook on best practices by the Secretariat together with IP offices involved in work sharing, which could

provide recommendations aimed at avoiding difficulties resulting from different laws and practices.

94. The Delegation of Japan, speaking on behalf of Group B, hoped that the studies and discussion of the session related to inventive step and the sufficiency of disclosure could form the basis for further work on that subject matter in future SCP sessions. In that regard, Group B proposed that the Secretariat further collect the relevant information on the practices of IP offices including guidelines or the like, and put them together with the studies and the information obtained in the session in a website in a manner that users and patent examiners across the world could easily access and obtain the relevant information, including information related to practices of offices as referred to by the Delegation of the United States of America in the context of the discussion on the studies. The Delegation also proposed that the Secretariat further provide the opportunity for Member States to submit inputs in response to the invitation to further update those studies. In order to evaluate inventive step and the sufficiency of disclosure, the Delegation noted that it was also critical to maintain up-to-date technical knowledge in the field in which a patent application was examined. In that context, the Delegation was of the view that the study by the Secretariat on professional education of patent experts at national IP offices to acquire and assure competency, scientific knowledge and required skills was also an item to be dealt with at the SCP. The Delegation reiterated that the proper understanding on the practice related to inventive step at other offices formed a basis of work sharing and collaboration because it had a strong connection with how the examination result of other offices could be used in an effective manner. In that regard, the Delegation suggested that the Committee take further steps towards the contribution to work sharing and collaboration based upon the enhanced understanding achieved at the twenty-second session. Group B expressed its belief that it was high time to proceed with the WIPO dedicated website to work sharing and collaborative activities and a conference in that regard as included in SCP/20/11 Rev. The Delegation noted that those initiatives could give continuity to the work of the Committee and would provide a tangible and fruitful outcome from which users and practitioners could benefit. As regards materials which could support aforementioned initiatives, Group B asked the Secretariat to conduct the following studies: first, a study on how the implementation of work sharing programs between patent offices could assist in conducting more efficient searches and examinations and in granting high quality of patents; and second, a study or survey on Member States' views concerning the sharing of examiners search strategies between offices. Turning to quality of patents in general, Group B remarked that the proposal by the United Kingdom, Canada and Denmark on a questionnaire included in document SCP/18/9 was still valid, and that the questionnaire could feed discussion on what the quality of patents was. The Delegation further stated that when the issue of quality of patents was discussed, the viewpoint of users of the system was essential, because they were the interested party directly impacted by the quality of patents both in cases where they enforced their patents and in cases where others' patents were enforced against them. Therefore, the Delegation suggested that a questionnaire should be submitted or a seminar should be held in order to obtain the direct inputs from users in that regard: for example, the users' view on what quality of patents was could be very useful for the future work of the Committee. Finally, the Delegation stressed that quality of patents had become more critical in the knowledge-based and innovation-oriented society, and that there was a trend that IP offices attached more importance in the quality management of the offices. Therefore, taking account of that trend, Group B proposed that WIPO create a webpage dedicated to quality management procedures including information from all Member States.

95. The Delegation of Chile noted that many elements related to the patent quality required national offices to have the necessary resources to carry them out. The Delegation considered that the support that WIPO could provide in that regard was very important. The

Delegation observed that during the two years prior to its designation as an ISA/IPEA office, the INAPI had developed an important plan to prepare its professionals. It had carried out an intensive training program of patent examiners in handling specialized databases as well as trainings on search strategies and the preparation of search reports and written opinions. In addition, the Delegation stated that INAPI had started to use the system WIPO Case, which was a very useful platform for the exchange of information on search and examination reports between local industrial property offices that served as a background for patentability analysis. The Delegation further noted that, because INAPI was quite aware that its work was relevant both for the applicant as well as for the other offices that used or consulted it, a quality control system to be able to provide optimal service was also implemented. Furthermore, with the purpose of demonstrating the quality of their operation and granting security to its users, the INAPI was also seeking ISO 9000/2008 certification for its processes. The Delegation thought that those elements were all aimed at improving patent quality both concerning procedures as well as substantive examination of patents. The Delegation considered that it would be an important contribution to the work of the Committee to have a study analyzing the implications of opposition systems in the quality of patents.

96. The Delegation of Portugal expressed its support to Spain's proposal related to a study on the prior art including the grace period. In the Delegation's view, that was very important because it would allow sharing information among Member States, thus providing a stronger knowledge and understanding of grace period and other issues related to prior art, which were, in the Delegation's opinion, very important to improve the level of legal certainty. The Delegation believed that that was also an important issue for the future work on quality of patents.

97. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States, referred to the statements it made on the previous day of the twenty-second session.

98. The Delegation of the United States of America believed that it was the appropriate time to deepen countries' understanding of other offices' practices including their willingness to engage in collaborative activities. The Delegation reminded that during the twentieth session of the SCP, the Delegation of the United States of America had proposed that the Secretariat dedicate a webpage on collaborative activities between patent offices. The purpose of that webpage would be to collect in one place information on work sharing and collaborative activities between patent offices so that both patent offices and users could educate themselves about the existing activities, and when desirable, take back better advantage of those programs (SCP/20/11 Rev.). The Delegation also recalled that during the twenty-first session of the SCP, the Delegation of the United States of America had proposed that the Secretariat conduct a study on when, how and under what circumstances 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. The Delegation asserted its interest in moving those work proposals forward, which they believed would be of interest to all Member States. In that context, the Delegation proposed some refinements in addition to the proposals that they had previously made regarding the topic of quality of patents. In relation to the quality management system (QMS), the Delegation proposed that the Secretariat provide a webpage on the WIPO website dedicated to quality management/assurance systems used by the offices of the Member States. The webpage would include descriptions of the QMSs, as provided by the Member States, with links to any statistics and data that the offices would be willing to share. The Delegation noted that international authorities under the PCT had exchanged information on QMS, which the Delegation felt had been useful. Thus, the Delegation thought that there could be valuable lessons learned from an exchange of experiences of all offices about their QMSs. With

regard to the sharing of examiners' search strategies, the Delegation explained that when performing automated searches of the prior art, examiners prepared a set of search queries to discover the most relevant prior art, and that the search terms and related logic used were generally preserved in the application file. The Delegation continued that when USPTO patent examiners were performing a search as a national office (Offices of Later Examination, OLE) having access to the search logic used by other offices that had already carried out the examination of related applications (Offices of Earlier Examination, OEE), the quality of the USPTO's work product was improved: for example, an examiner in an OLE could take advantage of the search strategy generated by an OEE to carry out its work more efficiently. The Delegation further noted that, alternatively, examiners might notice a gap in the search and deepen a search into areas not considered by earlier examiners. Thus, the Delegation proposed that the SCP conduct a study or survey of the views of Member States concerning sharing search strategies.

99. The Delegation of India reaffirmed its statement regarding other documents under quality of patents as made earlier in the session. The Delegation remarked that while the title of the agenda item was quality of patents including opposition systems, some of the member countries wanted to discuss work sharing, which was not compatible with that heading. The Delegation continued that a patent monopoly was granted to encourage the inventor with a larger public interest, and the private right should not affect the public right. The Delegation noted that to meet the international obligation, India had amended Section 25 of the Indian Patents Act by introducing pre-grant and post-grant opposition and that the mere filing of a patent application would not suffice to grant a patent, but should meet certain patentability criteria. The Delegation remarked that check and balances were provided in the Indian Patents Act to ensure the quality of patents, such as the opposition (pre-grant & post grant) and revocation systems. The Delegation explained that in the pre-grant system, any person (including the Government) could file opposition in writing along with evidence, to the Controller against the grant of a patent after publication till grant of the patent. The longer period provided to the public was to ensure the quality of the patent and prevent frivolous inventions. The Delegation further noted that if opposition was filed, the Controller would notify the details of the opposition to the applicant to allow him to submit his reply within three month time. After receiving the reply from the patent applicant, the Controller would effect a hearing with the material available, the documents filed, and based on that, the Controller would take a decision. The Delegation went on to say that in India's experience, when the product patent regime started in 2005, introduction of pre-grant opposition had paved the way to prevent frivolous product patents. As an example, the Delegation referred to the refusal in the pre-grant stage of anti-cancer drug imatinib mesylate 'Gleevec', where the invention had related to the modified form of known molecule which had been disclosed in an earlier patent application, while the patent had been granted in over 45 countries. In that case, the applicant claimed the salt form of a substance that had been known and the Indian patent office had refused the case for lack of novelty and inventive step and not being a patentable subject matter. The Delegation highlighted that the patent application had been opposed by pharma companies and NGOs working for the people with cancer. The patent office had refused the case after giving opportunities to all the parties and the Intellectual Property Appellate Board (IPAB) and the Supreme Court of India had upheld the decision of the Controller. The Delegation said that quality of patents should not be searched from the name of the company, country or product, but it should be interpreted according to the national provisions in light of the larger public interest. With regard to the post-grant opposition in India, the Delegation stated that any interested person could submit notice of opposition before the expiry of a period of one year from the date of publication of grant of the patent. According to Section 2(1)(t) of the Act, a "person interested" included a person engaged in, or promoting research in the same field as that to which the invention relates. In response to the notice of opposition, the patentee would submit a reply statement and evidence to the opponent and Controller for which the

opponent would submit reply and evidence to the Controller. Then, the opposition board, comprising three members appointed by the Controller, would examine and submit recommendations based on merit and after offering opportunities to all the parties. The Delegation pointed out that during the prosecution of the post-grant opposition, many pharma companies had opposed the *locus standi* of the NGOs working for the people living with diseases such as cancer and HIV for opposing the patent, since only the person working in the field doing research or doing business was allowed. However, the Controller had allowed NGOs in the post-grant opposition. By interpreting the open-end phrase “person including” and referring to the High Court of Delhi in AIR 1983 DELHI 496, the court held: “In our opinion, a ‘person interested’ within the meaning of Section 64 must be a person who has a direct, present and tangible commercial interest or public interest which is injured or affected by the continuance of the patent on the register.” The Delegation continued that in the appeal for the same case, the IPAB had upheld the decision of the Controller by saying that: “The continuance of an unworthy patent on the Register is not only against the interest of other persons carrying on the same business but also against the public interest. For the protection of valid patents, we have no doubt to prevent the busybodies and unnecessary interferences. But, it is as much against the public interest to allow unworthy patents to be on the Register, as it is to prevent third parties having no interest from attacking a deserving patent. While liberally construing the words ‘person interested’, we could balance the cause of justice by awarding exemplary costs against an opponent who really has no interest in the grant of patent. The interest should not be a fanciful interest.” The Delegation remarked that there were many trivial inventions refused in India in the post-grant stage and expressed its belief that a robust opposition system would not only improve the quality of patents but would also respond to public health interests. With regard to the sharing of priority documents, the Delegation stated that that could be allowed since that would not only save time, but would also improve the quality of the patent; however, the decision taken by other patent offices should not affect the Controller’s decision of the case. Finally, the Delegation proposed to further study pre-grant/post-grant oppositions and revocation of patents in greater detail to improve the quality of patent and for further discussion.

100. The Delegation of Brazil, speaking on behalf of GRULAC, reiterated that any new proposals should be submitted in writing so that the ideas proposed could be considered within the group. The Delegation stressed the importance of receiving those proposals, as well as refinements and additions to proposals, so that Member States could evaluate whether they were feasible or adequate for discussion in the Committee.

101. The Delegation of the Russian Federation reaffirmed its support to the proposals made by a number of delegations on the preparation of additional studies on the issue of quality of patents. The Delegation observed that the objective was to come up with general recommendations on that issue as well as the publication of a report. The Delegation endorsed the proposal to establish a database of national practices based on those reports that would be accessible to other patent offices, since that would offer the possibility of using the positive results of the studies and would allow to move forward significantly in dividing up the work among patent offices by using the information results available from patent offices. The Delegation stated the importance of quality of patents for the Russian Federation and remained committed to continuing discussions on that issue at the Committee. In the Delegation’s view, moving forward the study proposed by the Delegation of Spain, for example, was relevant to the Committee. The Delegation pointed out that the Russian Federation had provided information relatively late regarding the evaluation of the inventive step but that that information would be available to all participants. In conclusion, the Delegation considered that the exchange of information about the joint work of patent offices was something useful and they would support efforts in that direction.

102. The Delegation of the United States of America, in response to the Delegation of Brazil, stated that it planned to include the proposals made verbally in the written submission that was going to be prepared by Group B and presented to the Secretariat later that day.

103. The Delegation of Spain thanked the delegations who had come in to support its suggestion for future work. The Delegation considered that the request made by the Delegation of Brazil was reasonable, and stated that it would send the Secretariat its proposal with a translation into English.

104. The Representative of the EAPO, in relation to the experience of various Asian Patent Offices, noted that more than 80% of the applications were filed via the PCT and that international search and examination reports had been utilized. The Representative said that, in addition, to cover prior art more broadly, national offices tended to look at the results of search and examination conducted by the offices of the United States of America, Japan, the EPO and other national/regional patent offices; and whether the results were in line with the Eurasian standards according to the applicable national law would be checked by national examiners. In the Representative's view, the use of the results of the search and examination of other offices should not be something obligatory for examiners. However, as practice had shown, information on prior art as established by various offices had always had a positive effect on the quality of patents and on assessing the validity of patents in case of disputes. Considering that a broadest exposure to prior art had an impact on the quality of patents, the Representative supported any initiative within the framework of the Committee aimed at ensuring expanding access to the state of the art and cooperation between patent offices to that end.

105. The Representative of TWN acknowledged that the opposition system was an important mechanism to ensure the grant of patents to genuine inventions and that a robust pre-grant opposition could increase the quality of patent examination and act as a deterrent against the filing of patents on trivial inventions. In the Representative's view, most care should be taken before granting a patent monopoly that might trigger critical public concerns, and thus, the availability of an effective opposition system was very important. From an operational angle, the Representative noted that patent opposition systems provided a public scrutiny of patent applications and complemented scrutiny of patent applications by patent examiners, which had often suffered from limited financial and human resources. The Representative observed that within the last ten years, in India the generic versions of many lifesaving drugs had been able to be introduced into the market thanks to the pre-grant opposition: for instance, the pre-grant opposition system triggered the rejection in India of one of the patents on hepatitis medicine. Therefore, TWN suggested that the SCP study the opposition systems in the different Member States. The Representative also expressed its concern on the proposals on work sharing. She stated that the work sharing arrangements would bring functional harmonization of patent law and would compromise the flexibility related to patentability criteria. Therefore, TWN appealed to Member States not to proceed on work sharing. She continued that as far as the existing work sharing arrangements were concerned, there were plurilateral and bilateral arrangements on that issue and therefore, it should not be discussed or mainstreamed in a multilateral forum such as the SCP or WIPO. In her view, even providing information on PPH on the WIPO's website went against the spirit of multilateralism. Thus, TWN agreed with the view that work sharing did not fall under that agenda item. Finally, TWN called on Member States to engage in discussion to reach consensus on the meaning of the term "quality of patents". The Representative noted that there was no clarity regarding the meaning of the word "quality". She further noted that if quality of patents meant that the invention met the patentability criteria mentioned in the domestic legislation, then proposals on work sharing were contrary to the idea of quality of patents. She concluded that in the absence of a shared understanding of the word "quality", it was extremely difficult to discuss issues under that agenda item on quality of patents.

106. The Delegation of Iran (Islamic Republic of) thanked those delegations which had presented proposals on the issue of quality of patents and their related issues. The Delegation believed that in the framework of the SCP, any exchange of information would be beneficial to all Member States. Thus, the Delegation took note of those proposals, but it pointed out that as many delegations had expressed in the previous sessions and also in the current session, the Committee had not yet arrived at a common ground regarding the term “patent quality”. Therefore, the Delegation believed that a precise definition of that concept was a prerequisite for further discussions in the SCP on that issue and for deepening discussions on a detailed work program. The Delegation stated that it was important to continue discussions to come up with a definition commonly agreed to all. The Delegation believed that any work on patent quality should take into account the following elements: first, different nature and different role of patent systems in Member States as well as different levels of development in IP offices; second, the need for capacity building and training programs for IP offices; and third, any discussion on patent quality should take into account the relevant Development Agenda recommendations with the objective of strengthening patent offices in granting high quality patents based on the national law. Furthermore, the Delegation remarked that that process should be voluntary and be guided by Member States and not aimed at harmonizing patent laws. Any work on patent quality should ensure compliance with the requirements of patentability, including sufficiency of disclosure of inventions. The Delegation reiterated that any future work on quality of patents should not lead to harmonization of substantive patent law. The Delegation expressed its opposition to the idea of harmonization with regard to the quality of patents, be it on the basis of patentability requirements or on any other issue having to do with substantive patent law. The Delegation believed that every Member State could qualify its national patent law on the basis of its requirements and on the basis of its development concerns. The Delegation also supported further discussion on opposition systems and preparing a compilation of models on the opposition and revocation systems. Therefore, it supported the idea of preparing a study on opposition systems. Regarding work sharing and PPH, the Delegation agreed with the statement made by the Delegation of India that work sharing or PPH was not a remedy for patent quality. The Delegation stated its opposition to discussing the PPH in the SCP for the same reasons it had mentioned with regard to the quality of patents. In the Delegation’s view, PPH should take into account the diversity of the legal framework and the resources of patent offices in developed and developing countries. Further, work sharing and PPH could not lead to undermining the autonomy of national offices to conduct a comprehensive search and examination. The Delegation believed that there were a lot of legal ambiguities about PPH, as had been raised by many delegations at the sessions of the PCT Working Group, and thus, the Delegation could not go along with any idea about work sharing and PPH in the SCP or PCT.

107. The Representative of Innovation Insights noted that quality of patents was a critical topic for the Committee. In her view, quality simply meant that a patent deserved to be granted according to the law of a given jurisdiction. She said that there were good reasons for stakeholders not to want patents that did not deserve to be granted. Thus, the Representative suggested that a discussion of the definition of quality of patents take place so that the SCP could work on that important issue. With regard to work sharing, the Representative was of the view that work sharing meant taking into consideration the work already done by another office in one’s analysis under one’s own laws, in other words, it allowed looking at the search done by someone else in order to enhance his own decision making process and use the other office’s work only as a tool or input. Therefore, the Representative considered that work sharing was a way to enhance work quality, because it brought additional prior art to the attention of examiners.

(II) EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

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

109. The Delegation of Brazil, speaking on behalf of GRULAC, stated that its group attached great importance to the exceptions and limitations on patent rights. As a result of the discussions held in the previous session, the Delegation 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 proposed to develop a non-exhaustive manual on the topic as a reference to the Member States of WIPO.

110. The Delegation of Brazil, speaking on its national capacity, recalled that its proposal contained in document SCP/14/7 had been submitted in 2010, during the fourteenth session of the Committee. It considered that, five years down the road, the circumstances that motivated it had not changed, and adopting measures in that area was as necessary at present as it was back then. The Delegation stressed that the main goal of the IP system was to improve the well-being of all societies and, in particular, to provide the means for those in need of development. The Delegation continued that, for those results to be achieved, the protection and enforcement of IP rights needed to have, as a beacon to guide its operation, the objective set in Article 7 of the TRIPS Agreement, namely, to 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. In its view, that included measures to help countries to use in an effective way the flexibilities that were an integral part of the system. The Delegation stated that its proposal had demonstrated that, even though exceptions and limitations had been included in the multilateral set of rules, especially the TRIPS Agreement, the operation of the system had tilted towards enforcement, affecting the needed balance mentioned in Article 7 of the TRIPS Agreement. The Delegation further noted that more recently, those broad objectives had been reaffirmed when the Development Agenda was adopted. In recommendations 17 and 22 of the Development Agenda, it was decided that WIPO should take into account, in its activities, the flexibilities in international IP agreements and to address in its working documents for norm-setting activities issues such as potential flexibilities and exceptions and limitations for Member States. The Delegation noted that, as many others, those were recommendations that could not be just written-off once a project was implemented. Instead, the Delegation stated, they should also be used to guide work of the Committee and that applied to its proposal. Further, the Delegation acknowledged the progress which had been achieved since the proposal had been tabled. It acknowledged that most of the Member States had responded to a questionnaire on their national legislation and on the use of exceptions and limitations to patent rights. Based on the data obtained, the Secretariat had prepared a document for the focused discussion on nine clusters, which bore important fruits in terms of information gathering. Finally, a productive seminar had been held to debate all the aspects involved with that issue. The Delegation further stressed that it was time to implement the third phase of its proposal, which was the elaboration of an exceptions and limitations manual, to be used as a non-exhaustive reference for all members when crafting their national legislation and on the best way to use it. The Delegation stated that any of one-size-fits-all-type of advice or assistance that could be provided by WIPO would be counterproductive in the real life scenario of countries with different backgrounds and levels of development. Therefore, that manual was not supposed to be red, in any way, like the instructions handbooks. The Delegation continued that the name "manual" should be seen in a broader way, since it merely aimed at providing information about the series of flexibilities that were available for countries to adopt in order to use the policy space provided under the multilateral framework. While some would use them more than others, the Delegation observed that the important

thing was that WIPO would help making that set of flexibilities known to all policy makers through the creation of a manual. In conclusion, the Delegation reiterated that the Committee had gone a long way since its proposal had been tabled, and expressed its hope that the Committee could succeed in taking the final step for the benefit of all the membership.

111. The Delegation of Argentina expressed its support for the proposal made by the Delegation of Brazil on exceptions and limitations to the rights, and in particular to the commencement of the third phase of that work program by drawing up the referred manual. The Delegation emphasized the need for having a balanced patent system and that countries should be able to adapt their national legislation in line with their development strategies.

112. The Delegation of Nigeria, speaking on behalf of the African Group, reiterated its support to the proposal made by the Delegation of Brazil regarding exceptions and limitations to the rights. In particular, the Delegation supported the commencement of the third phase of that proposal. Echoing its statements made at the previous sessions of the SCP on that agenda item, the Delegation stated that exceptions and limitations to the rights was a fundamental for developing countries to achieve their development priorities.

113. The Delegation of Japan, speaking on behalf of Group B, stated that while recognizing the importance of the exceptions and limitations applied to very limited circumstances, it was concerned that exceptions and limitations sometimes regarded as a tool for development in themselves. The Delegation stated that exceptions and limitations could actually achieve its original purpose in an appropriate manner only in conjunction with an effective patent protection. The Delegation stressed that that aspect should be kept in mind when dealing with the subject matter. The Delegation stated that enormous amount of work in that area had been done by WIPO, including the SCP. In its view, the Committee had produced a great number of valuable reference materials that could be used by Member States in considering amendments to domestic legislations under the specific circumstances of each Member State. The Delegation expressed its belief that it was a time for reflection rather than adding new materials. In its opinion, if Member States were interested in any provisions of other members found in the documents prepared by WIPO, they could ask the latter countries the reason behind those provisions and how they were responding to the specific circumstances. The Delegation considered that that could deepen the understanding on those provisions in a comprehensive manner in the holistic context of patent protection.

114. The Delegation of Romania, speaking on behalf of the CEBS Group, expressed its view that a significant amount of time and resources had been dedicated to date to the topic of exceptions and limitations to patent rights, which had clearly contributed to a better reflection of some countries' concerns. At the same time, the Delegation considered that a deeper understanding of those issues and of their application in the specific circumstances was only possible if they were addressed, in a holistic manner, together with other topics essential to the patent system. It stressed the need of making comparable progresses on the issues such as the criteria of patentability, i.e., novelty, inventive step, and industrial applicability.

115. The Delegation of Chile stressed the importance of continuous development of the issues on the exceptions and limitations, since they were an essential part of the patent system. The Delegation observed that the Committee had already taken significant steps in materializing the relevant recommendations under the Development Agenda, through gathering information on laws, practices, policy objectives and implementation challenges. The Delegation noted that, for example, it had gathered information from the studies carried

out by the SCP in order to draft the provisions concerning exceptions and limitations in the draft law submitted to the Chilean Congress. The Delegation reiterated its support to the proposal made by the Delegation of Brazil, i.e., drawing up an exceptions and limitations manual. The Delegation expressed its strong interest in continuing work on the topic of exceptions and imitations and implementing the third stage of the proposal by Brazil.

116. The Delegation of Iran (Islamic Republic of) attached great importance to exceptions and limitations to patent rights that provided flexibilities in the IP system which recognized the needs to adapt national legislations on patents based on their respective economic and social situations, and the importance of exceptions and limitations for countries wishing to develop their own system. The Delegation considered that it was crucial for Member States to determine the exceptions and limitations that were in line with their own circumstances to allow the highest levels of economic development to be achieved, while respecting their treaty obligations. The Delegation supported the proposal made by Brazil at the fourteenth session of the SCP, which had suggested a three-phase work programme on exceptions and limitations in the SCP. The Delegation recalled that at its fifteenth session, the SCP had agreed to request the Secretariat to prepare a draft questionnaire on exclusions and limitations to patent rights. In its opinion, the questionnaire was in line with the aim of Phase I of the work plan proposed by Brazil, aimed at promoting the exchange of information among members for discussion and analysis in the SCP. The Delegation noted that the mandate which had been given to the Secretariat in preparing those studies was “based on input received from Member States” and “without evaluating the effectiveness of the exceptions and limitations”. Therefore, the Delegation considered that it was time for the SCP to consider undertaking the work proposed under Phase II of the proposal by Brazil, namely, to undertake an analysis of how those various exceptions and limitations were utilized by different countries in addressing various public policy objectives, particularly public health, food security etc.

117. The Delegation of India reaffirmed its firm support to the work program as proposed by the Delegation of Brazil, as contained in documents SCP/14/7 and SCP/19/6. The Delegation reiterated that the studies regarding exceptions and limitations were extremely important from the perspective of accessibility and affordability of medicines and also for socio-economic growth and development in the developing countries and least developed countries. The Delegation recalled that during the 18th session of the SCP, it had recorded its full support to the Brazilian proposal, especially with respect to its second phase where an analysis would be carried out on the exceptions and limitations as to their effectiveness in addressing development concerns, which was an essential part of the entire proposal. The Delegation stated that during the 19th session, it had further suggested that the study might focus upon the use of some exceptions, such as compulsory licensing, parallel imports, government uses, Bolar exception, etc., which were extremely important from the perspective of the accessibility and affordability of medicines. Further, the Delegation noted that in the 20th session, it had reaffirmed its firm support to the work program as proposed by Brazil in document SCP/19/6 on the exceptions and limitations, and had also shared its opinion that there had been a need to study the various impediments in licensing agreements relating to the transfer of technology in greater details so that appropriate steps could be taken to address that aspect. At that session, the Delegation had also stated that the mere compilation of data from different countries would not serve the purpose of extracting the specific exceptions and limitations, which had been important from the development concerns *vis-à-vis* the patent system. In its view, a thorough study based upon the questions of the use of the patent system for fulfilling the need of developing countries was extremely essential from the perspective of socio-economic growth. During the 21st session, the Delegation of India had appreciated the efforts of the Secretariat in compiling data from different countries regarding public policy objectives for providing the exceptions, the applicable laws and the scope of the exceptions, and implementation challenges in

documents SCP/21/3 to 6. However, it had been emphasized by the Delegation that those had been preliminary studies, which would not serve the purpose of extracting the specific exceptions and limitations. Thus, the Delegation had stated that it would have been more useful to describe the impact of those exceptions and limitations on the socio-economic development of those countries. The Delegation reaffirmed that stands and held the same views. The Delegation therefore expressed its belief that there should be a thorough study based upon the questions of the use of patent systems for the fulfillment of needs of developing countries and LDCs from the perspective of accessibility and affordability of medicines and the socio-economic growth and development.

118. The Delegation of China considered that exceptions and limitations were an important legal rule that reflected the balance between the right holders and the general public. Noting that on the basis of the questionnaire, the Secretariat had already compiled the collected information in a number of documents, the Delegation was of the view that such compilation could serve as a good basis for countries to further explore the issues. In order to carry out further work in that area, the Delegation supported the proposal by Brazil. It also suggested that Member States share their cases so that they could learn from each other's experiences and improve their work.

119. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States, expressed its belief that although limited and specific limitations and exceptions were justified, the evaluation of the impact of exception and limitations on development by the Secretariat and the preparation of a manual under the name of WIPO were not the right ways forward. The Delegation stated that exceptions and limitations to patent rights maintained an appropriate balance between the interest of right holders and the general public. Therefore, in its view, neither exclusions from patentability nor exceptions and limitations to patent rights should be discussed without any considerations on the corresponding legal standards used to determine whether an invention was patentable, such as novelty, inventive step and industrial applicability.

120. The Delegation of Pakistan strongly supported the work program proposed by the Delegation of Brazil. The Delegation stated that WIPO played a critical role in assisting Member States to use exceptions and limitations for realization of the right to health, both in developed and developing countries. In its view, exceptions and limitations allowed governments the policy space to ensure affordable medicines.

121. The Delegation of Peru congratulated the Chair for her election. The Delegation supported continuing work on exceptions and limitations, and stressed the need to conduct a concrete analysis of the issues and to move on to the next stage of the Brazilian proposal. The Delegation stated that it respected and advocated appropriate protection for intellectual property, especially patents, and noted that it was interested in sharing Member States' cases, such as the cases of compulsory licensing.

122. The Delegation of Belarus expressed its support for the proposal made by the Delegation of Brazil.

123. The Representative of TWN expressed her concern on the efforts of developed countries to limit a policy space with regard to exceptions and limitations to IP rights in general and patents in particular. The Representative was of the view that developed countries had been using free trade agreements to limit the policy space in developing countries for determining limitations and exceptions. According to the Representative, the leaked text of the Trans-Pacific Partnership (TPP) showed the proposals to prevent countries from rejecting patents on the grounds of lack of enhance efficacy, made it obligatory to grant patents on new use of known medicines, and contained provisions for

patent term extension. She stated that, of late, pharmaceutical transnational corporations used the bilateral investment treaty (BIT) to seek compensation against the rejection of their patents in Canada. In her opinion, such use of BITs was against the use of public interest exceptions and limitations, and might bring a chilling effect which had the potential to prevent other countries from take such steps. The Representative further noted that developed countries were using the political pressure to prevent developing countries from using those flexibilities, for example, use of the Special 301 report was a case in point. In that regards, the Representative referred to the recommendation of the Human Rights Council's social forum on access to medicines, i.e., the TRIPS flexibilities should be used to their fullest and resort to political pressure to undermine those tools or impose TRIPS plus provisions in trade agreements must be regarded as a violation of human rights, calling for accountability in the universal periodic review; the legally binding petitions procedure under the Optional Protocol to the Convention on economic, Social and Cultural Rights provided a means for interpretation and enforcement of the right to health. The Representative therefore called all Member States to respect the human rights obligation and access to medicines and the right to use the benefits of science and its applications, and desist from using pressure to prevent other countries from using the TRIPS flexibilities. Against that background, the Representative considered that it was of most importance for the SCP to carry out a robust work program on limitations and exceptions. The Representative was of the view that both Phase 2 and Phase 3 of the proposal by Brazil were important to have a good understanding as well as improving the actual use of exceptions and limitations. The Representative further stressed the importance of approving the work program contained in document SCP/19/6, i.e., to assess what exceptions and limitations were effective to address development concerns and what were the conditions for their implementation.

(II) PATENTS AND HEALTH

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

125. The Delegation of Nigeria, speaking on behalf of the African Group, stated that the topics and ideas referenced in the proposal submitted by the African Group in 2011 remained relevant to help developing countries make use of the flexibilities and the international patent system. It considered that those aims were also in alignment with international commitments to seek solutions to global health challenges. Taking into consideration the development since 2011 and current realities and advancement in that field, the Delegation stated that the African Group would update its proposal at the next session of the SCP, and would also introduce a program of work for the Committee under the agenda item, patents and health. The Delegation clarified that that was without prejudice to any proposals existing or that might be made by other Member States at the present meeting.

126. The Delegation of Japan, speaking on behalf of Group B reiterated that both innovation and access aspects were equally important for patents and health, while patents were more strongly linked with the innovation aspect. Looking at the whole picture of the development in the field of pharmaceuticals, the delegation considered that it was obvious that incentives given by patent protection were critical for R&D as a whole and even for R&D for pharmaceutical compounds having very small market. In its view, the most dangerous thing in that technical field was talking only about one specific part without keeping in mind the whole context. The Delegation further noted that it had to be kept in mind that various elements were related to the access aspect of medicines, and that aspect could not be properly discussed without taking account of such various elements other than patents. The Delegation reiterated that work sharing could make sense in that technical field because of more divergence of information accessible by different offices. In that context, the

Delegation reiterated that a study by the Secretariat focusing on the differences of available information and how to overcome those differences in that field through work sharing was also a way forward, taking into account the expertise of the Committee.

127. The Delegation of Romania, speaking on behalf of the CEBS Group, stated that the approach to the connection between the two issues, i.e., patents and health, should be balanced, taking into account the interests of patent right holders as well as users, and should avoid duplication with the work conducted by other organizations such as the WHO and WTO. In terms of substance, the Delegation supported further consideration of the proposal submitted by the Delegation of the United States of America at the 17th session of the SCP (document SCP/17/11).

128. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States reiterated its understanding of the challenges and the constraints certain countries might face in handling public health problems. The Delegation stated that the mere existence of IPRs on a product was not a barrier to, nor their absence a guarantee of, access to that product. The Delegation expressed its belief that any further work in the area of patents and health should reflect a balance, taking into account the various interfaces with reference to patents and health. It stated that future work in that area could build upon the proposal made by the United States of America (document SCP/17/11).

129. The Delegation of Brazil, speaking on behalf of GRULAC, stated that the topic of patents and health had been identified as a priority issue for its group. The Delegation therefore noted that its group was eager to continue the work on that topic.

130. The Delegation of Iran (Islamic Republic of) expressed its support for the joint proposal of the Development Agenda Group (DAG) and the African Group (document SCP/16/7). The Delegation considered that as a specialized agency of the United Nations, WIPO had the mandate to address the topic of patents and public health. In its view, the proposal submitted by the African Group and the DAG was in line with such mandate, and would not constitute duplication with any other processes within or outside of WIPO. The Delegation stated that any kind of study on the subject should not be one-sided, focusing only on the positive or negative role of the patent system. The Delegation was of the view that, following the outcome of the studies and information exchange, Member States should be in a position to fully utilize the flexibilities accorded to them under the international agreements. It stated that WIPO should give advice to the Member States, on the basis of those findings, in order to make appropriate revisions in their national laws to enjoy those flexibilities. The Delegation reiterated that the issue of public health and patents and having access to medicines at an affordable price were important issues for developing countries. The Delegation therefore considered that the SCP should explore practical ways to respond to existing challenges, including the use of flexibilities available under the international agreements. The Delegation further noted that any work program on health and patents should be balanced and based on a long-term approach. In its opinion, the work program of the SCP should also provide the possibility of analyzing potential impediments and obstacles created by the system in accessing medicines, such as legal and structural impediments and capacity constraints facing developing countries and LDCs in making full use of the flexibilities and how those constraints can be removed. On the issue of the inter-relation between patents and the right to health, the Delegation was of the view that WIPO's cooperation and contribution to the work of the WHO on the issue of patents and health should be reported to and discussed by the SCP. It considered that WIPO should represent the consensus view of its Member States in providing advice to the WHO, particularly in the course of the norm-setting process.

131. The Delegation of China stated that the patent system should be in line with promotion of innovation that took care of the public interest, including the people's access to medicines. The Delegation welcomed the continuation of exchange of opinions on the issue of patents and health so that national legislations could utilize the flexibilities available in the international patent system.

132. The Representative of JIPA noted that his statements was made in conjunction with the Japan Pharmaceutical Manufacturers Association (JPMA), comprising 72 research-oriented pharmaceutical companies, and was supported by IFPMA. Stating that its mission was to provide excellent pharmaceuticals for many patients in the world, the Representative expressed his belief that it was ideal to achieve that goal through cooperation between developed and developing countries. The Representative considered that from the viewpoint of pharmaceutical biotechnology-related companies, it was essential to protect pharmaceutical innovation by patents as an incentive to research and develop new drugs that required huge amounts of capital and human efforts. In its opinion, due to patent protection, the companies could develop new medicines in both developed and developing countries. The Representative stated that Japan had drastically benefitted from robust intellectual property protection. For instance, he noted that since the introduction of pharmaceutical product patents in Japan, the number of pharmaceutical products researched and developed in Japan had significantly increased. He explained that while there had been only four Japan-oriented pharmaceutical products in 1960s before the introduction of pharmaceutical product patents, after the introduction of pharmaceutical product patent system in 1976, the number of Japan-oriented pharmaceutical products had increased to 18 products in 1980s and 14 products in 1990s. The Representative was of the view that innovative pharmaceuticals should be properly protected and utilized by developing countries in order to promote R&D of innovative pharmaceuticals for patients in the developing countries suffering from neglected diseases. The Representative further noted that a Japanese pharmaceutical company, Eisai, had joined the WIPO Re:search, and Takeda Pharmaceutical company was preparing to join the WIPO Re:search. Furthermore, the Representative stated that Japanese pharmaceutical companies had been making efforts to provide new drugs for patients in developing countries through the following actions: (i) Eisai made efforts to realize the continuous supply of pharmaceutical products at affordable prices that matched the social, economic, and medical environment of each country; (ii) Takeda donated pharmaceuticals for patients in the Philippines who could not obtain pharmaceuticals because of poverty through the PHAP Cares Foundation; and (iii) many Japanese pharmaceutical companies participated in GHIT and support the development of anti-infective drugs in developing countries. In conclusion, the Representative state that fair patent protection of pharmaceutical technology would allow pharmaceutical biotechnology-related companies to continuously carry out R&D activities of new drugs for patients in developing countries.

133. The Representative of TWN stated that the issue of prevention of access to medicines due to patent monopoly was no more confined to developing countries. In her view, it was a problem in developed countries as well, as demonstrated by the public outrage against excessive prices of hepatitis C medicines in the United States of America and Europe where thousands of people gathered on the streets demanding access to those medicines. The Representative therefore considered that it was an ideal time to discuss patents and public health. The Representative regretted the fact that although the proposal had been submitted by the African Group at the 16th session of the SCP, there had been no concrete decision to start a work program in the SCP on the most pressing issue affecting the lives of millions of people. The Representative observed that the legal and political pressure from developed countries had constrained many developing countries from using flexibilities in the international patent regime. She further noted that many developing countries were also facing institutional and policy constraints in using the flexibilities. The Representative

therefore considered that it was the appropriate time for WIPO to initiate a work program contained in document SCP/16/7 and 7 Corr. The Representative noted that one of the important proposals in that document was to commission a study by a panel of independent experts to examine the challenges and constraints faced by developing countries and LDCs in making full use of the public health related flexibilities in the pre-grant and post-grant stages. The Representative was of the opinion that the public health challenges in the context of access to medicines and other health products demanded such a response from WIPO and from its Member States. The Representative observed that it was astonishing that WIPO, as a UN specialized agency, did not have a formal dedicated discussion on impact of patents on public health. In her opinion, as a UN specialized agency, it is utmost important for WIPO to discuss the issues in formal fora, such as the SCP, and to take measures to address the concerns emerging out of patent monopoly on public health. The Representative therefore appealed all Member States to approve a work program on patents and public health as indicated in document SCP/16/7 and 7 Corr.

134. The Representative of MSF reiterated her position stated in her opening statement, and urged the Committee and the Member States keep working on the issue of public health and patents. The Representative further recalled the increasing public health challenges facing developing countries, and increasing also in developed countries, with respect to different diseases, including non-communicable diseases. The Representative stated that WIPO had a mandate to work on the issue, especially in connection with the Global Strategy and Plan of Actions on Public Health, Innovation and Intellectual Property. The Representative encouraged the Committee to continue working on the issue, and especially adopting the work program proposed by the African Group.

135. The Representative of KEI noted that, as the TPP was currently reported to be in the final stages of negotiation, it was appropriate that the Committee was addressing the topic of patents and health. The Representative observed that bilateral and plurilateral trade agreements, such as the TPP, continued to be a cause of great concern with regard to the acute effects of TRIPS-plus measures on access to affordable medicines and medical technologies in both developing and developed countries. The Representative stated that, based on the leaked drafts of the TPP's intellectual property chapter, it was widely known that the United States of America and other developed countries had pushed for:

- (i) expanding the scope of patentability to include patents on new uses and methods, giving rise to the problem of the "ever-greening" of patents beyond the original term of the patent;
- (ii) granting adjustments that would extend the term of the patent beyond 20 years;
- (iii) "patent linkage" whereby a generic product could not be granted marketing approval until the patent had expired or been found invalid;
- (iv) more aggressive damages standards for patent infringement; and
- (v) an investor state dispute settlement system that would threaten the ability of sovereign governments to make independent decisions with regard to the subject matter of the IP chapter.

The Representative considered that those measures, and other related measures such as the provisions on data exclusivity for both pharmaceuticals and biologic drugs, drafted and negotiated in secret and without the fair input of democratic process, were all designed with the sole purpose of minimizing generic competition. In its view, the result would be the increase in prices and an increase in suffering. The Representative underscored his support for the joint proposal by the African Group and the DAG on a work program on patents and health, in particular, paragraphs 11 and 14 of document SCP/16/7. The Representative stated that, in developing modules on state practices, the Secretariat should examine how certain countries, such as the United States of America, implemented limitations and exceptions to remedies associated with the exclusive rights of patent, 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. Referring to the Brazil's submission on exceptions and limitations (document SCP/14/7) which complimented the proposed work

program on patents and health, the Representative observed that the Delegation of Brazil had called attention to the lack of policy coherence in a world where at one moment, countries endorsed the use of compulsory licensing to promote access to medicines for all, and in separate fora, criticized developing countries for actually considering or issuing such compulsory licenses. In his opinion, if the compulsory licensing of medicines was truly supported, it should not be subject to bilateral and unilateral trade pressures. Asking a question as to what role, if any, WIPO could play in addressing such lack of policy coherence, the Representative noted that the countries most committed to bilateral and unilateral trade pressures could be asked to elaborate the rationale and criteria they used to punish countries that simply tried to carry out the mandate of the Doha Declaration on TRIPS and Public Health, and to explain why they believed such pressures were in fact consistent with the Doha Declaration. In addition, the Representative drew the Committee's attention to the revised WHO Model List of Essential Medicines, which had announced the inclusion of 16 cancer drugs, including costly treatments as trastuzumab and imatinib, in addition to costly tuberculosis medicines (delamanid and bedaquiline) and hepatitis C drugs (including sofosbuvir and daclatasvir). In view of the Representative, the WHO's policy shift had signaled a change in thinking about access to essential medicines, i.e., the WHO had re-defined essentiality based on clinical need, and essentiality was not limited by cost or cost-effectiveness considerations. The Representative suggested that such an approach be considered by WIPO in its work on patents and health.

136. The Delegation of India observed that discussions on such an important topic like patents and health should be given ample time for discussion without rushing to the closure of the agenda item. The Delegation reaffirmed its support to the studies as proposed by the Delegation of South Africa on behalf of the African Group and the DAG (document SCP/16/7). The Delegation further reaffirmed its views expressed in the previous SCP meeting on the issues related to document SCP/21/9 concerning the feasibility study on the disclosure of INN in patent applications and/or patents as well as on the issues of a study related to Markush formulae. The Delegation reiterated its views with respect to the INN study. In particular, the Delegation referred to the point that although there was no primary legislation anywhere in the world in which the INN disclosure was a matter of compulsion, secondary legislation such as administrative guidelines at least indirectly indicated that the INN disclosure could be incorporated in the patent specification. The Delegation therefore considered that there was ample room for further discussions on the said study. It further reiterated that there were certain elements in that study, which needed further amendments. Those were: (i) negative bias with respect to the hardship cast upon the applicant for submitting the INN; (ii) evading the question of usefulness or advantage of mandatory disclosure of INN in the patent specification, when the applicant was fully aware of the corresponding INN; (iii) failure to acknowledge the tremendous hardship that an examiner or any third party faced when the compound was buried in a Markush structure, whereas the compound could be easily recognized had it been identified by its INN; and (iv) improvement of the document by inclusion of the cost and benefit of INN disclosure, particularly when an important pharmaceutical compound remained buried within the billions of compounds covered by a Markush structure claim. The Delegation further reiterated its views on the Markush formulae and proposed that a study on that issue be undertaken in the next session. The Delegation explained that the proposed study could be related to Markush formulae and the impediments which they created in the healthcare industry by creating mysterious cobweb of unreal compounds to be discovered in future, thus stifling the innovations in the field of technology. The Delegation noted that, particularly, the questions to be studied could be broadly divided into two vistas: one relating to the basic issues of patent law and other a set of questions arose from the barriers to the availability of essential medicines to the public. Those questions were: (i) An issue of actual enablement of compounds covered in a Markush formula. Do they meet the requirements of sufficiency and support? (ii) Do all compounds under the coverage of such a broad Markush claim

meet the requirement of usefulness or industrial applicability? (iii) What are actual scopes of such claims? (iv) To what extent they help to develop essential medicines? With respect to the proposal by the United States of America (document SCP/17/11), the Delegation reiterated that the proposal appeared to be unrealistic in the absence of any empirical data. Noting that in accordance with the agreement at the 20th session of the SCP, a study by the Secretariat (document SCP/21/8) had been presented in its 21st session, the Delegation reaffirmed its position that had been stated during the previous SCP session, in particular: (i) empirical studies examining the relationship between patent systems and technology transfer to make medicines available in developing countries and LDCs were very scarce; (ii) broad Markush claims might cover a vast number of compounds, which had not been assessed by an applicant and supported by the disclosure in a specification, and thus should not be allowed; (iii) the WHO publication had reported that the identification of the patent status of the particular pharmaceutical might prove difficult for a number of reasons, such as multiplicity of patents covering a pharmaceutical product, lack of reference to the INN in a patent application and the technical language of the specification, among other reasons. As a result, specific expertise might be required to assess the patent status of medicines; (iv) compulsory licenses might be most effective when the technology had been already known and only access to it was required; and (v) it acknowledged the incompleteness of sufficiency requirement in the context of transfer of technology and also, acknowledged the view expressed by some about the uncertainty brought in the patent disclosures by Markush formulas. Consequently, the Delegation suggested that further feasibility study on the disclosure of the INN and a study related to Markush formulae be prepared. In its view, further studies could only reveal the real picture in developing countries and LDCs. Furthermore, the Delegation noted that it would also be helpful if the study would focus upon the real impediments, which the health care systems faced in the wake of the product patent systems. As far as its experience was concerned, the Delegation stated that, as admitted in the Doha Declaration, patented products had been sold, in certain areas of health care, at exorbitantly high price in the post-TRIPS regime, thereby making them unaffordable for the ordinary people. Therefore, in its view, further studies would give the Committee the opportunity to discuss how developing countries could utilize patent systems for the betterment of their public health care systems.

137. The Delegation of Montenegro expressed its support for the statement made by the Delegation of Luxembourg on behalf of the European Union and its Member States. The Delegation considered that the proposal by the United States of America (document SCP/17/11) provided very good reasoning and explanation based on the studies that had been published on that very important issue. The Delegation expressed its agreement with the view that strong IP protection was better for technological progress in the field of medicines and for progress in public health.

138. The Delegation of Nigeria, speaking on behalf of the African Group, clarified that its updated proposal would enhance its previous proposal contained in document SCP/16/7 and 7 Corr., and would not constitute a vast departure from the previous proposal.

139. The Delegation of Nigeria, speaking in its national capacity, expressed its support for the statement made by the Delegation of India. The Delegation stated that it understood why the Delegation of India had wanted more time for discussion, noting that the Delegation of India had raised a number of issues, including those issues also found in the African Group proposal.

(III) CONFIDENTIALITY OF COMMUNICATIONS BETWEEN CLIENTS AND THEIR PATENT ADVISORS

140. The Delegation of Romania, speaking on behalf of the CEBS Group, thanked the Secretariat for the preparation of a half day seminar on the confidentiality of advice from patent advisors and practical experiences of clients as well as patent advisors during the previous session of the SCP. The Delegation expressed its belief that the seminar was a valuable, substantive contribution to the Committee's discussions and conveyed a clear message on the necessity to find solutions for cross-border aspects for the benefit of both holders and users of IP rights. The Delegation reiterated the importance it attached to confidentiality of communications between clients and patent advisors in relation to the cross-border aspects. The CEBS Group remained committed to continuing further work on that issue, which was relevant to all developed countries, developing countries and LDCs. The CEBS Group reaffirmed its position that a soft law approach, based on non-binding principles, guidelines or non-binding recommendations to address that topic would be the appropriate way forward and could be considered as a possible solution, acceptable to all regardless of the status of the country. The Delegation noted that the soft law approach would avoid any need to amend national legislation or change judicial systems. Therefore, the CEBS Group called on the Secretariat to engage in initial steps in this regard and work with Member States to deliver specific proposals. The CEBS Group reaffirmed its readiness to participate constructively in further discussions.

141. The Delegation of Japan, 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 regarding the subject. In that context, Group B supported the view that a soft law approach should continue to be pursued and noted that that would be beneficial for the patent system as such, and to all users within the system in both developed countries and developing countries. Thus, Group B suggested that the Secretariat collect brainstorming ideas from Member States relating to the soft law approach. 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. For example, such a survey might include the following questions: (i) are there any obstacles to expanding the types of professionals covered by the privilege?; and (ii) are there any obstacles or differences when it comes to domestic and foreign advisors?. 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.

142. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States, reiterated its view that the time was ripe to consider a concrete mechanism to address the recognition of foreign patent advisor's privilege. Without prejudice to existing national legislation and in order to ensure optimal flexibility, the Delegation suggested that a

soft law approach be considered, aiming at offering, under applicable national law, the same protection to communications between a client and its foreign patent advisors and to communications between a client and its national patent advisors. The Delegation remained convinced that the convergence of existing diverse systems in the area of confidentiality of communications between clients and patent advisors among Member States would be beneficial for users of the patent system irrespective of the level of development of each country.

143. The Delegation of Iran (Islamic Republic of) reiterated its position expressed during the twenty-first session 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 level of private law and regulation of professional services and hence fell outside of the mandate of WIPO. Therefore, it was not clear to the Delegation how the mandate of the SCP and WIPO could be extended to encompass such issue. The Delegation strongly believed that it was premature to discuss that issue before having an agreement on the extension of the mandate of WIPO in general and the SCP in particular.

144. The Delegation of India reaffirmed its stand on the issue as taken at the previous sessions of the SCP. The Delegation explained that there was no provision on client-attorney privilege in India's Patents Act with respect to patent agents who were required to be science graduates. It further reiterated that neither the Paris Convention nor the TRIPS Agreement provided for any such privilege. Therefore, in its 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. 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. Therefore, the Delegation stated that any attempt for the cross-border harmonization of the issue was not compatible with its perspective and thus, the Delegation had opposed and continued to oppose it. Finally, the Delegation expressed its concern over the manner in which the matter had been progressing in the Committee towards a soft law approach harmonizing client-patent advisor privilege.

145. The Delegation of Nigeria, speaking on behalf of the African Group, recalled its previous statements in relation to that topic as expressed in previous sessions of the SCP, and reiterated that the issue was a procedural matter that should be addressed by national law. The Delegation stated that that issue could be addressed through unilateral arrangements as had already been undertaken in some countries.

146. The Delegation of Japan noted that at the Patent Attorney System Subcommittee of the Industrial Structural Advisory Council's Intellectual Property Committee, the issue of attorney-client privilege was discussed as one of the discussion points for revising the overall patent attorney system. The Delegation explained that, as a result, the Japanese government had been urged to actively work on that issue, in order to accelerate international negotiations. The Delegation explained that that had been done to protect communications conducted between Japanese patent attorneys and their clients, so that their communications would not be disclosed in civil lawsuits in other countries. The

Delegation noted that in Japan, the revised Code of Civil Procedure clearly stated the right to refuse to submit documents about any communication or any fact, including what patent attorneys were obliged to uphold in strictest confidentiality. The Delegation explained that, as a result, the revision might increase the possibility that the attorney-client privilege could be applied to Japanese patent attorneys in common-law countries. The Delegation also stated that, in countries where no attorney-client privilege was allowed to be granted to foreign patent attorneys, protection for the attorney-client privilege was not considered effective. Therefore, the Delegation considered that that issue could not be solved simply by revising domestic laws. The Delegation of Japan expressed its belief that it was more desirable to adopt some frameworks based on international laws, so that the attorney-client privilege established through communications between clients and their patent advisors would be certainly recognized by the judicial authorities in every country. Recognizing the fact that legal systems differ in every country and that some countries had difficulties in adopting any binding international agreement, the Delegation was of the view that adopting an agreement based on non-binding, soft law was a more acceptable and highly feasible option than adopting a binding agreement. Finally, the Delegation noted that the Japanese Patent Office (JPO) had conducted studies on court decisions in the US as to how the attorney-client privilege had been applied to foreign patent attorneys. The Delegation explained that among court cases from 1999 on intellectual property issues involving foreign patent attorneys, including Japanese patent attorneys, the JPO had analyzed 42 cases in which court decisions had been made as to whether the attorney-client privilege should be granted to foreign patent attorneys. The Delegation pointed out that, as a result, the JPO had not found any cases in which court decisions had been based solely on the involvement of foreign patent attorneys who had made communications with their clients. The Delegation was of the view that that might be because, in the US, due to the so-called principle of “international comity”, the courts had ended up deciding to grant the privileges, based on the legal systems of the countries to which communications with patent attorneys about the cases had been most connected. The Delegation highlighted that the main reasons why the courts had denied the privilege were the following: (i) the attorney-client privilege was not allowed under the laws of the country in which the patent attorney was licensed; and (ii) it was not proven that communication was with patent attorneys. Thus, the Delegation stated its belief that it was essential to clarify more specific issues in judicial proceedings in other countries, and not only in the US.

147. The Delegation of Denmark reiterated its stand on the issue as taken in previous sessions. The Delegation stressed the importance of that issue for patent advisors. The Delegation noted that there was a strong need to create a mechanism to ensure the recognition of foreign patent advisors privilege. Given the international and cross border dimensions of that question, the Delegation stated its belief that it would be beneficial to explore the possibilities of a non-binding soft law approach which would not harmonize privilege provisions but would provide sort of a pick and choose option for interested countries. The Delegation therefore supported the statements made on behalf of Group B and the European Union.

148. The Delegation of China reiterated its position on that issue as taken in previous sessions of the SCP. The Delegation highlighted the following two points: first, confidentiality of communications between clients and their patent advisors was important to defend the public interest, but at the same time the difference between national legal systems should be recognized; and second, that issue fell within procedural law. Therefore, the Delegation considered that the SCP was not an appropriate platform to discuss that topic.

149. The Representative of JPAA stated that his comments were made from the point of view of the practitioner and expressed its hope that discussion on the issue would move forward in the SCP. The Representative stated that in Japan, the confidentiality between a

client and a patent attorney was protected by Sections 197 and 220 of the Japanese Civil Procedure Law introduced in 1998. The Representative noted that Japanese patent attorneys, not attorneys-at-law, had substantially been protected by forced disclosure of their advice to clients in intellectual property related disputes. The Representative explained that based on such national law provisions, attorney-client privilege of Japanese patent attorneys had been admitted by courts in lawsuits in the United States of America from the view point of international comity. The Representative pointed out that the question of attorney-client privilege of Japanese patent attorneys had been raised and examined by courts only in the United States of America, and not in other common law countries, for example United Kingdom, Australia, Canada or India. In the Representative's view, there were still three questions to be considered on that issue. First, the legal nature and the effect of Sections 197 and 220 of the Japanese Civil Procedure Law was different from attorney-client privilege in the United States of America due to the differences between the legal systems of Japan and the United States of America, civil law and common law, respectively. The Representative explained that those Sections regulated the right to refuse testimony and submitting documents to the court, not attorney-client privilege itself. The Representative also noted that there was no united single standard of attorney-client privilege at the Federal level in the United States of America, and therefore the question of admitting attorney-client privilege to Japanese patent attorneys in the United States of America was still not fully answered since it depended on the discretion of each court under each state law. The second question put forward by the Representative related to "touch base". The Representative stated that from the view point of touch base in case law in the United States of America, attorney-client privilege in the United States of America was not admitted to the communication of the comments on the United States of America's law itself by Japanese patent attorneys. The Representative noted that when a dispute concerning a Japanese company occurred in the United States of America, it was quite usual that the clients would ask to their Japanese patent attorneys whether they infringed a United States of America's patent or not. The Representative explained that if the attorney-client privilege was not admitted to the communication regarding the comments on the law of the United States of America, the clients would not be well protected. The third question pointed out by the Representative related to the communication between clients and legal assistants. The Representative stated that in certain United States of America's case law regarding attorney-client privilege on Japanese patent attorneys, the communication made by legal assistants of Japanese patent law firms was not protected by attorney-client privilege, while the confidentiality of the communication of legal assistants was protected as far as the administration and control of patent attorneys was concerned. The Representative considered that that issue should be discussed as "confidentiality between client and patent advisers" not attorney-client privilege as in the SCP, thereby including the possibility of the protection of the communication of the legal assistants controlled by patent attorneys. From that point of view, the JPAA expressed its willingness to fully support the position of WIPO on that issue at the SCP. The Representative further stated that the same situation had occurred to the patent attorneys of other civil law countries, for example many European countries and Asian countries. Therefore, in the Representative's view, the issue of whether the confidentiality on communications of patent attorneys in a certain country was admitted in other countries was not only a domestic question but also an international cross-border question. The Representative pointed out that if the client was not able to win the law suit in another country due to the confidentiality not being admitted in that country, that was not user-friendly. Therefore, the Representative reiterated the need to find the way to overcome the way of thinking of international comity and the question of touch base for the protection of clients. The JPAA considered that the best way to solve that question was to make a certain international harmonization including a soft law recommendation or guideline. The JPAA strongly hoped that the discussion of that issue would be forwarded.

150. The Representative of CIPA stated that the objective of maintaining confidentiality of communications between clients and their patent advisers was to protect advice by patent advisers and requests for advice, not to enable parties to conceal documents. The Representative noted that that confidentiality was just as important in developing countries as in developed countries. The Representative gave the following hypothetical example: an Indian car manufacturer who took preliminary advice from his patent agents in, for instance, India, the United Kingdom, Canada and the United States of America concerning sales of his cars in those territories, would not want the advice received from his patent agents to be disclosed to the other party in a patent infringement court proceedings in, for example, the United Kingdom or the United States of America. The Representative stressed that that was very clearly explained at the half day seminar during the previous session of the SCP.

151. The Representative of APAA stated that the APAA, comprising individual members practicing the profession of patent attorney in the Asian Region, had adopted a resolution on the issue of client-patent advisor's privilege at its 55th Council meeting in 2008, urging an international consensus on setting minimum international standard or any other remedies to protect client privilege against forced disclosure of confidential communications between clients and qualified intellectual property professionals. In consideration of the facts that intellectual property was international and cross-border IP disputes were raised in multinational jurisdictions, the Representative noted that confidential communications between clients and qualified intellectual property professionals were sometimes forced to be disclosed, in particular during litigations, thereby potentially undermining a client's ability to obtain legal advice on intellectual property related matters. Therefore, the APAA strongly supported the continuation of discussions and taking further efforts to study the feasibility of setting minimum international standards for mutual recognition of client-patent advisor's privilege in an accelerated manner.

152. The Representative of TWN stated that one of the fundamental principles of patent law was the disclosure of inventions: non-disclosure or partial disclosure was a ground for refusing patent grant or revocation of a patent. The Representative was of the view that extension of client-attorney privilege to patent advisers went against the fundamental principle of disclosure. The Representative considered that society could not afford another layer of opaqueness around patent specifications. In TWN's opinion, the extension of client-attorney privilege to patent advisers would compromise the transparency requirement in the administration of patents, which included patent prosecution procedures as well as litigation of patents. The Representative noted that the patent specification, a public document, as well as any related records used in the preparation of patent specifications, should be made available to public scrutiny in order to find or verify the truth about the claims in the specification. The Representative observed that there were wide-ranging public policy concerns associated with patent law, and consequently, absolute transparency around the granting of patents was particularly important. Further, the Representative remarked that the extension of client-attorney privilege to cover patent advisers would incapacitate patent offices and courts in developing countries from safeguarding public interest following the grant of patents. The Representative expressed her concerns about the unintended consequence of such extension, such as its effect on patent applications, TRIPS flexibilities, patent opposition systems and the transparency of patent procedures. The Representative further noted that that privilege compromised the power of authority, for example, judicial and quasi-judicial bodies, to discover quality evidence. In the Representative's view, that privilege took away the evidentiary value of a document which was exchanged between the client and patent attorney, and extending such privilege would be a backwards step and would encourage bad quality patents. Considering the potential impact of patents on people's lives, especially on access to medicines, the Representative reiterated that such a privilege should not be allowed. The Representative also pointed out that law and policy making should not be carried on mere speculation and that the demanders of the proposal

failed to provide concrete examples to prove that absence of such a privilege would affect the inventor's confidence. The Representative further stressed that even though that agenda item had substantial law implications, the issue was not a substantive law issue. She stated that the issue of cross-border recognition of client attorney privilege fell in the domain of trade and services and thus under domestic regulation. Therefore, TWN considered that that issue should be dealt with by the soft regulation of relevant parties and that SCP was not the right forum to discuss it.

153. The Representative of AIPPI stressed the importance of that subject and reaffirmed his favorable position towards discussing that issue at the SCP. The Representative endorsed the statements of all delegations that were in favor of pursuing discussions on that issue in the SCP.

(IV) TRANSFER OF TECHNOLOGY

154. The Chair recalled the preliminary study on transfer of technology prepared by the Secretariat that was discussed during the sixteenth session of the SCP and the revision of that study. The Chair then made reference to the seminar on patents and transfer of technology organized with the WIPO Chief Economist at the seventeenth session and the discussions of experiences and practical examples regarding patent related incentives and the impediments to transfer of technology that took place during the eighteenth, nineteenth, twentieth and twenty first sessions of the SCP.

155. The Delegation of Brazil noted that the expression "transfer of technology" could be understood in at least two different ways: first, transfer of technology between countries (cross-border technology transfer), and second, national transfer of technology among universities, other research institutions and also small and medium enterprises. In relation to the second type of technology transfer, the Delegation touched upon its national initiatives to expand the dissemination of technology. The Delegation stated that in 2015 the Ministry of Science and Technology of Brazil had started the operation of a platform (e-Tech), aimed at stimulating technology transfer and new business opportunities for open innovation involving research institutions in the private sector. The Delegation explained that that platform promoted match making of companies that sought solutions to technological challenges with other entities that could propose solutions, such as other companies, startups, incubated enterprises, small and medium enterprises, universities and research institutes, amongst others. The Delegation highlighted that when describing the technological challenges, companies were requested to point out the level of resources envisaged to solve those technological challenges as well as a work program. The Delegation further explained that entities that provided solutions were required to provide information on the stage of development of the technology including information on intellectual property rights, especially on patents and prior art search related to the technology, the difference between the new technology when compared to other solutions available in the market and information restrictions to the use of that technology. The Delegation noted that the first version of the project related to the e-Tech platform had been based on the creation of a patents database, and that in order to make it more effective, the project had evolved into a platform focused on the demand for solutions in order to increase the potential of technology transfer. The Delegation hoped that the sharing of national initiatives aimed at dissemination of technology such as e-Tech could benefit national and international efforts on transfer of technology.

156. The Delegation of Japan, speaking on behalf of Group B, reiterated the importance it attached to the issue of transfer of technology in general. The Delegation stated that in February 2015, an expert forum on international technology transfer as part of the

Committee on Development and Intellectual Property (CDIP) project had been successfully conducted. In particular, the Delegation recalled that the panel discussion 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 account of those thoughts coming 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; work on i.e., 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.

157. The Delegation of Romania, speaking on behalf of the CEBS Group, thanked the Secretariat for the preparation of document SCP/21/10. The Delegation noted that several members of the CEBS Group contributed to the summary and provided their practical experience and examples on various tools, technology transfer related initiatives, and examples of technology transfer incentives under the existing patent system. The CEBS Group considered that that further information confirmed previous findings in documents SCP/18/8 and SCP/20/10, in particular, that quality of patents and the 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 stated that discussing practical examples and experiences was also helpful in increasing the understanding of the role of the patent system in that respect. The CEBS Group highlighted that any duplication of work with other WIPO bodies such as the CDIP, which dealt with the "Project on Intellectual Property and Technology: Common Challenges-Building Solutions", should be avoided. The Delegation shared the view that, until the completion and analysis of that project, any new work on that topic should not be developed within the SCP.

158. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States echoed what had been said by the Delegation of Romania on behalf of the CEBS Group. The Delegation stated that until completion of the CDIP's "Project on Intellectual Property and Technology: Common Challenges-Building Solutions", new initiatives should not be launched within the SCP on that topic.

159. The Delegation of Nigeria, speaking on behalf of the African Group, reiterated its position taken in the previous SCP sessions that the work in the CDIP should proceed independently of the work in SCP. The Delegation proposed that the Committee prepare a study providing information on current practices in the transfer of technology in developing and least developed countries. The Delegation believed that such a study would facilitate discussion on that agenda item, and would not conflict with work on transfer of technology going on in other WIPO Committees.

160. The Delegation of China stated that in its view, transfer of technology also concerned the challenges to the free flow of technology. The Delegation therefore suggested that the SCP worked on the relationship between patent systems and transfer and technology to further promote the experiences of all countries.

161. The Delegation of India informed about the recent launch of a flagship program called "Making India", which was designed to facilitate investment, foster innovation, enhance skill development, protect intellectual property and transform India into a manufacturing hub. The Delegation noted that several measures had been taken by the Government of India to ensure continuous improvement of India's intellectual property ecosystem. The Delegation

further noted that the project was based on the idea of promoting creativity to develop a culture of respect to innovations. The Delegation asked the Secretariat about the possibility of submitting a detailed document in relation to the project for the record and to share it on WIPO's website for dissemination. The Delegation of India reaffirmed its views expressed during the twenty-first session of the SCP: "from the viewpoint of public interest, transfer of technology has been the central theme of the patent system. The protection and enforcement of the patent rights should contribute to the promotion of technological innovation and the dissemination of technology, retaining the mutual advantage of producers and users of technological knowledge and in a manner conducive to the social and economic welfare and to a balance of rights and obligations". The Delegation recalled that the objective of the TRIPS Agreement was embedded in Article 7 which reads: "the 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 further stated that one principle of the TRIPS Agreement, *inter alia*, was "to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology" as contained in Article 8. The Delegation also noted that in order to effect the maximum utilization of the patent specification for ensuring the transfer of technology, Article 29 of the TRIPS Agreement stipulated 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 the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application". In the Delegation's views, the use of "shall" and not "should" in Article 29 made that provision mandatory. The Delegation also pointed out that Article 5 of the Paris Convention was modeled on the basis of understanding that patents were utilized as a tool for the transfer of technology. Considering all those factors, the Delegation stressed that although the *quid pro quo* of the patent system was the disclosure embedded in the specification, it was time to trace the effectivity of the patent system as a stand-alone system in the process of transfer of technology. The Delegation stated that since the twelfth session of the SCP, India and other developing countries had been continuously and consistently pressing for a discussion on the issue of sufficiency of disclosure and transfer of technology, which had eventually been agreed and adopted in the agenda of the twenty-second session. The Delegation observed that in the patent system, in order to transform the patented invention into a technical reality, if a skilled person in a country where a patent application had been filed or a patent had been granted required the help of other secret technologies that were outside the coverage of the patent, and consequently the skilled person was not able to transform the invention into a technical reality using the patent as a stand-alone reference, it meant that the basic purpose of the patent system was not fulfilled. The Delegation stated that such inability to transform the invention into a technical reality posed a serious challenge to the very purpose of the patent system. The Delegation considered that the role of the patent system as a stand-alone system, in which the transfer of technology was enabled independent of any know-how or show-how, had not yet been firmly established, as could be seen from the practical examples in document SCP/21/10. The Delegation observed that under an ideal situation, a patent specification as a stand-alone document should contain all the necessary information for the transfer of specific technological knowledge. The Delegation stated that under the India's Patents Act, the patent specification should disclose the invention fully and completely, including its operation or use and the method by which it was to be performed along with the best method known to the applicant of performing the invention, and for which he was entitled to claim protection. The Delegation therefore believed that document SCP/22/4 concerning the study on sufficiency of disclosure could also be considered under the transfer of technology as it was closely related to the issue of transfer of technology as

well. The Delegation was of the view that the entirely rosy picture of the transfer of technology riding on the vehicle of the patent system was only a fairy tale. Thus, the Delegation stressed the need to do something more with the issue of transfer of technology *vis-à-vis* the issue of sufficiency of disclosure. The Delegation expressed its readiness to participate in further works in that regard.

162. The Representative of Innovation Insights made comments on that topic from a business perspective. The Representative stated that technology transfer was about the diffusion of knowledge and know-how. She noted that accumulating technological know-how was not easy, but it was sticky, and most effectively shared through learning by doing, in particular through collaboration over many years, which required trust, as well as certainty and predictability. The Representative pointed out that patents were a tool that facilitated the sharing of technology and related knowledge, a role that was often overlooked. In the Representative's view, collaboration or "open innovation" was an important new trend. She noted that technology and knowledge were routinely shared with partners in order to reduce costs and risks and to access others' expertise. The Representative said that, for instance, in-licensing technology could provide access to a solution that already existed without having to reinvent the wheel in-house. In her view, within collaboration, patents were used to clarify who brought what to the table and how the outcomes of joint work would be managed. She remarked that that provided certainty and clarity to partners, whether located in mature or emerging markets. In addition, the Representative pointed out that patent information in published applications could be used to identify potential partners, as well as trends in research and development (R&D). The Representative then observed that references had been made several times during the meeting to patent monopolies, but most often, innovation built on what had come before: an inventor might develop a feature that improved the operation of a technology solution that had existed for decades, his patent read on that feature and thus did not provide a monopoly over the whole technology solution, but his patented invention would compete in the marketplace with the other improved features developed by other inventors and the underlying technology would remain in the public domain. The Representative noted that the discussion so far seemed to veer between talks of exception and limitations, on the one hand, and patent protection, on the other. In her view, those issues were integrated, together, into patent systems all over the world. The Representative stressed the importance of not skewing patent systems too far in one direction, towards the interests of just one specific group of stakeholders, or in favor of any one business model; in other words, innovators needed business model-neutral patent systems. The Representative emphasized the fact that a patent owner needed to manage not only his own rights, but he also faced the intellectual property rights of others in the ecosystem, and therefore, he was in both offensive and defensive situations.

163. The Representative of TWN noted that the UN process on crafting a Post 2015 Development Agenda was about to conclude in two months' time at the General Assembly and there was consensus among UN Member States to adopt Sustainable Development Goals (SDGs) as the basis for the Post 2015 Development Agenda. She stated that in 2014, UN Member States had concluded negotiation on 17 of the SDGs with 169 targets. In that regard, she noted that access to technology was a key means to achieve the SDGs and that the importance of technology had been recognized by the UN Working Group in the previous year and endorsed by the General Assembly. The Representative said that, however, stringent intellectual property rights, especially patents, threatened access to technology and pointed out that in 2013, the Committee for Development Policy in its report to ECOSOC had stated that: "Stringent protection of intellectual property rights, particularly patents, can be a serious deterrent in countries' efforts to achieve sustainable development in general and to pursue appropriate industrial policies to that effect. In this regard, the international community should also consider several policy issues, including a broad research exemption for experimental users and judicial power to require non-exclusive licensing in the spirit of

public interest. Moreover, there is a need to install a minimum safeguard of public interests by ensuring transparency in licensing and allowing wider use of non-exclusive licensing, particularly in the patenting of results of publicly funded research". The Representative further noted that there were instances of intellectual property rights being used to block access to technologies in the field of information and communications technology, which clearly showed that patents had a negative impact on technology transfer: for example, in 2015, China had imposed a fine of 975 million US dollars on Qualcomm for indulging in anticompetitive practices for the licensing of the company's patented technology; in India, patent holders like Ericsson had obtained injunctions against the Smartphone manufacturers; and the EU Directorate-General for Competition had documented the increasing trend in litigation related to standardization of patents. In relation to the position of certain Member States that WIPO required an explicit mandate to discuss the technology transfers, TWN recalled Article 1 of the Agreement between the UN and WIPO, which stated that "the United Nations recognizes the World Intellectual Property Organization (hereinafter called the "Organization") as a specialized agency and as being responsible for taking appropriate action in accordance with its basic instrument, treaties and agreements administered by it, inter alia, for promoting creative intellectual activity and for facilitating the transfer of technology related to industrial property to the developing countries in order to accelerate economic, social and cultural development, subject to the competence and responsibilities of the United Nations and its organs, particularly the United Nations Conference on Trade and Development, the United Nations Development Programme and the United Nations Industrial Development Organization, as well as of the United Nations Educational, Scientific and Cultural Organization and of other agencies within the United Nations system". Therefore, in TWN's view, all WIPO Committees were mandated to discuss transfer of technology. In addition, the Representative welcomed the decision of the UN Member States at the Addis Ababa Financing for Development Conference to establish a technology facilitation mechanism in the UN that supported the SDGs achievement. She stated that the effectiveness of that mechanism would depend on whether it addressed IP barriers and the endogenous technological development of developing countries, which led back to the responsibility of WIPO. The Representative said that the CDIP work program on technology transfer was not designed to discuss patent barriers on technology transfer. She further observed that the High Level Forum on Technology Transfer had failed to take note of those concerns and even recommended accession to WIPO treaties such as the PCT and Madrid Protocol as a way to promote technology transfer. TWN said that that was because the experts were drawn from technology licensors and executives from private firms without any exposure on development and technology issues. The Representative also affirmed that the WIPO initiative on technology transfer was essentially a technology match-making platform and had nothing to do with addressing the patent barriers on technology transfer. In her view, the SCP was the only forum in WIPO that could discuss issues related to patents and technology transfer. Thus, TWN fully supported the long standing demand of developing countries to establish an independent commission on patent barriers to technology transfer and urged Member States to do so.

164. The Representative of IPO explained that the IPO was a trade association for owners of patents, trademarks, copyright and trade secrets that served owners in all industries and all fields of technology and therefore, its members had direct experience with technology transfer across many different sectors. The Representative wished to share a real world example of technology transfer involving Eli Lilly and Company, which was an IPO member. The Representative explained that for over ten years, Eli Lilly had been engaged in a technology transfer program aimed at enabling developing countries, including India, to produce quality medicines for the treatment of multi-drug resistant tuberculosis (MDRTB) and that that program had resulted in a successful transfer of technology that had enabled local generic companies in those regions to produce the medicines best suited to address this crisis at international quality standards. The Representative noted that in addition to the

technology transfer, the MDRTB partnership had supported the training of over 100,000 health care workers in the hardest hit regions in order to manage that complex disease and engaged in early stage research into new medicines. The Representative stated that Eli Lilly had been able to choose the countries with which they partnered through trust building with local partners, who were also eager for the collaboration to be a success. She further noted that knowledge and technology flow were a two way process which required a reliable legal framework including meaningful intellectual property protection, and that independence provided a level of trust and reliability without which such a program could not have succeeded. She finally affirmed that IPO industries were firmly committed to technology transfer, and IPO strongly believed that such partnerships worked best when they were entirely voluntary.

165. The Representative of ICC noted that technology was transferred or disseminated through several channels: through market transactions such as trade in products or services or licensing; or formal networks such as global value and supply chains, and R&D and innovation networks. The Representative further noted that technology and knowledge was also diffused through the movement of skilled workers between different organizations and countries; as well as through informal networks, which were particularly important for the transmission of non-codified tacit knowledge; i.e., knowledge gained from experience that was in people's heads. The Representative stated that many factors were necessary for successful technology transfer and that one important element was absorptive capacity, which was the ability to integrate and use new knowledge to generate innovation and which required sound education and training on relevant skills. The Representative pointed out that innovation networks and clusters were also very important factors in promoting knowledge and technology flows, as was a good communications infrastructure which could facilitate collaboration. She observed that an essential tool supporting all those factors were intellectual property rights such as patents and trade secrets: intellectual property rights supported collaboration as they enabled innovators to disclose and share their knowledge. She further noted that intellectual property rights also formed the basis for technology licensing transactions which were an important channel for technology transfer. To conclude, ICC stated that many different factors were necessary to create a conducive environment for effective technology transfer and diffusion, and intellectual property was an essential element though not sufficient in itself. She added that ICC had produced a research paper on knowledge and technology flows, which provided information on global trends in technology transfer and dissemination.

166. The Delegation of South Africa underlined that South Africa was moving from a resource-based economy to a knowledge economy, and that that was reflected in its new intellectual property rights policy framework, which was currently under discussion and would soon become legislation. The Delegation noted that as a developing country, South Africa had taken note of lessons learned from developed country experiences and had found that they did not always paint a comprehensive picture. The Delegation stated that while much of the focus had been put on commercial technology transfer, in South Africa, they had also taken note of the need for social technology transfer, which was the social responsibility to foster sustainable development. In that regard, the Delegation supported the statement made by the Representative from TWN, who had eloquently highlighted the need for technology transfer in order to meet the sustainable development goal. To conclude, the Delegation affirmed its support to the proposal made by the Delegation of Nigeria on behalf of the African Group on the preparation of a study of current practices in transfer of technology in developing countries and LDCs.

167. The Delegation of Ecuador stated that that topic was of great importance because transfer of technology was a key tool for the development of countries. The Delegation noted that from the public interest perspective, transfer of technology was a central topic

within the patent system. The Delegation continued that patent rights should contribute to promoting technological innovation and the diffusion of technology, benefiting both the producers and the users of technological knowledge, in a manner that they promote economic and social wellbeing as well as the balance between rights and obligations. The Delegation said that within the framework of the meetings of the TRIPS Council, Ecuador had proposed an agenda item concerning IP for facilitating transfer of technology in the field of environmentally sound technology. The Delegation underlined that that forum had shown that transfer of technology from developed countries to developing countries was necessary in order to be able to mitigate the harmful effects produced by climate change, in which patents and innovations are playing a very important role. The Delegation was of the view that discussions on the issue of transfer of technology should continue at the SCP through analyzing the national experiences in order to be able to reach a more precise understanding on the implications of patents on transfer of technology, which could facilitate Member States to explore new elements that could be used in the SCP as well as in other fora. Along those lines, the Delegation reiterated its position that the project carried out in the CDIP “Project on Intellectual Property and Technology: Common Challenges-Building Solutions” should not be used as an argument to prevent the SCP from continuing its work on that topic, despite the fact that that topic was being considered in another body of WIPO.

AGENDA ITEM 7: OTHER ISSUES - PROPOSAL BY THE GROUP OF LATIN AMERICAN AND CARIBBEAN COUNTRIES (GRULAC)

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

169. The Delegation of Brazil, speaking on behalf of GRULAC, briefly gave an account of the history of the 1979 WIPO Model Law for developing countries. The Delegation recalled that in 1965 the United International Bureaux for the Protection of Intellectual Property (BIRPI) had published a Model Law for Developing Countries on Inventions. About ten years later, in 1974, the need had been felt for revision of that Model Law and after a revision process, the final revised version of the WIPO Model Law on Inventions had been published in 1979. The Delegation stated that in the spirit of providing the Secretariat a useful tool for capacity building activities, GRULAC proposed the beginning of a discussion on the revision of that model legislation. The Delegation noted that that issue had been raised in two previous sessions of the Committee as a topic that deserved attention. The Delegation explained that discussions on the revision of the 1979 WIPO Model Law should take into consideration the following aspects, among other issues: (i) the availability of funds in the 2014-2015 Program and Budget to achieve a “progress on the revision of the Patent Model Law for developing countries and LDCs”; (ii) the relevance of such an exercise in addressing the main chapters related to patent law in a comprehensive and holistic manner; (iii) the need to respond to the increasing demand from Member States for legislative and policy assistance in line with the Development Agenda recommendations 13 and 14; (iv) 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 into force of the TRIPS Agreement in 1995 and the implementation of its provisions in national legislations; and (v) the usefulness of a revised document that would be the basis for consideration of Member States when updating or reviewing their patent legislations. Based on those elements, GRULAC suggested that Member States express their views on that approach and based on comments received, requested the Secretariat to allocate the funds necessary to carry on the revision of the 1979 WIPO Model Law in the 2016-2017 Program and Budget and to prepare for the twenty-third session of the SCP a proposal for consideration of Member States on the terms of reference and modalities that such a revision could follow. The Delegation remarked that Member States would be able to intervene and participate in that process as usual and that the final product would not constitute a binding document. The Delegation further noted that in order

to better organize the discussions on that agenda item, GRULAC proposed to divide discussions in three parts: the first part should be directed to discuss the usefulness of WIPO Model Law for the work of the Secretariat; the second part would focus on the situation of the Model Law, *vis à vis*, the international patent system; and the third part would be an exchange of views between Member States on what they would like to see in a Model Law from a UN agency such as WIPO.

170. The Delegation of South Africa gave a general overview of its point of view on the issue. The Delegation expressed its support to the GRULAC's proposal for the revision of the 1979 Model Law for Developing Countries on Inventions based on the following points: (i) the 1979 WIPO Model Law for Developing Countries was outdated and did not take into account recent developments in the multilateral fora, such as the TRIPS Agreement in 1995 and 2007; and (ii) the Model Law did not take into account the specificities of different socioeconomic realities and aspirations of developing countries, which was critical in developing countries. The Delegation noted that as the leading authority in IP issues and in line with Development Agenda recommendation 13, WIPO had the responsibility of dispensing legislative advice that was development oriented and demand driven, taking into account the priorities and special needs of developing countries. To that end, the Delegation considered that the revision of the 1979 WIPO Model Law would provide the opportunity to reflect on the many changes that had occurred since 1979 and assist developing countries to put in place an effective and efficient system when updating or reviewing their patent legislation. In the Delegation's view, GRULAC's current call for revision was also in line with the reasoning for the 1979 revision, which was to keep up with the trends regarding legislative and policy developments in developing countries at that time. Therefore, the Delegation supported the call for allocation of funds necessary to carry out that revision in the 2016/2017 biannual budget as well as the preparation of the proposal of the modalities and terms of reference that such a revision would entail for further discussion at the next SCP.

171. The Delegation of Paraguay congratulated the Chair and Vice-Chair for their respective appointments. The Delegation commended the Secretariat for its preparation of the documents which were debated during the meeting. The Delegation of Paraguay fully endorsed the statement made by the Delegation of Brazil on behalf of GRULAC, both with respect to the opening as well as the statement presenting the proposal of GRULAC (document SCP/22/5). The Delegation noted that Paraguay had a new institution, created a few years ago, entrusted with implementing public policy for intellectual property and carrying out procedures at different levels, political, normative, and institutional. The Delegation stated that one of the areas of the greatest interest was that of patents and the proposal of GRULAC of updating the Model Law of 1979. The Delegation thought that such proposal would be an interesting exercise which would provide benefits to the Committee and WIPO in general for the reasons outlined by Brazil as well as by the Delegation of South Africa. The Delegation reminded that, as the Director General underscored on the first day of the session, the Committee had a normative vocation. In that regard, the Model Law, though it was not a binding instrument, would enable Member States to make the process of legislative assistance which were provided by the Secretariat more transparent. In line with what was proposed by GRULAC, the Delegation was interested in knowing whether the Model Law in particular had been used in past activities for technical and legislative assistance. The Delegation noted that, since it was a model law, its main role was to provide flexibility for the countries who wished to use it as a basis for reviewing their national laws and that the said instrument would adopt and envisage different national realities and did not seek harmonization on any national level. The Delegation further noted that that could be an exercise that would allow to better understand how legislation on patents contributed to development, to transfer of technology, to innovation, and to aspects regarding health. In the Delegation's view, in order to serve as a tool for developing

countries which had little or incomplete legislation with regards to patents, the Model Law should take into account the evolutions in new technologies. The Delegation continued that the GRULAC's proposal was of a procedural nature: it did not seek to create a substantive discussion on the very content of the Model Law. The objective of the proposal was that the Secretariat prepare a proposal on the modalities and terms of reference which the revision process might include. If the proposal was approved, the Delegation considered that it was important to ensure that the Secretariat would take the necessary steps to have an effective participation of the Member States.

172. The Delegation of Trinidad and Tobago congratulated the Chair for her election and also the work of the Secretariat during the course of the twenty-second session of the SCP. The Delegation stated that its intervention would be general, such as those of the Delegations of Paraguay and South Africa. The Delegation supported the intervention made by the Delegation of Brazil on behalf of GRULAC and document SCP/22/5, and asserted its interest in engaging in discussions on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions. Noting that the Model Law was exactly that, a model, the Delegation considered that the proposed reform constituted soft law and was non-binding on Member States. It further noted that the Model Law needed updating and agreed that the revision was consistent with the recommendations 13 and 14 of WIPO's Development Agenda. The Delegation supported the preparation of the terms of reference and modalities of the revision as well as the three part structure proposed by the Delegation of Brazil on behalf of GRULAC.

173. The Delegation of Japan, speaking on behalf of Group B, stated that Group B had not yet reached to have a complete and detailed discussion on that issue and that it would make a general comment. The Delegation thanked GRULAC for its proposal on a revision of the 1979 Model Law for the Developing Countries on Inventions in document SCP/22/5. Group B recognized the importance of the legislative assistance provided by the Secretariat to developing countries in the field of patents for the purpose of establishing or improving patent systems in those countries. The Delegation noted that WIPO's assistance was very important in order to have a patent system function as a driving force in innovation. Group B felt that the revision exercise on the Model Law could be a part of harmonization of substantive patent law which Group B would like to pursue and which the Committee should pursue in line with its mandate. The Delegation said that if that exercise could lead to harmonization on issues such as data protection, patent term extension, grace period and privilege, among others, Group B would be interested in the item. In this context, the Delegation asked GRULAC to follow-up with their views of the expected results of that exercise, taking into account the points relating to patent harmonization which Group B had referred to. It noted that the view of GRULAC would be very useful for further consideration on that matter within Group B in the future.

174. The Delegation of the United States of America thanked the Member States of GRULAC for the preparation of document SCP/22/5 which proposed the revision to the 1979 WIPO Model Law for Developing Countries. In particular, the Delegation thanked the Delegation of Brazil for presenting that document. The Delegation noted that the proposal contained in document SCP/22/5 did not provide detailed reasons for the revision sought. The Delegation further noted that while the proposal claimed that requests for legislative assistance from WIPO were increasing and that WIPO had not been able to meet that demand, evidence of that had not been submitted. The Delegation offered some preliminary comments and views regarding the topics discussed in the document. The Delegation pointed out that the WIPO Model Law under discussion dated from 1979, more than 30 years ago. At that time, the international patent system had been poorly defined and had consisted mainly of the Paris Convention and of the PCT system that had been beginning to operate, thus there had been very little framework for the international patent system. The

Delegation recognized that the Model Law did not include modern elements of patent law, such as patent term adjustments and extensions or implementation of, for example, the Patent Law Treaty (PLT). The Delegation remarked that the situation was quite different from what it had been in 1979. It noted that the international patent system had been operating for many years under the multiple international, multilateral and bilateral agreements that had set up a framework between countries and between groups of countries and could guide international policies. The Delegation said that many developing and least developed countries had patent laws and that those patent laws were available on the WIPO website and might serve as a valuable resource for those considering new or revised patent laws. It added that international agreements provided minimum norms for countries to follow in protecting intellectual property rights and also provided for flexibilities available to countries within the framework of those international agreements, so that signatory countries to those agreements could also use them as necessary, based on their national needs and circumstances. The Delegation observed that the international patent framework was much more developed than it had been a few decades ago and thus the impetus for model laws to provide harmonized rules by which every country should abide was no longer present; instead, a much more flexible approach was in place to provide legislative and policy technical assistance directly to the Member States that requested it. The Delegation continued that that flexible approach was enshrined in the Development Agenda Recommendations which had been unanimously accepted by all Member States and which had been mainstreamed in WIPO technical activities: Recommendation I provided that WIPO technical assistance would be, *inter alia*, development oriented, demand driven and transparent, taking into account the priorities and the special needs of developing countries, especially least developed countries as well as the different levels of development of Member States, and that activities should include a time frame for completion. In that regard, the Delegation underlined that the design of delivery mechanisms, and evaluation processes of technical assistance programs should be country specific. A model law was a delivery mechanism for technical assistance and, as such, a one-size-fits-all was not consistent with that Recommendation. The Delegation was of the view that the individual approach provided by WIPO working directly with the requesting Member States was important and effective. The Delegation strongly believed that the technical assistance provided by WIPO should continue to be demand driven, country specific, and should take into account the different levels of the development of the Member States. The Delegation further stated that recommendations 13 and 14 of the Development Agenda reflected the overall approach under which assistance must be demand driven, must be country specific, and must take into account the specific needs of developing countries and the different levels of development of the Member States. The Delegation considered that model laws were a blunt instrument that did not recognize those differences between Member States and between their different circumstances, such as their different levels of development. Accordingly, the Delegation did not support work at WIPO on developing new model laws or revising the existing Model Law on patents. It believed that resources were better used if they were spent to address member-specific needs and circumstances. In the Delegation's opinion, it would be a more effective if WIPO provided tailored technical assistance on legislative and policy matters directly to individual Member States at their request, taking into consideration the specific needs and circumstances of those states. The Delegation observed that such approach, unlike the model law approach, was also in line with the Recommendations of the Development Agenda calling for individualized assistance to the Member States. The Delegation stressed that development or revision of a model patent law, implied patent law harmonization, and such discussion would necessarily have to include harmonization of substantive patent law and of patent procedures. Therefore, the Delegation wondered whether the proposed revision by the SCP of the 1979 Model Law would address the harmonization of all elements of patent law, including harmonizing substantive aspects, such as examination of applications and rights granted by a patent,

since any work on harmonization should not be limited to only certain patent law topics to the exclusion of other topics.

175. The Delegation of Brazil, speaking on behalf of GRULAC, stated that with regard to the discussion on the usefulness of WIPO model laws for the work of the Secretariat, GRULAC understood that the Secretariat was in the best position to indicate whether the Model Law had been useful or not for its work either in capacity building or in other kinds of works. The Delegation added that in relation to the second part of the discussion, GRULAC believed that Member States could take the lead based on the discussions and inputs that would come from the Secretariat about whether it had been using the 1979 Model Law and whether it would be useful as a tool for transparency.

176. The Delegation of Romania, speaking on behalf of the CEBS Group, thanked GRULAC for its proposal to revise the 1979 WIPO Model Law for Developing Countries on Inventions. The Delegation noted that while the CEBS Group appreciated its elaboration, they were not able to respond at that stage to the questions submitted by Brazil, but would provide only a general view. The CEBS Group believed that such revision would be a complex exercise which would involve a complete revisiting of all relevant patent law topics. The Delegation recalled that it had to be kept in mind that important developments between 1979 and today such as the adoption of the TRIPS Agreement, needed to be taken into account. In terms of substance, the Delegation shared the view that a possible revision of the Model Law should not touch upon interpretation of the TRIPS provisions. The CEBS Group considered that it was an eventual prerequisite to agree on that principle before engaging on discussions of a possible revision. In the understanding of the Delegation, the GRULAC's proposal would contribute to the harmonization of substantive patent law.

177. The Secretariat noted that the initial Model Law of 1965 had been used during the first ten years in providing legislative assistance to Member States as a basic framework for advice. About ten years later, the need had been felt for a revision of that Model Law, in particular because of new developments appearing between 1965 and 1975 in the legislations of certain countries, which had made the Model Law totally obsolete. In that context, a Working Group had been established under the guidance of the WIPO Permanent Committee for Development Cooperation Related to Industrial Property, which had met several times from 1974 to 1979 until the process finished with a new revised Model Law of 1979. The Secretariat continued that the Model Law had been used during the 80s and 90s as an instrument when providing legislative advice. The Secretariat explained that the Model Law was divided into three parts, and had been used for different purposes. The first part included model provisions that dealt with all types of substantive patent law issues that normally were put in place in the legislation of any patent law of Member States, such as the patentability requirements, right to a patent, exceptions and limitations, scope of the rights, enforcement provisions, etc. The Secretariat continued that when it came to put in place a patent law or patent system in a given country, as had been indicated by the Delegation of the United States of America, that first part was normally used for those purposes. The Secretariat continued that the second part of the Model Law consisted of complementary (commentary) provisions to the model provisions and explanations about each provision, particularly giving alternative when different alternatives existed among various countries. The third part of the Model Law was mainly model regulations to implement the model provisions, which normally coincided with the implementing regulations that were put in place at the national level. The model regulations would normally be used when a given patent law had been already put in place. The Secretariat thus highlighted two elements of the Model Law: first, that the Model Law was a model, it was an instrument that was there for those that would like to follow it; and second, that the Model Law was a model for national laws, so it was used mainly for countries that did not have a law in place or for countries that decided to revise the law and then they used the model provision and the

commentary part of the law in order to better understand the better different alternatives - the law made distinction between those two situations, countries revising the law or countries putting in place a patent system for the first time. In response to the question about the use of the Model Law, the Secretariat stated that at the beginning it was actively used. The Model Law was going through different scholars that made comments on the legislations in place in different countries like Thailand, Malaysia, Indonesia, Sri Lanka, or Nigeria, which showed that when scholars made reference to the law in place, they would normally start making reference to how the law followed the Model Law. Therefore, the Model Law was an instrument that facilitated implementation of laws at the national level and at the same time that instrument was very useful in promoting harmonization, because the law of those jurisdictions looked very similar one to another. However, the Secretariat recognized that the utility of that Model Law in recent times was not that much, because as had been indicated, the Model Law was not updated. Particularly, recent developments, especially multilateral treaties such as the TRIPS Agreement, or treaties including those administered by WIPO like the PLT, were not considered. The Secretariat also noted that more recent trends in patent law neither were included in the Model Law such as the regulatory review exception (Bolar exception), which had been included in many national legislations recently. The Secretariat remarked that, therefore, when they provided legislative assistance, they did not use the Model Law instrument since it was out of date, but the assistance was bilateral, confidential, and demand driven.

178. The Delegation of Brazil, speaking on behalf of GRULAC, noted that after the intervention of the Secretariat, every Member State had more information and would be able to discuss and comment on the other two issues: whether and which parts of the Model Law should be changed because they were obsolete, and also, what they would like to see in the possible new model law, as the Delegation of the United States of America had expressed its view in a general way. The Delegation stated that after hearing all the comments, it would intervene to explain what GRULAC would like to see in the Model Law.

179. The Delegation of Australia thanked GRULAC for the proposal set out in document SCP/22/5. The Delegation also thanked the Delegation of Brazil for introducing the paper and for further clarifying matters, and providing the three questions they sought Member States to address in the forum. The Delegation clarified that it would first make a general intervention on this issue and then would provide Australia's views in view of previous interventions. The Delegation recognized certain interest in revising the Model Law provisions for developing and least developed countries. The Delegation however envisaged that a comprehensive root and branch review of the model patent law could be a large item of work. Further, the Delegation highlighted that such exercise would duplicate many of the issues that were, in fact, on the agenda of the Committee which Member States failed to reach agreement on at any stage in the proceedings. In that context, the Delegation proposed to seek further information before actually deciding on the GRULAC proposal, in particular, information on experiences of how developing and least developed countries had implemented aspects of the Model Law over the preceding years. The Delegation suggested that, armed with information about how the Model Law had been used or had been implemented, or alternatively, what was the unmet need for the Model Law, the Committee could make an objective decision about what extent of resource it should place in revising the Model Law at that particular point in time, given the flux of actions that had occurred since 1979. In that context, the Delegation asked the Secretariat to prepare a written study on the experiences of how developing countries and least developed countries had implemented the model patent law and any issues that had been encountered and the extent of unmet needs. The Delegation continued that, should any model law be discussed in that forum or any other forum, Australia would exercise its right at that time to address the issues that it believed were important, such as grace period, client attorney privilege, etc. In its view, any model law would be wholesome for any country to use and properly deal with

all the issues set out in a patent law. While the Delegation appreciated the efforts made by GRULAC, it believed that the Delegation did not have sufficient information to adopt the recommendation from GRULAC, and thus proposed to gain further information from the Secretariat before making a decision on the specific proposal. In light of the information provided by the Secretariat, the Delegation understood that because the Model Law was fairly outdated and other developments had taken place, there had not been much use of the Model Law over the preceding years. Thus, the Delegation asked the Secretariat to gauge the unmet need from developing or least developed countries, which might give an indication as to the level of resource that would be put into that endeavor before the Committee decided whether to embark on that trek or not, since that could be a long and difficult road and possibly be duplicative of all the other things that the Committee had been discussing.

180. The Delegation of Luxembourg, speaking on behalf of the European Union and its Member States, clarified that they would make a general statement without taking the recent interventions into account. The Delegation thanked GRULAC for its proposal to revise the 1979 WIPO Model Law for Developing Countries on Inventions. In the Delegation's view, the proposal would lead to the harmonization of patent law and would also overlap with items on current work program, such as exceptions and limitations. On a substantive note, the Delegation emphasized that WIPO should not touch upon the interpretation of the TRIPS provisions. The Delegation stated that while it fully understood the importance of assistance in the area of patents, such assistance had been already provided by the Secretariat, taking into account the specific country needs and situation. The Delegation considered that such approach was much more comprehensive than a simple application of the Model Law. Furthermore, the Delegation remarked that, so far, it had not heard any convincing argument about the need to revise the Model Law.

181. The Delegation of India suggested that the work of the Committee for the twenty-third session be confined to fact finding and not lead to harmonization at the current stage. With respect to the proposal by GRULAC (document SCP/22/5), the Delegation believed that any revision of the 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.

182. The Delegation of Iran (Islamic Republic of) thanked the Delegation of Brazil for presenting the proposal on behalf of GRULAC. The Delegation stated that it could go along with the proposal to revise the WIPO model patent law for developing countries. The Delegation believed that that revision should be development-oriented and the revision should be in line with the Development Agenda Recommendations. The Delegation considered that, as the Delegation of India had mentioned, such revision should provide legislative and policy options for developing countries to utilize the flexibilities envisaged in the TRIPS Agreement. The Delegation further noted that it was imperative that the countries codifying their national law on the basis of development concerns, such as developing countries, use WIPO model laws as a complementary tool. The Delegation stated that the model provisions would not be translated directly into national law, but they would be adapted in accordance with the national requirements. The Delegation therefore was of the opinion that a model law for developing countries was not a one-size-fits-all.

183. The Delegation of the United States of America expressed its appreciation to the Secretariat for its explanation as to the harmonization effect of model laws. As pointed out by the Delegation of India, the Delegation noted that the Committee had been working on an understanding without prejudice to the mandate of the Committee, that the work would be confined to fact finding and not lead to harmonization at that stage. The Delegation continued that, as the Secretariat had explained, model laws did however lead to harmonization. Thus, in order to have a better discussion of future work, the Delegation

considered that it would be helpful to understand if GRULAC was considering reverting to the work of the mandate of the Committee, which could lead to harmonization.

184. The Delegation of Belarus, speaking on behalf of CACEEC, considered that it would be wise to carry out further discussions in order to reach a more developed understanding of the issues so that the goal, tasks and the proposed results would be clearly defined.

185. The Delegation of China welcomed and appreciated the GRULAC proposal in document SCP/22/5. In its view, revision of the 1979 Model Law could be useful in providing policy and legislative assistance. As to the detailed questions proposed by the Delegation of Brazil, the Delegation thought that it still needed some time to reflect on the question and prepare a reply, and expressed its intention to share its views at the later stage. The Delegation suggested that the Secretariat listen to opinions and views from all Member States, particularly views from developing countries on the need of the Model Law if it would prepare a document that would become the basis for discussion by Member States.

186. The Delegation of South Africa, speaking on behalf of the African Group, thanked GRULAC for the proposal on the revision of the 1979 Model Law for Developing Countries on Inventions. As a region comprising several developing countries, the African Group saw a merit in the proposal which sought to update and incorporate recent changes in the multilateral legal framework. The Delegation stated that the African Group looked forward to further discussions on that proposal in the Committee.

187. The Delegation of Spain thanked GRULAC for the submission of its proposal, which took use of the normative nature that the Committee had in the elaboration of patent law. The Delegation noted that revising the Model Law meant that it would be necessary to use a tremendous amount of resources. Therefore, the Delegation said that it would like to receive more information from GRULAC or the Secretariat as to how the different countries had applied the Model Law, and specifically, the procedure that would be followed for its drawing up, the necessary resources and time for the revision and all the details, when possible. The Delegation also pointed out that drawing up a model law would make the Committees return to discussions on patent law, and in its view, there should be the elements of substantive law included in the revision as well, which were of interest of all Member States.

188. The Delegation of Brazil, speaking in its national capacity, singled out some elements on the need to the update of the obsolete 1979 WIPO Model Law. The Delegation highlighted that the text in the Model Law made distinctions between technological fields, admitting exclusion of certain matters, while under the current international legal framework, in principle, patents were granted for inventions in all fields of technology according to the TRIPS Agreement. The Delegation further noted that the text of the Model Law indicated that the term of patent protection should be 15 years. The Delegation also noted that the part of the Model Law that dealt with limitations of patent rights did not address important issues for developing and least developed countries, such as exceptions and limitations that could facilitate the entry of generic drugs in the market, the so-called Bolar exception, was not included in the Model Law. Furthermore, the Delegation considered that the part that dealt with licenses also needed to be updated, since it did not include a number of measures to be taken by countries to make use of that instrument. Thus, the Delegation believed that those examples made clear that the Model Law was not an updated document. Finally, as mentioned by other developing countries, the Delegation understood that the text should address TRIPS flexibilities, providing policy options for developing countries.

189. The Delegation of Paraguay stated that in its understanding, the possibility of harmonization through the Model Law, described by the Secretariat, was something that had occurred in cases where different countries had taken into account the Model Law. In its

view, it was something accidental, and not that the Model Law was going to lead to harmonization. Taking into account the fact that that was a non-binding soft law instrument, the Delegation thought that it was very difficult to understand how the revision of the Model Law could interpret the TRIPS provisions. The Delegation considered that that was not a sound valid argument. With regard to legislative assistance, the Delegation noted that that was an activity which was undertaken on a bilateral basis and in a confidential manner. Thus, the Delegation underlined that if Member States were going to carry out an exercise for the revision of the Model Law where all could participate, that would ensure transparency and would allow countries to know exactly what the Secretariat based itself on when it carried out legislative advice.

190. The Delegation of Trinidad and Tobago explained that looking at the issue in a holistic manner, the development of a Model Law was oriented to the law reform commission in the jurisdiction of a developing country or LDC that wished to introduce patent law or to reform or update their patent legislation. The Delegation considered that there had been a consensus that the Model Law was obsolete, and thus any law reform commission in the jurisdiction of a developing country or LDC might not be obliged to look at the 1979 WIPO Model Law. The Delegation observed that rethinking the whole issue of the Model Law should provide policy guidance towards development of activities on legislative assistance. The Delegation supporting the Delegation of China, noted that the SCP could collect views from developing countries and LDCs regarding the areas to be reformed with respect to WIPO Model Law. The Delegation thought it would be pertinent to go through that process in a very incremental manner. The Delegation suggested that that process be about Member States asking themselves what they would like to see in the Model Law.

191. The Secretariat noted that one element for consideration was access to the Model Law. The Secretariat explained that since the WIPO Model Law provisions were not meeting multilateral standards, particularly the TRIPS Agreement, the Secretariat found difficulty giving away a copy of the Model Law for fear of misleading the recipients, even if it was still a WIPO publication. The Secretariat observed that the Model Law had been used in an appropriate manner in many occasions: for example, the case law of the report of the WTO panel in the case of Canada's patent protection of pharmaceuticals relied on certain provisions of the Model Law that were still valid. The Secretariat however remarked that a number of provisions were no longer applicable because of new developments or entry into force of new treaties: for instance, Section 118 on temporary exclusion went against Article 27 of the TRIPS Agreement according to which what could be excluded from patent protection was more limited; or Section 131(a) concerning the filing date, which was not in line with neither the PCT nor the PLT; or Section 138 on the duration of patent protection (15 year that could be extended for five more years), which had been established by the WTO panel that it had been against the TRIPS provision. On the other hand, the Secretariat pointed out that the Model Law also had a set of provisions that looked extremely close to the TRIPS Agreement, and some provisions of the TRIPS Agreement had gotten inspiration from the Model Law. Therefore, the Secretariat noted that the main difficulty was to identify which of those provisions and which of those commentaries were still valid and which were no longer applicable.

192. The Representative of KEI encouraged the SCP to engage and support the GRULAC proposal on a revision of the 1979 WIPO Model Law for Developing Countries on Inventions. In the Representative's view, the GRULAC proposal to produce a revised WIPO Model Law in the post-TRIPS context was a serious effort to improve technical assistance and to take stock of and shape new global norms regarding patents. He noted that in a post-TRIPS world with countless bilateral trade agreements relevant to patent law, the challenge was to provide more concrete implementation of promises and obligations for technology transfer, development, and access to medical technologies, in the context of other obligations that

may be relevant in trade agreements. The proposal challenges WIPO and its members. The Representative stated that GRULAC had proposed a transparent process that would be a welcomed alternative to secret and non-inclusive regional and bilateral trade agreement norms on patent policy: the GRULAC proposal requested the Committee to recommend allocating the funds necessary to carrying out a revision of the Model Law in the 2016/17 program and budget and to prepare for the twenty-third session of the SCP a proposal for consideration of the Member States on the terms of reference and modalities that such a revision could follow. The Representative suggested that perhaps that process could begin with a scoping study to ascertain the feasibility of producing an update to the Model Law and a proposal of topics that such a Model Law could address. He recalled that in the 1970s revision, WIPO, after consultation with interested governments, appointed experts from governments, intergovernmental organizations, and NGOs, who acted in their personal capacity to serve on the Working Group that drafted the 1979 Model Law. He continued that the 1979 Model Law now included 12 chapters and 164 sections covering a very wide range of topics, including, for example, novelty, inventive step, industrial application, both voluntary and non-voluntary licenses, government use, ownership of patents, fees, remedies for infringement, and dozens of other revisions. In his view, a revision should not only include revisions of the topics covered in those 164 sections, but should also address new issues. The Representative considered that as a soft instrument making proposals without binding obligations, the new model law could be more innovative than a text bound by the contours of existing state practice.

193. The Representative of TWN congratulated GRULAC for tabling the proposal on a revision of the WIPO Model Law. The Representative noted that the 1979 WIPO Model Law was not suitable to address the development concerns in the area of TRIPS Agreement. Further, she said that the model did not use the public interest flexibilities available in the TRIPS Agreement, for instance, the Model Law failed to use flexibilities to determine the scope of those flexibilities; and similarly, the provisions in granting compulsory, non-voluntary licenses were very limited. In TWN's view, the WIPO Model Law was not suitable to address the present challenges for Member States, especially developing countries, but also went against the spirit of the Development Agenda. The Representative understood that the Secretariat was using a version of the Model Law which was not available in the public domain, and which lacked flexibility since such confidential version of the Model Law went against the spirit of the Development Agenda. Thus, TWN appealed to Member States to ensure the transparency provided by WIPO by revising the WIPO Model Law based on the proposal by GRULAC.

194. The Chair concluded that the Model Law contained some provisions that were obsolete but some other provisions that were still actual. She recalled that access to the Model Law for consultation was still required in some instances, and that when access was required, the Secretariat found difficulties since some provisions might be misleading. In the Chair's opinion, discussions on the GRULAC proposal were well started and it had been useful to have the explanation of the Secretariat with regard to the Model Law. The Chair invited Member States to reflect on the discussion as well as on the explanation given by the Secretariat and to continue discussing the issue at the next session.

AGENDA ITEM 8: FUTURE WORK

195. The Delegation of Japan, speaking on behalf of Group B, supported the continuation of works on the five issues in the agenda of the Committee. The Delegation reiterated the importance that Group B attached to, in particular, the quality of patents and patent-attorney privilege. The Delegation strongly expected that meaningful and substantive items for the future work under those items could be agreed by all Member States at the end of the

session. The Delegation then touched on future works mentioned by some groups or delegates in the context of discussions on the specific five items. First, with regard to the idea of preparing a manual on limitations and exceptions in an isolated manner from the principle of patent protection, the Delegation stated that limitations and exceptions were options which could be justified only in specific and limited occasions within the whole context of patent protection. Therefore, Group B did not think that that was the appropriate way forward for the Committee. The Delegation considered that limitations and exceptions should not be evaluated from the perspective of development in a one-size-fits-all manner. Second, the Delegation noted that disclosure of origin or source was completely different from the sufficiency of disclosure, which was the subject matter of the study presented by the Secretariat. In its view, the requirement of the sufficiency of disclosure was supported by the fundamental principle of the patent system of granting an exclusive right in return to the contribution to the society in light of the technical development, but that was not the case with the disclosure of origin or source. Third, the Delegation believed that the disclosure of INN would just overburden the applicants and IP offices, and it could not see the justification through the study and discussion at the last session of the SCP. It therefore considered that further work on that issue should not be done. Finally, with respect to studies on Markush claims, Group B could not see any justification to discuss that topic in the context of patents and health.

196. 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. The Delegation considered that the current five agenda items reflected different priorities and were of utmost importance to maintain the balance. Concerning the proposal by GRULAC, the Delegation referred to its earlier statement. In relation to the other topics, the Delegation reiterated its point of view as expressed during the previous SCP session in November 2014. In reference to quality of patent, the Delegation stated that the work program should be 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 Delegation of Spain as endorsed by all other Member States of the European Union (document SCP/19/5 Rev.). The Delegation was also in favor of launching a questionnaire containing the elements of all the proposals by the Delegations of Canada, the United Kingdom, Denmark, and the United States of America. As regards opposition systems, the Delegation said that the elaboration of a compilation of models of opposition systems and other administrative revocation and invalidation mechanism systems in a non-exhaustive manner should be considered. On work sharing programs, the Delegation was of the view that a dedicated page on the WIPO's website for work sharing activities would improve awareness of existing initiatives and enable patent offices to collaborate more effectively. Furthermore, conferences on the margins of the SCP sessions would allow for the exchange of experiences on work sharing programs and explore ways to improve the usefulness of those programs to IP offices, to users of the IP system and to the general public. The Delegation suggested that a study by the Secretariat on how different laws and practices limit potential for work sharing and how 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. The Delegation pointed out that given the optional nature of the scheme, any efforts to improve the quality and efficiency of the patent system should not be hindered. As regards the topic of patents and health, the European Union and its Member States reiterated their understanding of the challenges and the constraints that certain countries might face in handling public health problems. The Delegation emphasized that the mere existence of IPRs on a product was not a barrier to, nor its absence a guarantee of, access to that product. The Delegation believed that any further work in that area should reflect a balanced approach taking into account the various interfaces and factors that were relevant to patents. In that regard, the Delegation concurred

with the proposal by the Delegation of the United States of America in document SCP/17/11. In relation to confidentiality of communications between clients and their patent advisors, the Delegation reiterated its statement made earlier in the session that the time was ripe to consider a concrete mechanism to address the recognition of foreign patent advisor's privilege. Without prejudice to existing national legislation and in order to ensure optimal flexibility, the Delegation considered that a soft law approach should be considered, aiming at offering, under applicable national law, the same protection to communications between a client and its foreign patent advisors and to communications between a client and its national patent advisors. The Delegation remained convinced that the convergence of existing diverse systems in the area of confidentiality of communications between clients and patent advisors among Member States would be beneficial for users of the patent system irrespective of the level of development of each country. On the topic of transfer of technology, the Delegation stressed that until completion of the CDIP's "Project on Intellectual Property and Technology: Common Challenges-Building Solutions", new initiatives should not be launched within the SCP on that topic. As regards exceptions and limitations, the Delegation believed that although limited and specific limitations and exceptions were justified, evaluation of their impact on development by the Secretariat and the preparation of the manual under the name of WIPO was not the way to go forward. The Delegation observed that patent rights should maintain an appropriate balance between the interests of right holders and the general public, thus neither exclusions from patentability nor exceptions and limitation to patent rights should be discussed without the corresponding legal standards used to determine whether an invention was patentable, such as novelty, inventive step, and industrial applicability. The Delegation expressed that it looked forward to constructive discussions and remained committed to contributing to establish a well-balanced program.

197. The Delegation of Romania, speaking on behalf of the CEBS Group, expressed its strong belief that a balanced work program that addressed the concern of all Member States could be achieved. In the Delegation's view, the primary objective of the Committee was to advance discussions on the quality of patents and substantive patent law issues, which was at the core of the SCP agenda. Based on the studies undertaken so far and the debates that had taken place, the CEBS Group shared the view that work on concrete steps to increase the quality of patents would be necessary for the benefit of all Member States. The Delegation reiterated its support to the launching of a questionnaire on the quality of patents. With regard to work sharing, the Delegation supported the proposal of a study to be prepared by the Secretariat on how different laws and practices limit the potential for work sharing. As an alternative, the CEBS Group would be interested in the elaboration of a handbook on best practices by the Secretariat together with IP offices involved in work sharing, which could provide recommendations aimed at avoiding difficulties resulting from different laws and practices. In relation to the confidentiality of communication between clients and patent advisors, the Delegation reiterated its support to adopting a soft law approach, and for a study to be conducted by the Secretariat to describe various types of soft law approaches in that area. With regard to other proposals, the Delegation said that the CEBS Group needed more time to consider them, and restated that in relation to exceptions and limitations, the CEBS Group would like to see comparable progress being made on substantive patentability criteria. Further, the Delegation stated that the CEBS Group was not convinced of the added value of a manual on exceptions and limitations to the documentation already prepared on that topic.

198. The Delegation of Belarus, speaking on behalf of CACEEC, expressed its support to the continuation of work on all issues on the agenda. The Delegation stated that CACEEC supported the issue of practical application of the requirements of inventive step and sufficiency of disclosure in various jurisdictions in the future work of the Committee. The Delegation also supported to include in future work the preparation of a study on prior art,

and in particular on grace period as proposed by the Delegation of Spain. Finally, in order to ensure access by a broader range of specialists in that area in the CACEEC region, the Delegation requested the Secretariat to provide full translation into Russian language of the two studies provided at the session.

199. The Delegation of India reiterated its belief that the future work of the Committee should be confined to fact finding and not lead to harmonization at that stage. Under exceptions and limitations, the Delegation proposed that the Secretariat prepare a study on the use of exceptions such as compulsory licensing, parallel imports or government use. The Delegation also proposed the preparation of a study analyzing various impediments in licensing agreements relating to the transfer of technology in greater detail. The Delegation said that a further study on the question of use of the patent system for fulfilling the need of developing countries from the perspective of accessibility and affordability of medicines and the socioeconomic growth and development, as well as a study on the impact of exceptions and limitations on the socioeconomic development of the countries in view of the documents SCP/21/3 to SCP/21/6, should also be considered. With regard to quality of patents, the Delegation believed that work sharing should not become an area in future work and that a study on quality of patents *vis à vis* sufficiency of description should be considered. On patents and health, the Delegation suggested that a further study to amend or revise document SCP/21/9 by studying the question of usefulness or advantage of mandatory disclosure of INN in the patent specification should be considered. The Delegation also proposed a study on the Markush formulae and the impediments created by them in the healthcare industry by creating mysterious cobwebs of compounds to be discovered in the future, thus stifling innovation. In relation to technology transfer, the Delegation stated that a study on transfer of technology *vis à vis* sufficiency of disclosure (SCP/22/4), and also a study on the role of the patent system as a standalone system in which the transfer of technologies was affected by the patent system independent of any know-how or show-how, should be considered.

200. The Delegation of France supported the statement made by the Delegation of Luxembourg on behalf of the European Union and its Member States, as well as that of Group B regarding future work. Concerning future work for the issue of quality of patents, the Delegation reiterated its support for the drawing up of a compilation of the different opposition systems and other existing procedures for invalidation of patents, since those systems played an important role in the quality of patents and it would be easy to set up those procedures.

201. The Delegation of Brazil, speaking on behalf of GRULAC, restated the points and suggestions that it had presented during the session. The Delegation also restated the proposals from GRULAC, most of which were included in the documents that had been presented at the twenty-second session or earlier so that Member States could analyze and comment on them. With regard to exceptions and limitations, the Delegation asked the Secretariat to prepare an analysis of the exceptions and limitations that had proven effective to address development concerns, and based on that analysis, prepare a non-exhaustive manual on exceptions and limitations as a reference to Member States of WIPO. Regarding the WIPO Model Law, the Delegation requested the Secretariat to prepare for the twenty-third session of the SCP a proposal for Member States with the terms of reference and modalities that such revision of the Model Law could follow. The Delegation stated that GRULAC also supported new joint efforts related to the discussion of topics of patents and health and technology transfer. However, the Delegation said that it would need more time to appreciate and to discuss within the Group the new proposals that had been made during the week, and also requested Member States, if possible, to present them before the next meeting so that experts who would come to Geneva could already be prepared to discuss those new ideas.

202. The Delegation of South Africa, speaking on behalf of the African Group, recalled that at the sixteenth session of the SCP in 2011, the African Group and DAG had submitted a joined proposal contained in documents SCP/16/7 and 7 Corr. aimed at enhancing the capacity of developing and least developed countries to adopt their patent regimes to make full use of the flexibilities in the international patent system to address public policy priorities related to public health. The Delegation pointed out that there were three interlinked elements to be pursued, i.e., studies, information exchange, and technical assistance activities. The Delegation looked forward to operationalizing or undertaking future work on one of those elements.

203. The Delegation of Mexico expressed its interest in the future work of the Committee. As part of the future work, the Delegation suggested to consider the work sharing initiatives between patent offices. In that regard, the Delegation expressed its willingness to make a brief presentation of IMPI's cooperation system CADOPAT, which was an example of the facilitation of work and cooperation amongst different patent offices. The Delegation explained that the system offered technical support in questions related to patents to Central American, Caribbean and some African countries. The Delegation noted that it was non-binding, and support was provided in compliance with the national legislation of each of the participating countries.

204. The Delegation of the Republic of Korea recalled its proposal with regard to work sharing between the offices in order to improve efficiencies over the patent system. Regarding future work, the Delegation noted that from the perspective of a balanced approach on the agenda and the productivity of the Committee, although other issues including limitations and exceptions or patents and health were important, the creation of an efficient and stable procedure for the implementation of the patent laws were also important. The Delegation supported the suggestion made by the Republic of Korea, the United Kingdom and the United States of America with regard to the quality of patents and for improving the efficiency of the patent system, including creating a page on the WIPO's website on work sharing and the collective activities. With regard to the confidentiality of communications between clients and their patent advisors, the Delegation suggested that a study on the possible contents of the model provisions regarding the confidentiality of the communications be included in the future work.

205. The Delegation of Iran (Islamic Republic of) stressed that it could not go along with some proposals on the confidentiality of communications and that the Delegation preferred to take out that item from the SCP agenda. The Delegation also noted that neither could it go along with some proposals on work sharing. Finally, the Delegation expressed its support to the inclusion of some proposals made by the Delegations of India and South Africa on the issue of public health in the future work program.

206. The Chair submitted her suggestions on the future work of the SCP. Following the consultations with the regional group coordinators, the Chair submitted a revised proposal regarding the future work of the Committee. After the consultations with the regional group coordinators, the Chair stated that a number of regional groups as well as individual delegations had expressed many good ideas for the future work. Noting that it had been difficult to pick and choose among them in order to propose a reasonable and concise future work of the Committee with a fair balance against many different viewpoints, she thanked all regional groups and delegations that had made active and constructive input to her proposal. The Chair said that she and the regional group coordinators had tried to strike the right balance to reach consensus. The Chair stated that while each group had said that the proposal had been imperfect and it had wished to have a slightly more favorable balance toward it, six regional groups had indicated their acceptance of the latest Chair's proposal.

207. The Delegation of Pakistan, speaking on behalf of the Asia and Pacific Group, noted that the proposal was not perfect, and different Member States of its group had varying degrees of concern about different agenda items, in particular, the agenda items regarding confidentiality of communications with patent advisors and transfer of technology. The Delegation further expressed its wish to add the aspect of the sufficiency of disclosure in a half-day seminar under the “quality of patents”. Despite the significant concerns of the Asian Group, the Delegation stated that its Group had felt that the Chair’s proposal was the best way forward for continuing the work of the Committee. The Delegation said that, in the spirit of constructive engagement and flexibility, the Asian Group had decided to accept the proposal as it stood, since it was the least common denominator that the Committee could have. The Delegation expressed its hope that the flexibility that it had shown would be reciprocated by other groups.

208. The Delegation of Brazil, speaking on behalf of GRULAC, stated that its Group had placed significant importance on the issues regarding the exceptions and limitations to patent rights and the update of the 1979 WIPO Model Law on Inventions. Recognizing all the efforts that had been put in the preparation of the Chair’s proposal to reach a balance, the Delegation stated that, even though members of GRULAC were not happy with the proposal, GRULAC could accept, in the spirit of compromise, the Chair’s proposal in order to have a future session of the SCP.

209. The Delegation of Nigeria, speaking on behalf of the African Group, noted that, with reference to the informal consultations with the Chair, all regional group coordinators had felt that the Chair’s proposal had not been the most ambitious one, but had seen the efforts the Chair had made to find the common denominator that could meet the support of all groups. Therefore, while nothing was agreed until everything was agreed, the Delegation stated that the African Group demonstrated flexibility in accepting the Chair’s proposal on future work without any further changes to its final proposal. It observed that any change to the proposal would unravel the whole effort. The Delegation expressed its hope that the group that had not accepted the Chair’s proposal yet would allow the Committee to work forward in a future session of the SCP.

210. The Delegation of Japan, speaking on behalf of Group B, expressed its appreciation for the Chair’s tireless effort to find a solution which tried to accommodate interests and concerns expressed by all groups. The Delegation stated that Group B would like to have a work program for the next session in order to let the Committee function according to its mandate: to discuss the substantive patent law. The Delegation explained that Group B had had a number of concerns regarding the original version of the Chair’s proposal due to the low ambition found in the activities under the agenda item “quality of patents”, which was the priority for Group B. The Delegation further stated that Group B, however, made a decision to accept the Chair’s original proposal as a package with the strong feeling that the Committee should have future work for the next session of the SCP. It indicated that Group B had showed the maximum flexibilities at that point, even though it had felt that the proposal had not been balanced and the level of ambition relating to its priority had been very low. The Delegation considered that the latest Chair’s proposal had shifted the balance further away from the interest of Group B. The Delegation reiterated that, in view of Group B, the Committee should have its future work for the next session of SCP in order to let the Committee advance. From that perspective, the Delegation proposed two amendments to the present Chair’s proposal. First, the Delegation suggested that, with respect to transfer of technology, the second activity found in the original Chair’s proposal, i.e., based on Member States contribution, the Secretariat would compile information on national/regional regulations, guidelines, practices and jurisprudence regarding licenses, to be submitted to SCP/24, be reintroduced. In its view, licensing agreements are the core part of transfer of technology that would bring benefits to all Member States, and without that item, the agenda

relating to transfer of technology would not advance sufficiently as it should. The Delegation further stated that, recognizing the concerns that some delegations had had expressed, Group B would accept the deletion of the word “voluntary” preceding the word “license”. Second, the Delegation proposed that, in relation to a half-day seminar regarding patents and health, the text found in the original Chair’s proposal “a half-day seminar on the relationship between patent systems and availability of medicines” be reinstated. The Delegation considered that the original proposal had struck the right balance, since the words “availability of medicines” could shed light on various aspects, including benefits and challenges derived from patent systems. In its view, as an explicit reference to challenges only would miss the neutrality of the seminar. The Delegation therefore suggested that the word “benefits and” be inserted before the word “challenges”. The Delegation expressed its belief that its request was legitimate and fair to accommodate concerns and interests expressed on various aspects from various members. It stated that with those amendments and without bringing in any further changes, Group B could accept the Chair’s proposal. The Delegation reiterated that Group B was ready to accept the Chair’s original proposal as it was for the sake of compromise and for the purpose of having complete future work for the next session.

211. The Delegation of China stated that it welcomed and accepted the Chair’s proposal, and thanked the Chair for her effort. With respect to the exceptions and limitations to patent rights, patents and health and transfer of technology, the Delegation expressed its satisfaction that the work in all those areas had seen the progress. Regarding the quality of patents, the Delegation considered that the experience and information sharing could be helpful to all countries. Concerning the confidentiality of communication between clients and their patent advisors, the Delegation was of the view that it was not appropriate to discuss it at the SCP. However, in view of the concerns raised by other members on the subject, in order to keep a balance and to take into account all the concerns, the Delegation wished to show its flexibility, and demonstrated its open attitude.

212. The Delegation of Romania, speaking on behalf of the CEBS Group, thanked the Chair for her significant efforts to identify common ground on the future work. The Delegation stated that the CEBS Group placed great importance on the work of the SCP. While noting that the CEBS Group had interest in some topics than others, the Delegation considered that the Committee could pursue its work only if all interests were accommodated. The Delegation said that unlike movie directors who could work with surreal scenarios, diplomats had to work with realistic solutions. From that perspective, the Delegation indicated that the CEBS Group had been able to accept the Chair’s original proposal, and had showed flexibility for accommodating other Groups’ concerns in the discussions that had followed. While noting that the latest proposal by the Chair was not fully satisfactory to the CEBS Group, the Delegation stated that its Group could accept it in order to continue the work of the SCP. The Delegation acknowledged that the Chair’s present proposal was still not acceptable to all delegations. It therefore presented the plea of the CEBS Group for all delegations to continue to show flexibility in order to successfully conclude the present session of the SCP.

213. The Delegation of Belarus, speaking on behalf of CACEEC, thanked the Chair for her efforts, and expressed its wish that the present session of the Committee would reach a positive conclusion. The Delegation stated that, with that in mind, CACEEC had been flexible and had been ready to accept the Chair’s original proposal as well as the present proposal, despite the fact that the Group had had some wishes and recommendations to make. The Delegation expressed its hope that other Groups would also show some understanding and flexibility in order to avoid delegations leaving the present session of the SCP empty-handed.

214. The Delegation of India stated that it understood the challenge faced by the Chair of maintaining a delicate balance for keeping all the concerns of Member States. The Delegation appreciated that the future work of the Committee would be confined to be fact-finding and not led to harmonization. It noted that, on the specific proposal for future work, the Delegation would have ideally liked to have the following to be part of the future work: (i) a sharing session on the sufficiency of disclosure should also be considered under the agenda item, quality of patents, because the two studies regarding inventive step and sufficiency of disclosure had been discussed in the SCP/22; (ii) the Delegation desired to have continuation of the study on INN, because, in its view, document SCP/21/9 needed further amendments; (iii) the Delegation wanted a study on the Markush formulae and the impediments created by them towards affordability of essential medicines in developing countries and LDCs, thereby adversely affecting access to the public health care; and (iv) the Delegation also wanted a study in place of a mere discussion on the issue of transfer of technology *vis-à-vis* sufficiency of disclosure. Further, the Delegation would have liked to discontinue discussion on the issue of client-attorney privilege, because that was the issue of substantive nature and could be governed by the applicable national law of respective Member State. The Delegation, however, was aware that Member States had their own strong positions on specific issues mentioned in the Chair's proposal. Therefore, keeping in mind the spirit of multilateralism and building a constructive consensus among the Member States for the continuous engagement in the Committee, the Delegation stated that it would be comfortable with the latest proposal by the Chair. The Delegation expressed its hope that other members would show the desirable flexibility and reciprocate its gesture so that the Committee could arrive at a concrete proposal for the 23rd session of the SCP.

215. The Delegation of the United States of America aligned itself with the statement made by the Delegation of Japan on behalf of Group B. Noting that having a balanced agenda had been a long-standing goal for the SCP, the Delegation sought continuation of that trend. The Delegation explained that Group B had requested only small changes, which were the reintroduction of the texts found in the Chair's original proposal. In its view, the request from Group B had added nothing new to the present Chair's proposal. With respect to the future work on patents and health, the Delegation stated that, in order to prevent the seminar from being prejudiced before being organized, not only challenges but also benefits of patent systems to availability of medicines should be mentioned in the title of the seminar. Concerning transfer of technology, the Delegation noted that, since licenses were an important tool for technology transfer, the Committee should look at licensing and the effects of licensing on technology transfer as part of the work of the Committee.

216. The Delegation of Iran (Islamic Republic of) expressed its appreciation to the Chair and regional group coordinators for their dedication and tireless efforts. The Delegation stated that it could go along with the latest version of the Chair's proposal for the sake of compromise and moving forward. It observed that multilateralism required a room for taking and giving, and that it was difficult to satisfy all members and accommodate all positions. The Delegation nevertheless raised its concern on the two issues, namely, work sharing and confidentiality of communications with patent advisors. In its opinion, they were outside the mandate of WIPO and of the SCP.

217. The Delegation of Switzerland thanked the Chair for her great work and leadership in guiding the Committee through the work program discussions. The Delegation noted that as it attributed much importance to the work of the SCP, it regretted deeply that the Committee had not been able to reach an agreement at the previous session of the SCP. In its view, it was very important to reach an agreement at the present meeting. The Delegation expressed its confidence that delegates would work with an open and constructive spirit to come to a positive end of the session. The Delegation however supported the concerns that had been expressed by the Delegation of Japan on behalf of Group B. It stated that the

Delegation would be very interested in having discussions on licensing agreements in the context of technology transfer, which was the subject of interest of many delegations. In its view, voluntary license agreements were at the core of technology transfer, since they allowed patent holders and third parties to engage in technology transfer in a spirit of positive, mutual cooperation. The Delegation therefore considered that more information on national and regional implementations of such licenses and cases might be useful in order to understand challenges and opportunities of voluntary licenses or licensing agreements in general. It expressed its belief that there were many important undiscovered areas in that topic that should have been revealed. Noting that some delegations had a concern with the term “voluntary” in the relevant paragraph contained in the first Chair's proposal, the Delegation explained that the Group B's proposal, which had not been opposed by other delegations so far, did not contain the word “voluntary”. The Delegation expressed its hope that it was acceptable for all Member States and the meeting would come to a positive end.

218. The Chair asked the Committee whether there was consensus to adopt the Chair's proposal as amended by Group B.

219. The Delegation of Brazil, speaking on behalf of GRULAC, stated that since the Chair's proposal had been understood as a package, it could not accept going back to drafting exercise.

220. The Delegation of Japan, speaking on behalf of Group B, said that the first proposal by the Chair was a package for Group B. It stated that while Group B had exhausted its flexibility with the first proposal by the Chair, it had engaged in the further discussions in order to have future work for the next session. The Delegation, therefore, asked other groups to continue to engage in the exercise and to consider the proposal by Group B from the substantive perspective. The Delegation invited other groups to express any substantive concerns on the amendments proposed by Group B.

221. The Delegation of Pakistan, speaking on behalf of the Asia and Pacific Group, noted that many Member States had felt that their concerns had not been reflected fully in the Chair's proposal. In its view, if the possibility of modification of the text would be kept open, other delegations would also keep on coming with their proposals without any end in sight. The Delegation stated that while it respected the position of Group B and they must have substantial reasons for their concerns, multilateralism was about living with the bare minimum. The Delegation therefore seriously entreated the Member States that had concerns to see if they could show flexibility.

222. The Delegation of Nigeria, speaking on behalf of the African Group, stated that there had been a lot of flexibility demonstrated in between the informal consultations and a lot of give and take had been made. The Delegation reiterated that the African Group had agreed to have the package proposal that could meet the barest minimum that was acceptable to everyone. It noted that as the African Group had had concerns about different aspects of the Chair's latest proposal, it would be counterproductive to open the text. The Delegation, therefore, encouraged Group B to reconsider their positions and accept the Chair's latest text for moving forward. The Delegation acknowledged the pressure the regional group coordinator must have been facing, since all regional group coordinators had that in their individual groups to agree to accept the text to move the process forward.

223. The Delegation of Japan, speaking on behalf of Group B, reiterated that its proposal had not introduced new elements and changes to the original Chair's proposal.

224. Having heard the comments from the regional group coordinators and individual delegations, the Chair asked delegations whether there was a consensus to adopt the

proposal by the Chair without the amendments presented by Group B.

225. The Delegation of Pakistan, speaking on behalf of the Asia and Pacific Group, stated that the members of its Group would be willing to accept the Chair's revised proposal, as it stood without any further amendments.

226. The Delegation of Brazil, speaking on behalf of GRULAC, stated that the Member States of its Group supported the revised proposal by the Chair, as it stood.

227. The Delegation of Nigeria, speaking on behalf of the African Group, stated that the African Group supported the Chair's revised proposal.

228. The Delegation of Indonesia supported the statement made by the Delegation of Pakistan on behalf of the Asian Group. The Delegation considered that the Chair's revised proposal was balanced. It noted that if one delegation would suggest a modification to the text, the Delegation of Indonesia would also propose another modification and so would other delegations. In its view, such discussion would lead the Committee nowhere.

229. The Delegation of Romania, speaking on behalf of the CEBS Group, stated that its Group was able to accept the latest proposal of the Chair, and at the same time it remained flexible with respect to the positions that had been presented in the room. In its view, the most important and remaining goal was to have a future work program of the Committee.

230. The Delegation of Japan, speaking on behalf of Group B, expressed its regret that many proposals coming from Group B, which completely fit the activities of the SCP, had not been taken up in the future work program. As regards the latest version of the Chair's proposal on patents and health, the Delegation shared its understanding that discussions at a half-day seminar would take into account all important aspects related to patent systems and availability of medicines, including both benefits and challenges. Noting that the coordination within its Group had been very difficult, the Delegation expressed its hope that the Committee would work and continue to function in the future, because the core mandate of the SCP formed the core part of the objective of the Organization. From that perspective, the Delegation stated that while Group B was not happy with the content of the Chair's latest proposal which lacked balance, it joined the consensus to adopt that proposal on work program for the next session. The Delegation expressed its appreciation to the Chair for her efforts to keep the Committee alive.

231. The Chair thanked Group B for its flexibility and its spirit of compromise, and expressed her appreciation to all delegations for their efforts.

AGENDA ITEM 9: SUMMARY BY THE CHAIR

232. The Chair introduced the Summary by the Chair (document SCP/22/6 Prov.).

233. The Delegation of India suggested that the Summary by the Chair, in paragraph 17, mentioned the fact that some delegations had asked for discontinuation of discussions within the SCP on confidentiality of communications with patent advisors.

234. The Delegation of Iran (Islamic Republic of) supported the statement made by the Delegation of India.

235. The Delegation of China supported the statement made by the Delegation of India.

236. The Chair stated that, taking into account the comments given by the Delegations of India, Iran, and China, she would introduce a new sentence to that effect in the final Summary by the Chair.

237. The Delegation of Brazil sought clarification with respect to paragraph 20, asking whether the text reflected the agreement among the regional group coordinators that the proposal by GRULAC on the revision of the 1979 WIPO Model Law would be discussed at the subsequent session.

238. The Chair clarified that discussion on that issue would continue at the next session.

239. The Summary by the Chair (document SCP/22/6) was noted.

240. 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 10: CLOSING OF THE SESSION

241. The following written statements were submitted by the Delegations of Pakistan on behalf of the Asian Group, Brazil on behalf of GRULAC and Luxembourg on behalf of the European Union and its Member States for their inclusion in the report.

242. The Delegation of Pakistan, on behalf of the Asia and Pacific Group expressed its appreciation to the Chair for her leadership of the Committee which had resulted in the adoption of a future work program. It considered that the adoption of the work program was a step forward in the right direction. The Delegation, however, noted that it was also the least common denominator and the result of large compromise made by the Asian Group. Therefore, the Delegation expressed its hope that such flexibility would be reciprocated by others in the future. The Delegation stated that the work of the Committee must balance the rights of the patent owners in a manner which was cognizant and sensitive of the socio-economic realities of all Member States. In its view, that was essential specially to allow governments the necessary policy space to meet health needs and for the realization of the basic human right to health of all individuals in all countries. It, therefore, observed that inclusiveness and flexibility in multilateralism were prerequisite for progress, and looked forward to discussions in future sessions of the SCP.

243. The Delegation of Brazil, on behalf of GRULAC, expressed its appreciation to the Chair for her effective guidance of the work of the Committee. The Delegation considered that the SCP had made good progress regarding the exchange of views on the two studies, namely, inventive step and sufficiency of disclosure. In its view, the Committee also had had interesting exchanges of views on exceptions and limitations to patent rights, patents and health and transfer of technology. Referring to the discussion held on the proposal by GRULAC that had aimed at starting the discussion on the revision of the WIPO Model Law, the Delegation noted that even though all objectives pursued by the GRULAC proposal had not been achieved, the Group understood that the exchange of views had been positive. It, therefore, looked forward to continue that exercise in the subsequent session. Regarding future work, the Delegation recalled that as a result of the discussions held in the previous sessions, GRULAC requested the Secretariat to prepare an analysis of exceptions and

limitations to patent rights that had proven effective to address development concerns. Similarly, based on such analysis, GRULAC had also proposed the development of a non-exhaustive manual on that topic as a reference to the Member States of WIPO. While the future work of the next session on the subject fell short of its proposals, the Delegation nonetheless recognized the value of hearing the views of all Member States. It, therefore, stated that GRULAC was ready to constructively engage in discussions at the 23rd session of the SCP on a compilation by the Secretariat of Member States experiences and case studies on the effectiveness of exceptions and limitations, in particular, in addressing development issues. The Delegation noted that GRULAC also had signaled its interest in new joint efforts related to the discussion of topics of patents and health and technology transfer. On patents and health, GRULAC welcomed the proposal of a half-day 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. The Delegation noted that its Group understood that the focus of the seminar must be the relationship between patent systems and challenges related to availability of medicines in developing countries and LDCs and challenges related to the promotion of innovation in developing countries. The Delegation further noted that GRULAC would constructively engage in discussions on technology transfer *vis-à-vis* sufficiency of disclosure, which was, in its view, a step forward. On confidentiality of communications between clients and their patent advisors, GRULAC was of the view that the SCP was not the appropriate forum for discussion. On quality of patents, including opposition systems, GRULAC acknowledged the proposed half-day sharing session on experiences of experts from different regions on inventive step assessment in examination, opposition and revocation procedures. In that respect, GRULAC considered that special attention should be given to opposition and revocation procedures, since that matter had not been dealt with in the most recent SCP sessions.

244. The Delegation of Luxembourg, on behalf of the European Union and its Member States, expressed its appreciation to the Chair for her indefatigable efforts in identifying compromise solutions in order to achieve consensus on future work and congratulated the Chair on her success. For the record, it 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 SCP, could have had accepted the Chair's initial proposal on future work. While that proposal had contained elements with which the European Union and its Member States were uncomfortable, in their view, the overall package had represented a fair reflection of the balance of interests expressed by delegations during the meeting. The Delegation had understood that proposal to be a closed package, but it had been subsequently reopened and amended to reflect the needs of some groups. In that respect, the Delegation noted with regret that no EU proposal had been taken on board. That being said, the Delegation very much welcomed the agreement that had been reached and looked forward to the Committee engaging in substantive work at its subsequent session.

245. The Secretariat commended the Chair, the regional group coordinators and all delegations for having worked their way toward an agreement on a plan of work for the subsequent meeting. Recognizing the fact that the regional group coordinators on behalf of their respective members and ultimately all delegations had sweated blood to reach a compromise, the Secretariat noted that it was in the nature of compromises in multilateral institutions that it represented often the lowest common denominator that everyone had been able to agree to. The Secretariat stated that while delegates often felt they had compromised more than they had gained, reaching an agreement on a plan of work provided for some opportunities for the Committee to move forward on the implementation of its mandate. The Secretariat explained that in order to hold the present SCP session, WIPO

had spent 215,000 Swiss francs. The Secretariat observed that the Committee had spent 50 percent of its time talking about what to talk about and 50 percent talking about the substance. The Secretariat expressed its hope that, with the work plan that had been adopted for a subsequent meeting, there would be a slightly different proportion of time to be spent. He further stated his hope that the Committee could begin to focus more on the substance of what brought delegations together, and not spending too much time on the process of what brought delegations together. The Secretariat observed that the Committee had made a positive and constructive start for the subsequent meeting. The Secretariat thanked all delegations for their support, and stated that it would do its part to carry out the preparative work requested by the Committee and to fulfill the expectations as it understood them of what delegations would like to do with the SCP.

246. The Chair closed the session.

247. In accordance with the procedure previously adopted by the Committee (see paragraph 240 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]

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