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## Standing Committee on the Law of Patents

**Twentieth Session**  
**Geneva, January 27 to 31, 2014**

### DRAFT REPORT

*prepared by the Secretariat*

### INTRODUCTION

1. The Standing Committee on the Law of Patents ("the Committee" or "the SCP") held its twentieth session in Geneva from January 27 to 31, 2014.
2. The following States members of WIPO and/or the Paris Union were represented: Afghanistan, Algeria, Andorra, Angola, Argentina, Australia, Austria, Barbados, Belarus, Benin, Bosnia and Herzegovina, Brazil, Burundi, Cambodia, Chile, China, Colombia, Congo, Costa Rica, Côte d'Ivoire, Croatia, Cuba, Czech Republic, Democratic People's Republic of Korea, Denmark, Djibouti, Ecuador, Egypt, El Salvador, Estonia, Ethiopia, Finland, France, Georgia, Germany, Greece, Guatemala, Holy See, Hungary, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Italy, Japan, Jordan, Kenya, Kuwait, Latvia, Lithuania, Madagascar, Malaysia, Mauritania, Mauritius, Mexico, Monaco, Montenegro, Morocco, Mozambique, Myanmar, Nepal, Nicaragua, Nigeria, Norway, Oman, Pakistan, Panama, Paraguay, Peru, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Saudi Arabia, Senegal, Serbia, Sudan, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Tajikistan, Thailand, Togo, Trinidad and Tobago, Tunisia, Turkey, Ukraine, United Kingdom, United States of America, Uruguay, Uzbekistan, Venezuela (Bolivarian Republic of), Viet Nam, Yemen, Zambia and Zimbabwe (102).
3. Representatives of the Eurasian Patent Organization (EAPO), the European Patent Organisation (EPO), the European Union (EU), the Patent Office of the Cooperation Council for the Arab States of the Gulf (GCC Patent Office), South Centre (SC) and the World Health Organization (WHO) took part in the meeting in an observer capacity (6).

4. Representatives of the following non-governmental organizations took part in the meeting in an observer capacity: Asian Patent Attorneys Association (APAA), European Law Students' Association (ELSA International), International Association for the Protection of Intellectual Property (AIPPI), Centre for International Intellectual Property Studies (CEIPI), International Center for Trade and Sustainable Development (ICTSD), International Chamber of Commerce (ICC), CropLife International, International Federation of Pharmaceutical Manufacturers Associations (IFPMA), International Federation of Intellectual Property Attorneys (FICPI), Japan Intellectual Property Association (JIPA), Japan Patent Attorneys Association (JPAA), Knowledge Ecology International, Inc. (KEI), Médecins Sans Frontières (MSF), Medicines Patent Pool Foundation (MPP) and Third World Network (TWN) (15).

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 of SCP/19" (SCP/19/8 Prov.2); "Draft agenda" (SCP/20/1 Prov.3); "Report on the International Patent System: Certain Aspects of National/Regional Patent Laws" (SCP/20/2 and 2 Corr); "Exceptions and limitations: private and non-commercial use" (SCP/20/3); "Exceptions and limitations: experimental use and/or scientific research" (SCP/20/4); "Exceptions and limitations: extemporaneous preparation of medicines" (SCP/20/5); "Exceptions and limitations: prior use" (SCP/20/6); "Exceptions and limitations: use of articles on foreign vessels, aircrafts and land vehicles" (SCP/20/7); "Information regarding work sharing programs among Member States and use of external information for search and examination" (SCP/20/8); "Confidentiality of communications between clients and their patent advisors: compilation of law, practices and other information" (SCP/20/9); "Transfer of technology: further practical examples and experiences" (SCP/20/10); 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.).

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 of the Delegation of Spain for the improvement of understanding of the requirement of inventive step" (SCP/19/5); and "Proposal by the Delegation of Brazil regarding exceptions and limitations to patent rights" (SCP/19/6).

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 twentieth session of the Standing Committee on the Law of Patents (SCP) was opened by the Deputy Director General, Mr. James Pooley, who welcomed the participants on behalf of the Director General, Mr. Francis Gurry. Mr. Marco Aleman (WIPO) acted as Secretary.

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

10. The Delegation of Algeria, speaking on behalf of the African Group, proposed Mr. Mokhtar Warida (Egypt), as a candidate for the Chair.
11. The Delegation of China supported the proposal by the African Group, and proposed the candidature of Ms. Song Jianhua (China) for one of the Vice Chairs.
12. The Delegation of Belarus, speaking on behalf of the Caucasian, Central Asia and Eastern European Countries (CACEEC), supported the proposal by the Delegation of China regarding the Vice Chair.
13. The Delegation of Japan, speaking on behalf of Group B, supported the nomination of the African Group on a non-precedential basis, while expressing its belief that the SCP, as a technical Committee in which technical issues on patent law was discussed, should be chaired by a capital expert who had a deep technical insight of the patent law.
14. The Delegation of the Czech Republic, speaking on behalf of the Group of Central European and Baltic States (CEBS), supported the proposal of the African Group, while its acceptance was on a non-precedential basis due to their strong preference of the SCP being chaired by a capital-based expert.
15. The SCP unanimously elected, for one year, Mr. Mokhtar Warida (Egypt) as Chair and Ms. Song Jianhua (China) as Vice-Chair.

## **AGENDA ITEM 3: ADOPTION OF THE AGENDA**

16. The Delegation of Egypt, speaking on behalf of the Development Agenda Group (DAG), proposed the addition of a new agenda item regarding the contribution of the SCP to the implementation of the Development Agenda.
17. The Delegations of Japan, speaking on behalf of Group B, and the Czech Republic, speaking on behalf of the CEBS Group, supported the proposal made by the Delegation of Egypt on behalf of the DAG, with the understanding that the new item would not be a standing agenda item.
18. The SCP adopted the revised draft agenda (document SCP/20/1 Prov.3) with the addition of a new agenda item 11: Contribution of the SCP to the implementation of the respective Development Agenda recommendations (see document SCP/20/1), on the understanding that it was not a standing agenda item.

## **AGENDA ITEM 4: ADOPTION OF THE DRAFT REPORT OF THE NINETEENTH SESSION**

19. The Committee adopted the draft report of its nineteenth session (document SCP/19/8 Prov.2) as proposed.

## **AGENDA ITEM 5: REPORT ON THE INTERNATIONAL PATENT SYSTEM**

20. Discussions were based on documents SCP/20/2 and SCP/20/2 Corr.
21. The Secretariat noted that since the nineteenth session of the SCP, information concerning the national patent laws had been received from the following Member States: Australia,

Costa Rica, Germany, India, Lithuania and Spain.

22. The SCP agreed that the information concerning certain aspects of national/regional patent laws [[http://www.wipo.int/scp/en/annex\\_ii.html](http://www.wipo.int/scp/en/annex_ii.html)] would be updated based on the input received from Member States.

## **GENERAL DECLARATIONS**

23. The Delegation of Japan, speaking on behalf of Group B, thanked the Secretariat for its hard work in preparing the current session. The Delegation recalled that at the previous session, the SCP had finally agreed on the future work program, which was a small step forward. Group B expressed its belief that the Committee should continue to make steps forward toward further work on issues of substantive patent law. Group B wished to attach great importance to the SCP, and expressed its expectation that the Committee should involve technical discussions on the issues of substantive patent law in line with its core mandate. The Delegation stated that Group B remained strongly interested in pursuing further work on the issues of quality of patents, including opposition systems, and confidentiality of communications between clients and their patent advisors. Under the agenda item "Quality of patents, including opposition systems", the Delegation noted that many interesting proposals had been put on the table. Group B looked forward to further elaboration of those proposals. Furthermore, Group B welcomed the new proposal submitted by Japan, the Republic of Korea, the United Kingdom, the United States of America regarding work sharing between offices in order to improve efficiencies of the patent system. Group B expressed its firm belief that the proposal would be a good step forward to contributing to the objective of that agenda item and the core mandate of the Committee, while paying due attention to concerns expressed so far by some Member States. In conclusion, the Delegation expressed its readiness to engage further in discussion on other topics on the agenda, and reiterated the importance of finding a balanced approach that would avoid duplication.

24. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, thanked the Secretariat for its hard work in preparing relevant and updated documents for the twentieth session of the SCP. The CEBS Group remained committed to continuing discussions on all topics under the Committee's current balanced working program, namely, on quality of patents, including opposition systems, exceptions and limitations to patent rights, patents and health, confidentiality of communications between clients and their patent advisors and transfer of technology. The CEBS Group expressed its hope that the discussion would be constructive and fruitful, and all issues would be considered in an efficient and appropriate manner. The CEBS Group also expressed its continuing interest in quality of patents, including opposition systems. In the opinion of the Delegation, quality of patents was of an utmost importance for all users of the patent system. Therefore, the Delegation reiterated its belief that the discussion on technical issues concerning patent law under balanced work program should be developed as soon as possible. The Delegation stated that the information provided on work sharing programs among patent offices and use of external information for search and examination (document SCP/20/8) was valuable and helpful in better understanding the development of the international patent system. The Delegation also thanked the Delegations of Japan, the Republic of Korea, the United Kingdom and the United States of America for their proposal on work sharing between offices in order to improve efficiencies of the patent system (document SCP/20/11 Rev.). The CEBS Group expressed its strong interest in various channels for obtaining valuable information on that issue. Further, it stressed the importance of the work on confidentiality of communications between clients and their patent advisors (document SCP/20/9). The CEBS Group welcomed and appreciated a compilation of laws and different practices submitted by the Secretariat and stated that it was an excellent basis for further discussion. The CEBS Group expressed its readiness to further discuss other topics on the agenda, such as exceptions and limitations to patent rights, patents and health and transfer of technology. The Delegation also reiterated that any duplication of work should be

avoided within all WIPO bodies and with other relevant international organizations such as the WHO or WTO. In conclusion, the CEBS Group reiterated its commitment to cooperate and actively participate in discussions of the Committee.

25. The Delegation of South Africa, speaking on behalf of the African Group, expressed its assurance to the Chair in its support and full cooperation, as well as its willingness to make the meeting a success. The African Group further thanked the Secretariat for the hard work in preparing the documents. The Delegation stated that the implementation of the Development Agenda in WIPO since 2007 meant that the work of the SCP in relation to international aspects of patent law should give due account to development considerations. The Delegation then stated that Member States were primarily responsible for ensuring that the Development Agenda was implemented in the SCP through its substantive work. That included recognizing the need for policy space for developing countries to design and implement national patent law in the manner conducive to their national development. In the opinion of the Delegation, 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. The Delegation noted that the agenda of the twentieth session of the SCP provided the opportunity for fruitful exchange of views on a wide range of topics related to patents. The Delegation stressed the particular importance of the discussions within the Committee for members of the African Group because of the direct and significant impact of patents on innovation, economic growth and social development. The Delegation therefore underlined the necessity of strengthening the fundamental balance between the private interest of right holders and public interest, especially in the patent system. Accordingly, the Delegation stated that the activities of the SCP should facilitate the dissemination and transfer of technology and ensure that the patent system contributed to the promotion of progress and innovation. Regarding the issues to be discussed during the present session, the African Group recalled its position on each of those issues. The African Group attached great importance to exceptions and limitations to patent rights that provided flexibilities in the IP system. It recognized the need 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 African Group was keen on seeing the SCP contribute to a better understanding and better application of exceptions and limitations on the basis of the proposal by the Delegation of Brazil. Further, the Delegation welcomed the holding of a seminar on exceptions and limitations to patent rights with the expectation that the seminar would contribute to a better understanding on how exceptions and limitations served specific development objectives and the challenges faced by countries in implementing those exceptions and limitations. With regard to the quality of patents, the African Group reiterated its concern about the lack of the precise definition of the concept of the quality of patents. From the perspective of the African Group, the quality of patents was largely based on the criteria of patentability, which depended essentially on the development objectives of each country. The African Group expressed its belief that the initiative would not result in harmonization of practices in the field of patent law, which may be prejudicial to the flexibilities in national legislation on patents in various countries. Referring to the proposal to develop a work program in the SCP to address how patent offices could coordinate and collaborate in conducting search and examination work in order to improve the quality of granted patents, the Delegation stated that quality improvement efforts could not be improved by simply adopting the practice of other patent offices, and the harmonization of patent law might undermine the flexibilities existing under various national patent laws. The Delegation stressed the importance for a national office to retain its discretion in determining the patentability criteria as defined in their respective national legislations. Concerning the issue of patents and health, the African Group expressed its belief that WIPO should strengthen its commitment and involvement in that area. The Delegation explained that it was within that context that the African Group and the DAG had jointly submitted a proposal that had covered a work program aiming to assist Member States, particularly developing countries and least developed countries (LDCs), to adapt and adjust their patent systems in order to take full advantage of the flexibilities in the international patent system to promote their policies on public health. The

Delegation further stated that the sharing session on the countries' use of health-related patent flexibilities would offer the opportunity to exchange experience on such use and the implementation challenges. The Delegation looked forward to a fruitful exchange and progress towards a work program on that issue. The African Group also took note of the proposal by the Delegation of the United States of America with respect to patents and health. Although the Delegation found that proposal interesting, in its view, the proposal could guide discussions in the SCP to issues that were not related to patents, and hence it was outside the mandate of the Committee. The African Group expressed its hope that that would not distract the main objective of the African Group's proposal, namely, to enable developing countries and LDCs to take advantage of the flexibilities in the international patent system to meet their public health needs. With regard to technology transfer, the African Group expressed its hope that the documents submitted by the Secretariat on the activities of WIPO in the context of technology transfer would enable the SCP to undertake concrete actions in that area.

26. The Delegation of Belarus, speaking on behalf of the CACEEC Group, expressed its belief that the Committee was one of the key substantive technical bodies in the Organization, and therefore, the Delegation attached a particular importance to it. The Delegation stated that quality of patents and confidentiality of communications between clients and their patent advisors were some of the key elements in strengthening the patent system and ensuring its proper work. Therefore, the Delegation expressed its hope that the Committee would make substantial progress on those issues. The Delegation further shared its opinion that transfer of technology was one of the most important issues within the whole United Nations (UN) system, and that the Committee was a unique forum for discussing that topic in relation to patents. The Delegation, therefore, stated that the CACEEC Group attached great importance to that issue. The Delegation further stated that achieving an agreement on the issue of exceptions and limitations, particularly, in respect of health-related patents, was something that would help to use the patent system in a more effective and fair way. Finally, the Delegation expressed its hope that the Committee would have constructive discussions and would be able to achieve a positive outcome at the end of the session.

27. The Delegation of Uruguay, speaking on behalf of the Group of Latin American and Caribbean (GRULAC), expressed its willingness to make a positive contribution to the work of the Committee, and thanked the Secretariat for preparing the documents to be examined during that session. The Delegation reiterated its support to the work of the Committee with a view to addressing important aspects of the progressive development of patent law, thus fulfilling its mandate. In the view of the Delegation, the basic purpose of the Committee was to provide guidance to the WIPO Secretariat on its activities, including technical assistance, owing to the need for information on the various issues that were of interest to GRULAC members. The Delegation observed that certain issues had yet to be solved, and therefore, it was unclear as to whether they could be integrated into their development policies or not. Referring to the future work, the Delegation stated that GRULAC was aware of the diversity of priorities of the various regional groups with respect to the future work of the Committee. In addition, the Delegation noted that all Member States should recognize the relevance of the Committee, a body within which they enjoyed the opportunity to gain a better understanding of the experiences and viewpoints of others. Further, the Delegation expressed its particular interest in making progress on issues such as the exceptions and limitations to patent rights, patents and health, quality of patents, including opposition systems and the patent-related activities of the IP and Global Challenges Program (Program 18). The Delegation however clarified that such a list of priorities for the GRULAC could and must be enriched by the inclusion of the priorities of other regional groups. Referring to the fact that that session of the SCP was the last before the next General Assembly, GRULAC considered appropriate to discuss the contributions made by the Committee to the Development Agenda. The Delegation also called the Committee to make headway on the revision of the Patent Model Law for developing countries and LDCs, as it had been approved under Program 1 of the Program and Budget for 2014/2015. The Delegation stated that the Committee could make a

substantive contribution to making further progress on that issue, since no modification had been made on the Model Law since 1979. Finally, the Delegation welcomed the traditional practice of having two sessions of the Committee per year. The Delegation stated that it would give the Committee sufficient time and opportunity to have a full discussion and to make better progress on the issues on the Committee's agenda.

28. The Delegation of Bangladesh, speaking on behalf of the Asian Group, thanked the WIPO Secretariat for excellent arrangements for the session. The Delegation underlined the importance of the session for all Member States, especially for the developing countries and LDCs. The Delegation noted that the session would provide the Committee with an opportunity to discuss and share experiences on important issues such as exceptions and limitations to patent rights, quality of patents, patents and health and transfer of technology, which were extremely relevant for everyone to get benefit out of the present patent system. The Delegation also stated that the session would help Member States further understand how to establish a balance between rights and obligations and how the present patent system could contribute to the cause of development. It further stated that the session would give the Committee an opportunity to explore how the current patent system would function even better and more efficiently. The Delegation expressed its confidence to the Chair who had all the expertise and knowledge to guide the Committee to a successful conclusion of the session.

29. The Delegation of China expressed its gratitude to the Secretariat for the documents prepared for the meeting. The Delegation looked forward to an in-depth and adequate discussion on important topics related to the patent system, including exceptions and limitations to patent rights, patents and health, transfer of technology, quality of patents and the contribution of the SCP to the implementation of the Development Agenda recommendations. The Delegation expressed its hope that, through the efforts of all parties, the outcome would satisfy all participants. The Delegation noted that the discussions in the SCP would play a positive role in facilitating the development of economy, science and technology as well as the encouragement of innovation through the improvement of the patent systems of different countries.

30. The Delegation of Benin, speaking on behalf of LDCs, expressed its gratitude to the Secretariat for the preparation of the documents. The Group of LDCs welcomed the ongoing work on exceptions and limitations and hoped that the seminar on those issues would make it possible for the members of the Committee to have a better understanding of how they could be implemented and effect on economic and social development, particularly in LDCs. The Delegation attached a major importance to that work, and hoped that it would take into account the appropriate balance to be respected between protection of patents, thereby encouraging innovation and creativity, and the legitimate needs of some countries to achieve economic and social development. The Delegation observed that due to the disparity of the level of development among countries, several viewpoints on the quality of patents existed. The Delegation stated that it would support any work that would help the Committee to reach a common understanding of that concept. Referring to patents and public health, the Delegation welcomed a sharing session on the use of flexibilities provided by the patent system and expressed its hope that conclusions of the session would enable further progress of work on that topic. The Delegation urged that such work should be accelerated on the basis of a clearly defined program so that LDCs could make the most effective use of the flexibilities available to them to design their public health policies. To that end, the Delegation requested that improved technical assistance be provided in order to boost their capacities to use and adapt the patent system. With respect to transfer of technology, while noting the experience of other countries, the Delegation stated that the effectiveness of transfer of technology to a certain extent depended on beneficiary country's ability to absorb the technology. The Delegation further stated that more effective cooperation was needed in order to draw the greatest possible benefit from the transfer of technology. In the view of the Delegation, a better use of flexibilities would help LDCs to receive the technologies they needed for their development, while protecting the legitimate rights of patentees. Appreciating the fact that Member States, in the

spirit of compromise, had taken a constructive attitude in the Committee in the past, the Delegation hoped that they would continue to do so during the present session so that the Committee could reach acceptable conclusions and a positive outcome by the end of the session.

31. The Delegation of Greece, speaking on behalf of the European Union and its Member States, associated itself with the statements made by the Delegations of Japan on behalf of Group B and of the Czech Republic on behalf of the CEBS Group. The Delegation remained committed to the work of the Committee and looked forward to a constructive session. The Delegation also thanked the Secretariat for its extensive work in preparing for the meeting. The Delegation noted that the present session of the SCP would continue discussions on significant issues such as quality of patents, including opposition systems, exceptions and limitations to patent rights, patents and health, confidentiality of communication between clients and their patent advisors and transfer of technology, addressing important and complex questions of the international patent system, with the hope of getting a more efficient and accessible patent system as a whole. In particular, the Delegation attached considerable importance to advancing work on the quality of patents along the lines proposed by the Delegations of Canada and the United Kingdom, Denmark, Spain and the United States of America. The Delegation expressed its commitment to continuing work on issues of opposition systems and confidentiality of communication between clients and their patent advisors, which were of benefit to users of the patent system. The Delegation also highlighted its great interest in the topics of work sharing, which had the potential to enhance international cooperation and bring a more efficient, effective and high quality patent system to all. In its view, that topic presented problems only solvable through an international approach. The Delegation also expressed its readiness to continue discussions on exceptions and limitations to patent rights. The Delegation, however, emphasized the utmost importance of striking an appropriate balance between exceptions and limitations on the one hand, and patent rights and corresponding legal standards on the patentability on the other hand, as those two topics were closely interlinked. Given the importance of the issue of patents and health for tackling public health problems in developing countries and LDCs, the Delegation expressed its full understanding of the interest of those countries to include that topic in the future work of the Committee. However, in the view of the Delegation, any possible future initiative of the Committee in that area should be carefully considered in light of the great incentive the patent system could provide to innovation in order to address the evolving global disease burden and other health challenges. Similarly, possible further activities of the Committee in relation to transfer of technology should be balanced and objective, and should be considered in light of the many examples of the benefits of the patent system to technology transfer and the relatively fewer examples of the patent system as an impediment. The Delegation expressed its hope that the pursuit of a balanced work program would lead the Committee to working towards discussions on the international harmonization of substantive patent law in the long term to which the Delegation was strongly committed. In closing, the Delegation reiterated its full commitment to cooperate and participate actively and constructively in discussions of the Committee.

32. The Delegation of India expressed its complements to the Secretariat for preparing the documents for the session. The Delegation supported the statements made by the Delegation of Bangladesh on behalf of the Asian Group and the Delegation of Algeria on behalf of the African Group. The Delegation expressed its belief that the development of a patent system and the use of patent rights should operate in a balanced manner meeting the objective of providing protection for the moral and material interests of inventors, and at the same time, promoting the enjoyment of human rights of the other members of the society. In its view, a patent was a social product and had a social function. The Delegation stated that it attached great importance to the work of the SCP and was pleased to see the balanced work program for that session, which retained issues such as patents and health, transfer of technology and exceptions and limitations to patent rights in the agenda of the Committee. Referring to the issue of patents and health, the Delegation welcomed a session for sharing information on health-related patent flexibilities. The Delegation noted an urgent need not only to study the flexibilities under the Agreement on Trade-Related

Aspects of Intellectual Rights (TRIPS Agreement) and effective implementation or utilization of its compulsory licensing provisions under patent law in order to provide the lifesaving drugs at affordable price, but also to study the impact of grant of compulsory licenses and consequential impact on prices of patented drugs. The Delegation expressed its full support to the work program proposed by the African Group and the DAG (document SCP/16/7). The question of effective use of compulsory licenses, government use, disclosure of International Nonproprietary Names (INNs) in patent specifications and costs and benefits of allowing Markush claims, according to the Delegation, were extremely important from the point of view of health and access to the essential medicines. The Delegation emphasized that the ever-greening policies for patenting incremental innovations without substantial improvement would have adverse impact on delivery of healthcare services. With regard to the quality of patents, the Delegation expressed its belief that patent offices across the world alone would not be able to maintain the quality of patents without maintaining the standards of examination and search. In the view of the Delegation, the quality of examination of patent applications needed a substantial improvement in order to avoid creating the huge social cost of granting patents to insignificant improvement, which only led to litigation and created barriers to technology dissemination. The Delegation stated that sharing of the work of other offices was not the remedy for improving the quality of patents and consequently could not be considered to be a solution for addressing backlog and an answer to the improvement of quality of patents. The Delegation expressed its strong belief that work sharing would adversely affect the capacity of the IP offices in developing countries in assessing an application. Therefore, according to the Delegation, it should not become an area for norm-setting in the future. In the opinion of the Delegation, steps should be taken to build capacity among IP offices of developing countries to enable them to carry out their quasi-judicial functions in the best manner possible. In addition, the Delegation reaffirmed its support to the work program as proposed by the Delegation of Brazil (document SCP/19/6) on exceptions and limitations. It reiterated that the study focusing on the use of some exceptions, such as compulsory licensing, parallel import, government use, Bolar exception etc., was extremely important from the perspective of the accessibility and affordability of medicines. The Delegation also shared its opinion that there was a need to study the various impediments in licensing agreements relating to transfer of technology in greater details so that appropriate steps could be taken to address that aspect. The Delegation stated that a compilation of data from different countries would not serve the purpose of extracting the specific exceptions and limitations which were important from the development concerns *vis-à-vis* the patent system. In the view of the Delegation, 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 the socio-economic growth. The Delegation also took note with pleasure that its request for practices adopted by companies across Member States concerning voluntary licensing of patents had been noted by the Secretariat in document SCP/20/10. Finally, the Delegation also welcomed the organization of a seminar on exceptions and limitations to patent rights, and expressed its commitment to engaging constructively in the discussion of the Committee.

33. The Representative of the ICC shared its business perspective on work sharing and technology transfer with the Committee. The Representative stated that work sharing was a way for offices to use all resources available to them in an optimal way. The Representative further highlighted the results of the two pilot projects that had been undertaken by the EPO, the Korean Intellectual Property Office (KIPO) and the United States Patent and Trademark Office (USPTO) in the context of the Patent Cooperation Treaty (PCT). Those projects, according to the Representative, demonstrated that collaborative search, a form of work sharing, enhanced the quality of search reports. The Representative further stated that, in the second project, collaboration resulted in the addition of citations to the first examiner's reports (87%) and in a stronger report (92%) in nearly all instances. The Representative believed that collaborative search could improve the quality not only of searches but also of rights granted. In his view, that would improve legal certainty and predictability, enabling businesses to better manage their activities in relation to their own IP position and that of competitors. The Representative further stated that work sharing neither compromised sovereignty, nor was a synonym of harmonization.

The Representative pointed out that it also did not require offices to rely upon the decisions of other offices, but to integrate the work of other offices into their own work. Referring to the technology transfer, the Representative stated that the transactions that resulted in technology diffusion and in the building of absorptive capacity over time were accelerated and supported by robust, enforceable IP rights. According to the Representative, IP rights enabled companies to develop, refine and deploy their technology solutions, and most importantly, to share with partners the know-how that was necessary to maintain the technology. Especially for smaller companies, the Representative underlined the importance of the IP rights as facilitators of technology diffusion. According to the Representative, small and medium sized enterprises (SMEs) tended to occupy a niche and to lack the non-core business expertise necessary to get their inventions to the market. Therefore, in his opinion, a strong IP position could help them to attract partners as well as investors, and enable them to retain control over their intellectual assets through the collaboration. The Representative looked forward to hearing the perspectives of Member States on those important topics.

34. The Representative of KEI expressed its views on some areas relevant to the work program. With respect to exceptions and limitations to patent rights, the Representative commented on the limitation on the remedy for the injunction, referring particularly to Article 44 of the TRIPS Agreement. In addition, the Representative noted a provision of the Affordable Care Act in the United States of America, which had eliminated the availability of injunctions in the case of infringement of a patent in cases where a manufacturer of a biologic medicine did not do a constructive disclosure of the patented inventions relating to that medicine to companies that wanted to provide biosimilar competitive products. The Representative further noted the decision of the Supreme Court of the United States of America which had ruled that in the efforts to get an injunction to stop an infringement of a patent, the court had to consider the possibility that a compulsory license on the patent would be a more equitable outcome. That, according to the Representative, had led to the largest number of compulsory licenses that had been issued in the United States of America since 2006 in the context of those injunction proceedings. The Representative therefore suggested the preparation of a paper by the Secretariat on that matter. Referring to the work sharing, the Representative expressed its interest in sharing the information about the disputes over the patentability of granted patents. Having noted that many countries had post-grant re-examination litigation and procedures, the Representative suggested discussions on the related challenges in different jurisdictions. With regard to the analysis of the patent system, the Representative expressed its interest in more engagement between the Committee and the Office of Chief Economist, in particular concerning its studies organized by the Chief Economist to improve the evidence base for evaluating policies in the area of patents. The Representative was also interested in more information about the work of the Chief Economists of different offices around the world. Finally, the Representative underlined the importance of the issue of transparency in the patent system, and therefore expressed its interest in further discussions on that matter.

35. The Representative of AIPPI made a general statement on the positive roles of the SCP and WIPO in relation to the study on the protection of confidentiality in IP professional advice. The Representative noted that document SCP/20/9, prepared by the Secretariat, was a good summary of the progress made over the previous six years. The Representative observed that whether nations were ready to adopt any particular remedy or not should not be a factor in deciding whether they should or should not have a say in what remedy should be adopted, including how it should be expressed. The Representative pointed out that the previous process of the SCP had been enriched by the inclusiveness of all Member States in dealing with that issue. Therefore, AIPPI urged the Member States to continue studying the issue of the confidentiality in IP professional advice through the process involving all Member States.

36. The Representative of TWN attached great importance to the SCP deliberations. In the view of the Representative, the deliberations would inform Member States to better equip their national

patent laws to achieve their development needs by balancing the public and private rights in their patent legislations. The Representative stated that since the development concerns were the core of the patent system, the patent law should be treated as a subservient to the development objectives and it should serve the development goals of each Member State. The Representative further noted that the agenda of the twentieth session of the SCP contained important issues, such as exceptions and limitations to patent rights, patents and public health and technology transfer. Referring to the documents providing factual insights on the use of exceptions and limitations in five selected areas, the Representative noted that they failed to provide the institutional and policy constraints for Member States to use those limitations and exceptions. The Representative stated that since the previous sessions, key development related to patent rights had been taking place at least in three developing countries. The Representative congratulated the efforts by the Brazilian and South African governments to reform their patent laws in order to incorporate the flexibilities in a more concrete way. The Representative also mentioned the judgment of the Supreme Court of India which effectively curbed the practices of ever-greening of patents in the pharmaceutical area. At the same time, the Representative expressed concerns related to the efforts of pharmaceutical industry to create barriers to those progressive developments in Brazil, South Africa and India. The Representative also took note of the efforts by certain Member States to exert political pressure on countries, such as India, to prevent them from using the TRIPS flexibilities. Having expressed those concerns, the Representative was of the view that the deliberations on quality of patents should not be used to pursue the work sharing arrangements and also to harmonize patent law through procedural harmonization of examinations. Similarly, on transfer of technology, the Representative underlined the importance of discussion on the barriers created by patents on transfer of technology, and stated that the SCP should also discuss WIPO's technical-assistance activities in the area of patents.

#### **AGENDA ITEM 6: EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS**

37. Discussions were based on documents SCP/14/7, SCP/19/6 and SCP/20/3 to 7.
38. Pursuant to the decision taken at the nineteenth session of the Committee, a half day Seminar on Exceptions and Limitations to Patent Rights was held. The Seminar addressed the following five exceptions and limitations: (i) private and/or non-commercial use; (ii) experimental use and/or scientific research; (iii) preparation of medicines; (iv) prior use; and (v) use of articles on foreign vessels, aircrafts and land vehicles. The Seminar consisted of the following three segments (see document SCP/20/INF/2):
  - (a) a presentation of documents SCP/20/3 to 7 by the Secretariat;
  - (b) presentations by the Chief Economist and two external experts on the effectiveness of exceptions and limitations when addressing developing concerns and how national capacities affect the use of exceptions and limitations; and
  - (c) presentations by Member States of case studies on implementation of the above exceptions and limitations.
39. The Secretariat made a presentation of documents SCP/20/3 to 7.
40. The Delegation of El Salvador expressed its gratitude to the Secretariat, in particular, for the important information contained in the documents. Referring to the use of articles on foreign vessels, aircraft and land vehicles, the Delegation noted that the provisions contained in the Paris Convention for the Protection of Industrial Property (Paris Convention) and the TRIPS Agreement were applied directly in El Salvador, even though the national legislation did not exactly reflect

those provisions.

41. The Secretariat confirmed that those provisions were directly applicable in that country as reflected in document SCP/20/7.

42. The Delegation of Brazil expressed its appreciation for the cooperative spirit of Member States. The Delegation was pleased with the discussions about the questionnaire in the Committee, which constituted the first stage of the working program in its proposal. It noted that the proposal presented a broader aspect, aiming at not only the compilation of the information, but also the discussion as to which exceptions and limitations would offer greater benefits to developing countries. It further stated that exceptions and limitations were essential to the patent system. In its view, they contributed to the balance between broad societal interests and patent holders' interests. From that perspective, an accurate mapping and analysis of the implementation of exceptions and limitations by matured national systems would allow developing countries to identify which of them were best suited for their level of development and for their capacity to absorb and reproduce technologies. The Delegation could not accept the argument that the work of the Committee would duplicate discussions in other WIPO bodies. In its opinion, the different mandates of each WIPO body reflected the different perspectives and debates. It looked forward to continuing discussions on exceptions and limitations at the twenty-first session of the SCP. Furthermore, the Delegation requested clarification from the Secretariat as to how it had made conclusions on the non-existence of challenges to the implementation of certain exceptions and limitations, specifically in relation to the scientific research exception, since some Delegations had manifested that they had been in the process of improving or changing their national legislations. The Delegation drew attention to document SCP/20/10 with regard to transfer of technology where one LDC country had expressed its interest in having a more flexible system in order to allow for reverse engineering. In its view, that statement implied that they were facing a challenge which might be addressed by exceptions and limitations.

43. The Secretariat clarified that with respect to a number of exceptions and limitations, no concrete or specific challenge had been expressly mentioned by Member States in the responses to the questionnaire. At the same time, there were some Member States that had indicated that they were in the process of revising laws, exploring such possibility or evaluating legal changes, which could implicitly indicate some challenges that they would like to address through such legal changes.

44. The Delegation of Algeria noted that the exception on private and non-commercial use was useful to achieve broader public policy objectives in some countries where scientific research was included within that exception. Therefore, it suggested that a mapping of countries that provided a broader scope of that exception be made, and further analysis regarding the needs of some countries to amend their laws be conducted. Further, the Delegation noted that the experimental use exception was used more broadly in some countries than in others. It further stated that, while there was a lack of information on practical challenges in using that exception, the extent to which that could be used depended on the sufficiency of information disclosed in patent applications. Therefore, in its view, the relationship between sufficiency of disclosure and the use of the research exception should be further analyzed. With regard to the exception on extemporaneous preparations of medicine, it stated that, with the exception of a few countries, that exception could be used for the preparation of medicines based on prescriptions without limiting the amount of medicines that could be prepared. It therefore suggested exploring how that exception could be used for responding to public health challenges. As a general comment, it noted that, with the exception of the private and non-commercial use, the Secretariat had not indicated any implementation challenges. In that respect, the Delegation expressed its belief that in some countries, especially developing countries and LDCs, there was no implementation challenge, because there was no implementation at all due to the lack of human or financial resources in order to understand and implement that exception. Therefore, in its view, that could be the real

challenge that prevented countries from implementing such useful exceptions. In that respect, it raised a question to the Secretariat as to whether it had noticed such lack of understanding in some countries, especially in developing countries.

45. The Secretariat acknowledged the challenges related to the issue of understanding of how those exceptions and limitations worked, while the documents were prepared on the basis of information received from Member States.

46. At the second segment of the Seminar, the Secretariat introduced two external experts, Dr. Cathy Garner, Board Member of the Council on Health Research for Development (COHRED), London, United Kingdom and Dr. Nikolaus Thumm, Visiting Fellow, Max Planck Institute, Centre for Innovation and Entrepreneurship, Munich, Germany.

47. Ms. Garner made a presentation on the effectiveness of exceptions and limitations in the context of development. She noted that patents were tools for innovation. She further emphasized the key exceptions and limitations in a development context. She also introduced, beyond patents, the global health perspective. The presentation is available at the WIPO's web site at:  
[http://www.wipo.int/edocs/mdocs/scp/en/scp\\_20/scp\\_20\\_ref\\_garner.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_20/scp_20_ref_garner.pdf)

48. Mr. Thumm presented the economic effects and trends related to the patent system, the economics of patent exceptions in general and an economic analysis of the research exception in Switzerland in particular. He further highlighted some challenges in relation to Member States' national capacities and made some recommendations to regulators and patent offices. The presentation is available on the WIPO's web site at:  
[http://www.wipo.int/edocs/mdocs/scp/en/scp\\_20/scp\\_20\\_ref\\_thumm.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_20/scp_20_ref_thumm.pdf)

49. The Delegation of El Salvador raised a question as to how developing countries such as El Salvador could optimize the use of initiatives such as WIPO Re: Search and WIPO Essential. The Delegation expressed its gratitude to WIPO for its field visit and looked forward to knowing more about those initiatives. Further, it invited Mr. Thumm to briefly explain the meaning of "high quality patents".

50. Mr. Thumm emphasized that there was no single definition of the quality of patents. He explained that, normally, quality of patents referred to the quality of the examination, but also to enforcement. He referred to the definition the Economic and Scientific Advisory Board of the EPO had agreed upon: "a high quality patent satisfies the legal patentability requirements at a given patent office, it has been granted, and it is likely to withstand invalidity proceedings in court or before an administrative body". He explained that while the said definition had been found for practical and economic purposes, there were many different ways in approaching that complex issue.

51. Without knowing the specific situation of El Salvador, Ms. Garner emphasized that, in general, WIPO Re: Search combined with the WIPO Development Agenda was very valuable, since both were looking at the provision of patents as a tool, and assisting in scaling up the capacity building for better use of such tool. She emphasized that it was generally important to open dialogue to identify the needs of a country's innovation and research system, in order to be able to reach out to get support for a wider development goal.

52. The Delegation of Brazil expressed its agreement with Mr. Thumm that any regulation had to be seen in its context and its environment. It recalled that the presentation regarding the research exception was mainly based on the experience from Switzerland and about data from that experience. The Delegation requested more information or any other studies about how those exceptions and limitations would affect different contexts or different environments, in particular, in a developing country or an LDC. In the same line, it inquired how exceptions and limitations in

research would be applied to neglected diseases. On that point, it recalled that the presenters had stated that there was a failure in the system as to how to foster innovation in those fields, because for private companies, there was no incentive for developing new medicines in those areas. It invited ideas about how exceptions and limitations could be used as a tool for improving research in those fields.

53. Mr. Thumm regretted that he was not aware of any specific economic research with respect to exceptions and limitations impacting rights in developing countries or LDCs. He encouraged WIPO or any other entity to examine that issue. Although it was not specifically on the use of exceptions and limitations, he explained that data accessibility was the difficulty he had encountered in conducting a study at the EPO on clean energy patents in Africa. While there was significant development in specific countries in Africa, he indicated that he was not aware of any study on exceptions and limitations in relation to neglected diseases.

54. Ms. Garner emphasized that one of the big challenges in the context of neglected diseases was the lack of market pull mechanism. One example was the Chagas disease, where there had been a potentially potent invention being licensed from a university in the United States of America to a pharmaceutical company for the market pool. The license had contained the restriction to the fields of use and separation of purpose in order to allow development in a non-profit public sector. The speaker noted that, despite efforts made, she had no information of whether that had been successful. In the context of neglected diseases, she emphasized that much had been done in the last 15 years to create funds and market pools. There were funds for the bigger global diseases, such as tuberculosis and malaria. Work had been done by biopharmaceutical companies in donating patented products to initiatives such as WIPO Re: Search. Many companies were taking measures, since there had been a major move to corporate social responsibility in the world. She however explained that difficult issues remained, and that it was necessary to help build up the research and the innovation capacity. She emphasized that there was not one silver bullet. She observed that although some efforts had been made to overcome those barriers through pooling mechanisms and access to patented pharmaceuticals, the issue involved a number of complex questions.

55. The Delegation of India expressed its gratitude for the illuminating presentations. With respect to the question by the Delegation of El Salvador on quality of patents, it commented that one of the parameters that had been stated was the quality of an individual patent, i.e., the capacity of the patent to withstand the challenge in case of litigations. It indicated that most of the countries had a layer of courts, i.e., district courts, high courts, division benches and the Supreme Court. Further, there were also specialized tribunals. In cases where a patent had been litigated before a district court and its decision was reversed by a high court, the Delegation raised a question as to whether that could be an indication of the low quality of the patent. The second question by the Delegation referred to the fact that litigations were dependent on many extraneous factors, such as a party's financial capacity to appeal. It posed a question to Mr. Thumm: to what extent could the capacity to withstand the legal challenge be a parameter for the quality of patents?

56. Mr. Thumm acknowledged that those were complex questions which were difficult to answer. He highlighted that quality of an individual patent was one issue and quality of the patent system was another matter. On the first question, the issue of quality of an individual patent had some elements which were dealt with the patent system, in order to guarantee higher quality, such as certain court proceedings and specialized courts so as to increase the overall quality. As the court process took a long time, he advocated for opposition systems and reexamination procedures as an important element for patent quality. He underscored that, before going to court, offices provided a certain list of remedies. He also reiterated the importance of the quality of data, since all the details in the data could contribute to avoiding litigation, or, at least, providing competitors and other persons with the essential information. Referring to a hearing in Brussels with IP experts from industry, he noted that quality remained a very fishy concept. For instance, one expert from a

big international company had told him that, if somebody was suing him on a specific patent, that expert would always go back into the file and conduct his own review of that patent. In the view of the speaker, the need to check again the whole examination process before going to court shed some light on the concept of quality.

57. The Representative of TWN expressed his gratitude for the excellent presentations. With regard to the quality of patents, he referred to the recommendations of the Royal Society in its report of 2003, according to which follow up research might be constrained by patents being granted with too broad claims. In his view, such patents posed a particular risk in the technological areas in the early stage of development and were bad for science and society. Therefore, he considered it important that patent offices were sensitive to that risk, ensuring that patent examiners were properly trained and patent applications were thoroughly examined. The Representative asked the speakers about other mechanisms or ways Offices such as the EPO had been taking in addressing that issue. On the question of the definition of patent quality and the ability to withstand a legal challenge, he commented that it might be an indicator from an applicant's point of view, but not an indicator from a patent offices' point of view. In his view, the burden was on the applicant to file an application which should withstand the challenge. Finally, he requested Mr. Thumm to clarify what exactly was meant by harmonization, and asked Ms. Garner what the elements of a "long view" perspective could be.

58. Ms. Garner responded that at a very high level and as a general point without going into the details of any specific patent law, the "long view" perspective referred to the scope of some patents which had been granted in the very early stage of development in a new field of technology and had been leading to some of the current challenges. She noted that in emerging areas where there had been little experience, one should therefore be cautious that the scope of patents was not too broad. Thus, referring to the statement of the Royal Society in its 2003 report, she noted that the consequences of having too broad patents should be considered from a long term perspective as to the development of downstream research.

59. Mr. Thumm emphasized that patents were market tools, to be used or not used and enforced, on a market for economic purposes. That meant that an applicant who considered the highest gain on the market started with the broadest possible scope of claims, which would be often reduced during the process of granting a patent. In the discussions about the shortcomings of patent quality, he indicated that offices, including the EPO, frequently referred to the quality of patent applications, although that was a voluntary element depended on the applicants. Thus, he acknowledged that patent quality was not only an issue of patent offices, but also depended on the applicants. If an application containing claims with clearly defined scope was received, the process of examination would be easier and would lead to a more clear-cut solution. He pointed out that while some companies had understood that mechanism because it fitted into their strategy, their behaviors were very much related to the economic use that a company made out of a patent. On the question of harmonization, he explained that, from a general point of view, if an exception for a certain research use existed in one country, whereas not in other countries, that might be a reason, for instance, to move that research to the former country.

60. Referring to the consideration of patents as a "social contract" within the presentation, the Delegation of the Bolivarian Republic of Venezuela was of the view that any monopoly was generally supposed to be harmful as part of any civilization, and patents were an exception to prohibiting monopoly. The Delegation wondered how exceptions and limitations to the patent rights that were the exception to monopoly had been created at some point in history.

61. Mr. Thumm clarified that, speaking about a social contract, economists did not refer to monopoly, since anything that could be invented around a specific patent could be on the market. He clarified that the word "monopoly" was deliberately not used by economist, because, as a matter of fact, there were very few cases where a patent created monopoly on a market. On the

contrary, he noted that the benefits from a patent was to make information contained in the patent available to the benefit of all – usually known as the second pillar of the patent system. In his view, that was a very important element and equally important to the exclusivity aspect. He agreed with the idea of an exception to the exception since, in his view, it reflected very well the economic aspects of patents as an exception to the free market. Therefore, he noted that the attitude to regulations was more restrictive on the part of economists.

62. The Chair opened the third segment of the Seminar, namely case studies on implementation of exceptions and limitations, presented by Member States.

63. The Delegation of Costa Rica expressed its gratitude for the holding of the Seminar. It informed the Committee that the Costa Rican Law No. 6867 on Patents, Industrial Designs and Utility Models provided for the following exceptions and limitations: private use, research use, prior use, actions to obtain regulatory authorization by the authorities, exhaustion of the patent rights and granting of compulsory licenses and government use. Those exceptions and limitations should neither affect the normal working of a patent nor cause significant damage to the legitimate interests of a patent holder or a licensee. Similarly, Article 5ter of the Paris Convention provided for the exception of use of articles on foreign vessels, aircraft, and land vehicles. The Delegation noted that the Costa Rican Law did not contain any exception regarding extemporaneous preparation of pharmaceuticals or exceptions and limitations for the use by farmers or plant breeders of patented inventions. Regarding the exhaustion of patent rights, its legislation provided for international exhaustion. In addition, the patent law provided for compulsory licenses in Articles 18 and 19. The grounds for issuing those licenses were non-working, inadequate working or insufficient exploitation, that meant anticompetitive or unfair competition, or dependent patents. With regard to the exception of government use, Article 20 contained a so-called “public use license” or “license for public use”. For example, in cases of national emergencies, a granted patent or a patent application could be subject to a compulsory license at any point, even without the patent holders’ authorization, so that it could be exploited by third parties or the government. The law also stated the reasons why a compulsory license for exploitation by the government might be issued. Further, the Delegation informed that the patent office of Costa Rica had not documented cases where use of exceptions and limitations had been made. For example, it was not possible to know when use had been made of the exceptions for the purposes of scientific research or exhaustion of rights because, as commonly known, those activities were carried out in the purely private sphere. For the Delegation, it was important to highlight that neither use of a compulsory licenses nor use of licenses for public use had been made in Costa Rica. The Delegation reiterated that it had submitted further information in its response to the questionnaire on exceptions and limitations. In its view, it was very important to continue to look at those issues in the Committee and to make progress on the items on the agenda. It suggested that experiences should be shared so as to adopt best practices implemented by offices with greater experience.

64. The Delegation of Brazil expressed its gratitude to the Delegation of Costa Rica for bringing important information about how exceptions and limitations were used and which were the most important for development. In its view, that was of the utmost importance for the SCP, since it touched upon vital development concerns. It reiterated that a number of recommendations of the Development Agenda addressed that issue directly or indirectly, be it in connection with norm-setting, public policy, technology transfer, access to knowledge or impact studies. For instance, recommendations 17 and 22 of the Development Agenda stated that WIPO should take into account in their activities the flexibilities in international agreements, as well as address in its working documents for norm-setting activities, as appropriate and as directed by Member States, issues such as potential flexibilities, exceptions and limitations for Member States. With that in mind, the Delegation had tabled document SCP/14/7, which contained a work program on exceptions and limitations in three phases. In the view of the Delegation, the widespread support that its proposals had received demonstrated the relevance of discussions of exceptions and limitations for WIPO Member States. The Delegation further underscored the underlying rationale

of the exceptions and limitations through patent law. In its view, exceptions and limitations were intrinsic elements of every law. They served a number of purposes by conferring the necessary flexibility, for example, to guarantee national security and to shape public policies, to meet *inter alia* development, competition and public health surveillance, to build roads, to prevent crimes, to promote elections or to avoid pandemics. Governments sought to ensure compliance with rules and protect private goods and rights, as well as to make use of exceptions and limitations. In order to fulfill the purposes above, the Delegation observed that patents were also subject to a special treatment. In the view of the Delegation, the patent system had to strive for equilibrium of rights among its users and accordingly, it should not only comprise benefits for IP holders but also for the society as a whole so that the welfare of the society prevailed. All those elements constituted clients of the system. Exceptions and limitations to patent rights were standard parts of laws and legal doctrine. Therefore, the Delegation noted that there was substantial convergence among Member States as to the importance of those flexibilities to the patent systems. It noted that the existence of different approaches to exceptions and limitations might raise Member States' doubts regarding: (a) why and how they could use their policy space; and (b) how the use of exceptions and limitations was linked to innovation policies addressing public health, nutrition or environmental concerns. As provided in the answers to the questionnaire (see document SCP/16/3), Member States from different levels of development made use of exceptions and limitation in order to ensure that the patent system in place was balanced, both with respect to the rights granted to right holders and third parties, which included not only companies and governmental institutions but also the society as a whole. In the Delegation's view, the exceptions and limitations, however, greatly varied in its scope, since the objective reality of each Member State influenced the details of the exceptions and limitations in place. For instance, the exceptions and limitations for experimental use and/or scientific research might be applicable or not, depending on as to whether the individual researcher had a commercial intent. In some countries, experimental use with commercial purpose was not allowed, while, in others, it was believed that a patentee would not suffer a direct loss as long as the product was not put on the market. In the view of the Delegation, such differences illustrated the necessity of a flexible policy space that each Member State was able to adapt its legal framework to its level of development and thus reach the goals of public policy. In its view, that was another argument against international harmonization of patent laws since harmonized patent laws would impair the ability of States to adjust their legislation and encumber the attainment of the objectives of the patent system. Considering the examples of experimental use and scientific research, a well-designed law that made use of the exceptions and limitations should attract foreign direct investments to create legal certainty. Thus, the Delegation was of the opinion that exceptions and limitations would not weaken the patent system but rather calibrate it in order to reach a common ground where the right holders and third parties were adequately addressed. The Delegation further noted that the social aspect of exceptions and limitations was also relevant. One of the answers to the questionnaire had stated that the goal of a patent was to protect the right holder against the commercial exploitation of the invention. That perspective was often found in the answers of other Member States. In the view of the Delegation, technical knowledge found in patents should be the basis for further research and education. The Delegation highlighted that the single information on exceptions and limitations was not enough. A more forward investigation should be made with the intent of identifying which exceptions and limitations were potentially more effective to address the development concerns and what should be the conditions for Member States to fully take advantage of them since national capacities affected to a large extent the individual ability of States for using exceptions and limitations. The Delegation suggested it as another area for future work of the Committee, provided that it remained in line with the Development Agenda recommendations, especially in line with those ensuring the policy space.

65. The Delegation of India, referring to the metaphor used by Ms. Garner in her presentation, that patents were tools, stated that it was most appropriate to raise a question as to how the tools could be used. In the Delegation's view, while the tools could be used in various ways, keeping in mind that a patent was a social product, such tools had to be used for the purpose of the public

good. The Delegation welcomed that proposal in her presentation and suggested that the Committee continue to extend ideas on that issue. Referring to the statement made by the delegations from developing countries, the Delegation of India suggested that their needs be explored further through a study by the Committee.

66. The Delegation of the Russian Federation expressed its wish to the Secretariat for preparing new documents based on the questionnaire detailing national practices in applying limitations and exceptions. It stated that the information contained in the documents was useful for further analysis in its country, such as in improving national law enforcement (e.g., on issues of extending limitations and exceptions to means of transport, storing and importing vehicle spare parts, and the right of prior and subsequent use, etc.). In its view, the sections of the respective documents which defined the concepts and terms used in the applicable law of Member States should be highlighted in particular. That information facilitated a deeper understanding of the content of the legal norms and the objectives of government regulation with regard to exceptions and limitations. The Delegation of the Russian Federation supported the standpoint of several Member States regarding the adequacy of the legal framework in terms of achieving the objectives for which the limitations and exceptions had been introduced. It informed that the general requirements of the Russian legislation were focused on the provisions of Articles 30 and 31 of the TRIPS Agreement, under which members could stipulate limited exceptions to patent rights. It then elaborated on the theoretical approaches and practical examples in the Russian Federation for the five designated clusters of exceptions and limitations. As to private and/or non-commercial use, Article 1359(4) of the Civil Code of the Russian Federation stated that “use of the invention for personal, family, domestic or other non-business needs shall not infringe the exclusive right in an invention where the purpose of such use is not to generate profit or income.” According to the judicial practice, use of a product or process in safeguarding an organization’s or entrepreneur’s business (e.g. office equipment, office furniture, vehicles, etc. (Resolution No. 18(5) of the Plenum of the Supreme Arbitration Court of the Russian Federation of October 22, 1997)) constituted purposes unrelated to personal use. Given the court’s decision, use of patented subject matter was permissible where a person directly manufactured a product containing the patented solution. In addition, it was irrelevant as to whether the product was manufactured as a result of parallel, independent, creative work, or using other people’s ideas (including directly using patent application materials). It should be noted that importation into the territory of the Russian Federation by a person intending to use a product for private purposes also constituted free use of the product. As to experimental use and/or scientific research, Article 1359(2) of the Code stipulated that “conducting scientific research on a product or process incorporating an invention, or performing an experiment on such a product or process, shall not constitute an infringement of the exclusive right in an invention”. In the Russian Federation, the application of that exception to patent rights was limited to the performance of scientific research or experiments on the patented subject matter (for the purposes of testing, and assessing effectiveness for scientific purposes, etc.). Under the legislation of the Russian Federation, third parties could only study the patented subject matter, but not use it as a means of conducting research, without infringing the exclusive right of the patent holder. The legislators in the Russian Federation had not treated scientific research on a product or process in which patented inventions were incorporated as an infringement of the patent holder’s exclusive right. The Constitutional Court of the Russian Federation had recognized that the limitation had been established in order to safeguard the balance of interests of all parties for whom freedom of scientific and technical creativity had to be guaranteed, and did not presuppose the introduction of the patented solution (Opinion of the Constitutional Court of the Russian Federation No. 389-0 of October 16, 2003, Resolution of the Plenum of the Presidium of the Supreme Arbitration Court of the Russian Federation No. 2578/09 of June 16, 2009). Specifically, in the case of Novartis AG, the Supreme Arbitration Court of the Russian Federation had confirmed that in using the drug Imatinib, manufacturing and submitting drug samples to a scientific examination center for subsequent quality testing, as well as officially registering the drug with the Federal Supervision Service for Healthcare and Social Development (Roszdravnadzor), could not be deemed as an infringement of rights. However, the manufacture or storage of the product prior to the patent-

expiry date for the purpose of sale or introduction into civil circulation had not been permitted. As to the preparation of medicines, according to Article 1359(5) of the Code, “one-off preparation in pharmacies based on physicians’ prescription of medicines using an invention shall not constitute an infringement of the exclusive right in an invention”. The Delegation noted that the legislators in the Russian Federation had formulated the exception to the patent monopoly narrowly. In adjudicating legal disputes, the courts deemed the preparation of medicines to be one-off only to the extent specified in the prescription. Preparation of a medicine for subsequent storage and sale could not be considered a single use: therefore, preparation of a patented medicine for future use could be regarded as an infringement of the patent holder’s exclusive right. As to prior use, Article 1361 of the Code provided that “any person who, before the priority date of an invention, was using in good faith within the territory of the Russian Federation an identical solution created independently from the author, or made the necessary preparations for such use, shall have the right to proceed with that use free of charge provided that the scope thereof is not extended (the right of prior use)”. The right of prior use was a subjective civil right with unique characteristics within the territory of the Russian Federation. The classical meaning of prior use was to incentivize parallel creativity of persons who, for one reason or another, had been unable to patent the results of their technical work at the appropriate time. Paragraph 11 of Resolution of the Plenum of the Supreme Court of the Russian Federation No. 14 of April 26, 2007, had established that the right of prior use referred to conditions precluding liability for use of patented subject matter. The prior user could apply to a court to request the establishment of the right of prior use. However, the overwhelming majority of judicial cases concerning recognition of the right of prior use had involved examining objections to the patent holder’s action against the prior user to prevent infringement of exclusive rights. In any case, the right of prior use had arisen not as a result of a court decision, but as a result of the act of creating and using the subject matter. The court judgment had confirmed that the right of prior use could be established in law, subject to proving the following factors: use by the prior user of a solution identical to the patented solution, independent creation of the identical solution, fair use of the solution, and use of, or making preparations to use, the identical solution within the territory of the Russian Federation before the priority date of the patented subject matter. The identical nature of the solution used by the prior user was to be confirmed by forensic examination. Further, independence of creating the identical situation was manifested in the independent nature of the prior user’s art, which was presumed unless proven otherwise by the patent holder. Specifically, where judicial examination of a dispute concerning prior use had established that the work had been created with the participation or assistance of the inventor of the patented solution, or based on information obtained from the patent holder, the independence of the creation of an identical solution would not be established. Specifically, the courts had upheld the defendant’s inability to claim the right of prior use in the case of production of a therapeutic food additive using a method created by one of the co-inventors of the patented method under the scientific supervision of the patent holder. As case law had shown, an individual requesting the right of prior use had to provide evidence of *bona fide* of his own identical solution. Regarding the use of or preparation to use, an identical solution within the territory of the Russian Federation before the priority date of patented subject matter, the Delegation observed that that fact was particularly important in recognizing the right of prior use, and was subject to confirmation by the prior user. It noted that legal arbitration provided examples of how use of a solution identical to a patent was established on a specific date or over a period of time. In that case, the “use” meant delivery of goods containing a patented solution and a sale of manufactured products. At the same time, the following were taken into account as evidence: the act of commissioning equipment for the production of goods; bills of lading; and the act of accepting services rendered for the production of leaflets and manufactured products. It added that technical documentation containing the patented solution and used for manufacturing the products, played a special part in proving the right of prior use. Drawings, certificates of conformity and test reports might be subject to investigation. The existence of approved technical specifications and technical descriptions for production was likewise regarded as evidence of preparation for manufacture. Purchase of equipment for the manufacture of products, for example, served as proof of the date of preparation to use the said solution. The Delegation noted that it was worth noting that many uses of an

identical solution, including the importation of products, and not only manufacture thereof, had already been defined in the judgments of the Russian courts in establishing the right of prior use. The courts had recognized that the importation of the product (or article), and its subsequent sale or lease, constituted use of the identical solution which was covered by the right of prior use. In one case, the court had established recognition of the right of prior use not only in relation to a product, but also in relation to the method of using the patented product with patent No. 2125298, "a display device and a method of operating the display device" (specifically, in that case, the issue had been whether to allow the defendant to use the article free of charge, as had been the case before the priority date). A similar judgment had been made in recognizing the right of prior use when importing products from abroad, covered by an industrial design patent. The courts found that the defendant did not manufacture the disputed article, but imported it from other countries; the courts likewise identified the defendant's right of prior use, referring to the defendant's *bona fide* sales of the product up until the priority date of the plaintiff's patent. As to the scope of prior use, the defendant should specify the scope of use and provide evidence of such scope. The burden of proof, that the scope of using an identical solution, had not been extended lay with the prior user. Case law specified that the scope of use meant the number of products or articles manufactured using a patented solution, or in relation to which the necessary preparations had been made. In determining such scope, not only should the actual number of articles manufactured up until the priority date be taken into account, but also the number of products for the manufacture of which the necessary preparations had been made. In addition, the Delegation explained the issue of legal regulation on transferring the right of prior use. Transfer of the right of prior use was only possible together with a business in which an identical solution had been used, or necessary preparations to that end had been made. As a business entity, the prior user could exercise his right not only in his own business, but also in renting and manufacturing facilities and necessary equipment and supplies from other persons. The right of prior use, together with manufacturing equipment used in order to exercise it, could constitute property and could be bought and sold, exchanged, leased, and used in a number of other transactions. The right of subsequent use could be considered as a limitation to the patent monopoly. The right of subsequent use was granted under the Russian legislation, subject to the following conditions: (i) use of the invention commenced when preparations to that end had been undertaken during the period between early termination of the patent and reinstatement thereof; and (ii) the scope of use of the invention, for which patent protection had been reinstated, had not to be extended by the subsequent user. The Delegation explained that the right of subsequent use was the opportunity for the subsequent user to use the invention after the reinstatement of the patent monopoly without the threat of accountability for infringing another person's patent. It was worth noting that, unlike the right of prior use, the right of subsequent use could not be transferred to another person together with an enterprise. Regarding the use of articles on foreign vessels, aircrafts and land vehicles, Article 1359 of the Code stated that "use of a product incorporating the invention in the structure, in auxiliary equipment, or in operating vehicles (river and marine, air, automobile, and railway transport) or spacecraft of foreign States, provided that such vehicles or spacecraft are located within the territory of the Russian Federation, temporarily or accidentally, and that the aforesaid product or article is used solely for the needs of vehicles or spacecraft shall not constitute an infringement of the exclusive right in an invention. Such an act shall not be recognized as an act of infringement of the exclusive right with respect to vehicles or spacecraft of those foreign States that grant similar rights with respect to vehicles and spacecraft registered in the Russian Federation". The auxiliary equipment meant equipment which facilitated operation of the vehicle, but was not a constituent part thereof. The provisions of Article 1359 of the Code amended the principle of territoriality with regard to the scope of the exclusive right: if a solution used in a vehicle had only been patented in the Russian Federation, foreign countries were not bound by said patent – in such countries, use of the solution was free. While, "importation" of those vehicles into Russia was an infringement of the Russian patent holder's exclusive right, use of a product incorporating an invention in vehicles of foreign States located temporarily or accidentally within the territory of the Russian Federation was generally accepted as an exception

to the patent right under global practice on the basis of reciprocity. An exception to the exclusive right provided by a patent right was provided for in Article 5ter of the Paris Convention, for instance.

67. The Delegation of Japan, speaking on behalf of Group B, thanked the Secretariat for preparing the series of documents on how five different exceptions and limitations were implemented in Member States (documents SCP/20/3 to 7). The Delegation stated that those documents provided useful information on the implementation of exceptions and limitations in other countries, providing a valuable reference when Member States considered arrangements which were appropriate and adapted to their domestic circumstances. In its opinion, the documents showed that the current existing exceptions and limitations worked well. Further, the Delegation reiterated the fundamental principle that all Member States should keep in mind, i.e., exceptions and limitations should be used in very limited and specific circumstances and should not be the general rule. It explained that appropriate patent protection was the general basis on which exceptions and limitations could be built upon, where necessary and justified. Therefore, the Delegation stated that exceptions and limitations should not be considered or discussed in an isolated manner, namely, outside of the context of appropriate patent protection. It further considered that policy making should always be evidence-based.

68. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, appreciated work done by the Secretariat in preparing a number of new documents concerning exceptions and limitations to patent rights, which contained information received from Member States on how the five exceptions and limitations under discussion had been implemented in Member States. The Delegation also thanked the Secretariat for its presentation of those documents. The CEBS Group considered a comprehensive and comparative overview of the practical implementation of relevant exceptions and/or limitations under the applicable laws of Member States, as provided in those documents, together with an accompanying seminar on exceptions and limitations, very useful and helpful for further discussion. The Delegation shared the view of other Member States which had stated that further work on the issue should maintain an appropriate balance between the interest of right holders and the interest of the general public. In its opinion, the discussion on exclusions from patentability and the exceptions and limitations of patent rights should take into account corresponding legal standards relating to substantive conditions of patentability of an invention, such as novelty, inventive step and industrial applicability. The Delegation reiterated the Group's readiness to participate constructively in continuing discussions on exceptions and limitations to patent rights.

69. The Delegation of Greece, speaking on behalf of the European Union and its Member States, expressed its gratitude to the Secretariat for the preparation of documents SCP/20/3 to 7 containing a summary of how certain exceptions and limitations to patent rights were provided for in national laws, as well as the practical challenges encountered by Member States in implementing them. The European Union and its Member States recognized the importance attached to the issues of exceptions and limitations to patent rights, and expressed its belief that those documents would serve as a useful reference for academics, law and policy makers working in the area. The Delegation considered that exceptions and limitations to patent rights maintained an appropriate balance between the interests of rights holders and the general public. Thus, in its view, neither exclusions from patentability nor exceptions and limitations to patent rights should be discussed without corresponding legal standards used to determine whether an invention was patentable, such as novelty, inventive step, and industrial applicability. The Delegation noted that the nineteenth session of the Committee had mandated the Secretariat to prepare a further document in that area for the twenty-first session of the Committee, covering the remaining exceptions and limitations to patent rights contained in document SCP/18/3. It emphasized that, in preparing those documents, the Secretariat should be objective and not seek to judge the effectiveness of exceptions and limitations in meeting national development or other criteria. The Delegation looked forward to the similar seminar on exceptions and limitations to patent rights to be held at the following session of the SCP.

70. The Representative of TWN made some general comments about the studies which had been prepared by the Secretariat. Unfortunately, the mandate which was given to the Secretariat in preparing those documents was limited, as it had to be based on the input from Member States and without evaluating the exceptions and limitations. Therefore, as provided by the mandate, there was no wider assessment of whether any of the exceptions or limitations were being used for the purpose of meeting public policy goals and society needs and excluded important elements, such as developing needs and public health goals as found in the proposal by the Delegation of Brazil contained in document SCP/19/6. Further commenting briefly on the question of implementation of the exceptions and limitations, he noted that the documents which were prepared by the Secretariat had taken a narrow approach to the implementation and seemed to be a cursory and factual overview of the responses submitted by Member States. On the issue of constraints, he noted that, even if exceptions and limitations existed in national legislation, developing countries and LDCs might not be able to implement them due to other various constraints, as had been mentioned by the African Group, such as lack of human resource capacity and existence of other policies and laws at the national and international levels. In his view, there was a need to emphasize those aspects when discussing national implementation. The Representative added that the existence of those exceptions and limitations from a legal perspective was not enough and should only be considered as a first step. In his opinion, another important challenge for the implementation of research use exception was judicial intervention that had reduced its scope in some countries.

71. The Delegation of the Bolivarian Republic of Venezuela requested clarification with respect to the statement made by the Delegation of Brazil, in which it had stated that exceptions did not weaken the patent system.

72. The Delegation of Senegal expressed its gratitude to the Secretariat for providing the documents and supported the statements made by the Delegations of India, Brazil and other members of the African Group on exceptions and limitations.

73. The Delegation of Brazil responded to the Delegation of the Bolivarian Republic of Venezuela that in accordance with a traditional position of Brazil, having a strong patent system equaled to having a balanced patent system that would, strike the balance between the patent rights on the one hand, and the obligations to disclosing information as well as exceptions and limitations to the patent right, on the other hand.

#### **AGENDA ITEM 7: QUALITY OF PATENTS, INCLUDING OPPOSITION SYSTEMS**

74. Discussions were based on documents SCP/17/7, 8, 10, SCP/18/9, SCP/19/4 and 5 and SCP/20/8 and 11 Rev.

75. The Delegation of Japan, speaking on behalf of Group B, reiterated the importance of the issue of quality of patents, including opposition systems, and thanked the Secretariat for the preparation of document SCP/20/8. Taking account of significant difficulties experienced by the IP offices in meeting the increasing demand for patents and reducing existing backlogs, the Delegation stated that further efforts were required to expedite examination and promote innovation. Work sharing between IP offices was an important solution which was essential to make the most of limited resources of IP offices and to make the patent system operate in a more efficient and effective manner and enhance the quality of patents. In the opinion of the Delegation, it was useful for the IP offices to know the programs adopted by other offices in order to learn from them. It was also beneficial for users to know the kinds of programs they could use in order to acquire greater international protection for their inventions. The Delegation stated that document SCP/20/8 gave detailed information about various initiatives, categorized them based on the character of the initiatives and further identified challenges and initiatives supporting the work

sharing environment. In its view, it also provided a very useful source of information both for the IP offices and users. The Delegation stated that there was further room for that information to be complemented by the Secretariat in cooperation with national and regional offices. It further stated that Group B appreciated efforts by the Secretariat to further improve the quality of that document. Turning to the proposal contained in document SCP/20/11 Rev. regarding the dedicated webpage on the WIPO website, the Delegation considered that it could positively contribute to both IP offices and users. In its opinion, annual conferences on the margins of the SCP sessions could further deepen the understanding of those activities and further improve the initiatives. Therefore, in the view of the Delegation, that proposal should be further pursued for the benefit of users whose contributions promoted the activity of WIPO and which were important priority for WIPO. Group B continued to be convinced that a questionnaire covering the elements found in the proposals by the Delegations of Canada, Denmark, the United Kingdom and the United States of America would provide further valuable insights on the issue of patent quality. The proposal by the Delegation of Spain on inventive step which encompassed the issue of quality of patents could also provide great insight on that issue. The Delegation stated that the SCP was and should be a technical Committee where experts on patents developed technical discussion keeping in mind the purpose of the patent system and how the system could contribute to innovation through its development. In that sense, the Delegation believed that the agenda item "quality of patent", should form a very fundamental basis of further work of the Committee.

76. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, thanked the Secretariat for preparing and presenting document SCP/20/8. The CEBS Group stated that it attached great importance to quality of patents and further improvement of the patent system. The Delegation reiterated its interest in continuing discussions on various aspects of that important issue, based on all related proposals submitted to the Committee by the Delegations of Canada and the United Kingdom, Denmark and the United States of America. The CEBS Group was also in favor of launching a questionnaire containing elements of all above-mentioned Delegations' proposals. In addition, the Delegation supported the various channels of information-sharing, provided they were efficient and non-duplicative. In that light, the CEBS Group welcomed the recent proposal made by the Delegations of Japan, the Republic of Korea, the United Kingdom and the United States of America. The CEBS Group considered the gathering of information on work sharing programs among patent offices extremely useful and helpful for discussing legal and technical issues related to the improvement of quality of patents, namely patent search and examination. The Delegation considered that clarification and identification of different concerns and practices relating to work sharing, including its benefits, might facilitate greater sharing of work among different Patent Offices. The Delegation was of the opinion that the proposed webpage on the WIPO website and annual conferences on the margins of SCP were suggestions towards the above mentioned aims. The Delegation also supported the proposal by the Delegation of Spain, and considered it useful to launch a comparative study on the inventive step concept. The Delegation was convinced that such a study would increase the knowledge in that respect and support furtherance of work on quality of patents for the benefit of all Member States. The CEBS Group further expressed its belief that a working program on quality of patents should be created by the Committee, and expressed its readiness to participate actively and constructively in the Committee's discussion.

77. The Delegation of India stated that quality of patents was very important issue not only for the development of any patent system of a nation but for the smooth transfer of technology and for enriching further stock of technical knowledge of that nation. The Delegation noted that a good patent served the nation by escalating its technological standard and, consequently, its competence to protect its society. It further noted that the question of the quality was proportional to the public policy objective of a nation. Accordingly, in the view of the Delegation, the perception of the quality would not be uniformly equal for all the countries with different levels of development. The Delegation then stated that the *raison d'être* of the patent system was the disclosure of the invention in an enabling manner so that a patent could be used as the best mode of transfer of

technology in preference to trade secrets. The Delegation was of the opinion that in the present system, however, they had drifted far away from that idealistic notion of the patent system. Therefore, in the view of the Delegation, the quality of the patent system was better understood from the perspective of the degree of technological content of a patent specification and its efficiency as a tool for transfer of technology. The Delegation believed that quality of a patent could not simply be improved by adopting the practice of other patent offices. The Delegation opposed any attempt of harmonization in the name of quality issues. As a matter of principle, the Delegation neither favored the automatic validation of international search and examination reports, nor did it consider that a national patent office was under any obligation to accept automatically any report prepared by another national patent office. In the opinion of the Delegation, the work sharing would create a dividing line, i.e., the offices of some countries would forever remain on the receiving side of the dividing line thus depending upon the product delivered by the other countries. The Delegation therefore considered that enhancement of the competence of the offices would thus be a more preferred option. In accordance with the Indian Patents Act, the Delegation explained that its examiners were duty bound to conduct their own search and examination. Although they could use the results of the search and examination done by other patent offices, they must use them *vis-à-vis* the provisions of the Indian Patents Act. With respect to document SCP/20/11 Rev., the Delegation restated its position that work sharing could not be the ultimate solution for improving quality of patents. The Delegation noted the DAG statement made at the third session of the PCT Working Group in June 2010 (see document PCT/WG/3/13): "Member countries of the PCT will always be divided across a line separating those that are international search and examination authorities (ISEA) and those that are not. The former would ideally produce top-notch quality examinations within the PCT system whereas the latter would have little if any capacity for conducting substantive examination of patents, thereby limiting themselves mostly to validating the work of the ISEA. We do not favor this approach that only freezes a divisive situation rather than contributes to the better integration and operation of the overall PCT system". With respect to the proposal made by the Delegation of Spain on the study of inventive step, the Delegation reaffirmed its interest in the study as the notion of a skilled person had the most vital role in determining the inventive step. The Delegation noted that Article 27 of the TRIPS Agreement did not define the level of the skilled person and kept a room for flexibility for setting the floor of that hypothetical addressee as per the policy norms of a Member State. It considered that lowering of the level of the skilled person would allow the entry of the frivolous inventions. Moreover, in the view of the Delegation, the patent system had to promote the progress of useful arts in conformity with public policy objectives. It was stated further that with the passage of the time, horizons of inventions were continuously redefined and every day needed to begin from the new horizons. The Delegation stated that the concept of the skilled person in the context of the inventive step had to be judged from that perspective. Reiterating its support to the study, the Delegation, however, clarified that such support should not be construed to mean that harmonization of the concept of the skilled person was a desired result of that discussion. The proposed study might be useful to understand the differences in terms of inventive step. The Delegation reiterated that a study related to the different thresholds of a skilled person for the determination of sufficiency of disclosure would also be useful in the context of quality of patents.

78. The Delegation of the Republic of Korea noted that the business activities, as well as patents, had become increasingly international. According to the WIPO Statistics Report, over 35% of the patent filings in the world were made overseas. Since the introduction of the PCT, which was the first and largest scale multinational work sharing program established in 1978, all the multinational work sharing programs pursued by patent offices had served the same purpose of avoiding duplicative work, enhancing consistency in examination results, speeding up the securement of patent rights and bringing efficiency to the patent system as a whole. In that context, the Delegation believed that the active engagement of all delegations of the Committee and the Secretariat in the preparation of document SCP/20/8 that dedicated that explored the inter-office work sharing programs was truly praiseworthy. KIPO had been also actively implementing bilateral and multilateral work sharing programs and information-sharing platform, including the PPH, PCT

Collaborative Research and Examination, Joint Prior Art Search Program, KIPO-USPTO pilot and IP5 One Portal Dossier. The Delegation explained that those programs had contributed to enhancing the efficiency of the patent system and improving the quality of patent examination. The Delegation stated that, for example, over 90% of the KIPO examiners expressed their strong support to the PCT collaborative search and examination between the KIPO, USPTO and EPO, as it had made remarkable contribution to the quality of the international search reports by making timely exchange of information between participating offices. The Delegation noted that, in the process of enhancing work sharing programs, during the IP5 meeting in 2013, KIPO had proposed a work sharing program entitled "Collaboration before the Office Action" to ensure reception and utilization of all necessary information from other IP offices before the launch of a first office action on the part of The Office of Early Examination. The Delegation further explained that KIPO had proposed other collaborative programs between the ISAs and national offices. In line with the positive feedback on the work sharing activities, KIPO was internally preparing work sharing enhancement package called the "Work sharing 3.0" which included timely exchange of information between the offices, including the Office of Early Examination and the Office of Later Examination, expanding the volume of the work sharing programs, and the involvement of users in the operation of the work sharing programs. Considering the increasing importance of the multinational work sharing, the Delegation expressed its firm belief that the dissemination of the latest information regarding worldwide work sharing activities would contribute to the enhancement of the international cooperative works which might ultimately serve users benefit worldwide by improving quality and consistency of the examination. Therefore, establishing a special webpage reserved for the work sharing activities on the WIPO homepage and hosting an annual work sharing Conference were considered by the Delegation as timely and beneficial for any patent-related entities. Finally, the Delegation stated that it looked forward to continued discussion of the important issue of work sharing.

79. The Delegation of Greece, speaking on behalf of the European Union and its Member States, reiterated its support for advancing work on quality of patents as proposed 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 the Delegation of Spain (document SCP/19/5). The Delegation considered those proposals fully complementary to the mandate and the core expertise of the Committee, taking into account a number of the Development Agenda recommendations. The Delegation noted with pleasure that some WIPO Member States, including six European Union Member States, had already contributed to the discussions on quality of patents with comments, additional proposals and further information about the subject matter, compiled in documents SCP/17/INF/2 and SCP/18/INF/3. The Delegation continued to encourage a broader range of members to do the same. The European Union and its Member States were of the view that the Committee should establish a work program on quality of patents. As to the next steps to be taken by the Committee in relation to the subject matter, the Delegation was in favor of launching a questionnaire containing the elements of all the proposals by the Delegations of Canada and the United Kingdom, Denmark and the United States of America, taking into account relevant comments/suggestions from other groups. Furthermore, in relation to the third component of the work program proposed by the Delegations of Canada and the United Kingdom, i.e., "process improvement", the Delegation supported the proposal of the Delegation of Spain to look further at the inventive step concept and methods of evaluating inventive step used in the WIPO Member States. In the view of the Delegation, that proposal had the potential of becoming a new agenda item that could help the Committee opening new areas of work to make further progress. In relation to opposition systems, the European Union and its Member States recognized the important role of opposition procedures, and similar administrative revocation and invalidation mechanisms, in ensuring the proper functioning of patent systems. In particular, the Delegation was convinced of their contribution to increasing the quality of patents by providing a simple, rapid and inexpensive alternative to litigation. While the Delegation reiterated that the freedom of all WIPO Member States in deciding whether or not to introduce such procedures or mechanisms into their national legislation should

be preserved, the European Union and its Member States were of the view that the Committee should continue its work on opposition systems, and consider the elaboration of a compilation of models of opposition systems and other administrative revocation and invalidation mechanisms, in a non-exhaustive manner. As regards work sharing programs, the European Union and its Member States thanked the Secretariat for its preparation of document SCP/20/8 on work sharing programs among patent offices. It noted that all the work sharing regimes identified in that document aimed at enhanced international cooperation to improve the quality and efficiency of the patent system overall. It further noted that many delegations also endeavored to support and improve the PCT system toward the same goal. The Delegation observed that the work sharing initiatives listed most frequently involved the sharing of information and work products related to the search and substantive examination of patents, through specialized IT systems. Some also involved the use of collaborative patent classification regimes, and standardized documents. The Delegation supported the proposal by the Delegations of Japan, the Republic of Korea, the United Kingdom and the United States of America regarding works-sharing. In the opinion of the Delegation, a dedicated page on the WIPO website would improve awareness of existing initiatives and enable patent offices to collaborate more effectively. In its opinion, annual conferences on the margins of the SCP sessions would also provide a valuable opportunity to share experiences on work sharing programs and find ways to improve the usefulness of those programs to IP offices, to users of the IP system and to the general public. Given the positive benefits described in relation to work sharing and the optional nature of the schemes, the Delegation encouraged more widespread use of work sharing products among patent offices of different sizes and from different levels of development. The Delegation observed that work sharing among patent offices of different sizes could be further enhanced if some difficulties identified in document SCP/20/8 were removed. In the view of the Delegation, it would be useful for WIPO to further explore those challenges. Therefore, the Delegation proposed that the Secretariat, together with the Member States, prepare a study examining how different laws and practices limit the potential for work sharing, and what voluntary measures could be put in place to address problems at the international level.

80. The Delegation of Brazil attached great importance to the discussion on quality of patents, which was a priority issue to Brazil, as expressed by the investments in the improvement of its patent system in order to reach its public policy goals. The Delegation, therefore, underscored the importance of having an inclusive debate that encompassed all users of the system, such as inventors, companies, public and private R&D institutions. The Delegation stated that the debate on the relationship between the patent system and the fulfillment of national objectives should be assessed in the framework of the implementation of WIPO's Development Agenda. That debate, according to the Delegation, led to the conclusion that the "one-size-fits-all" approach was not adequate to address different socio-economic realities. Thus, in its view, every Member State needed to calibrate its patent system according to its national priorities. The debate on the quality of patents, in the view of the Delegation, should not be restricted to the accelerated processing of patent examination. It should include a high-level requirement of novelty, inventive step and industrial application. The scope of protection and the sufficiency of disclosure requirement must also be determined to protect only the innovative technologies. The Delegation further stated that a dysfunctional patent system could harm society. The Delegation expressed its understanding that patent monopolies must be well delimited in order not to foreclose the possibility of all forms of short-term and long-term competition. Therefore, according to the Delegation, a deeper debate on the quality of patents was a prerequisite to the eventual evaluation of the benefits of information exchange mechanism and process improvements between WIPO Member States. Regarding the proposal found in document SCP/20/11 Rev., the Delegation thanked the sponsors of the proposal for preparing that document. The Delegation, however, expressed its regret that, since the first version of the proposal had been circulated only 11 days before the opening of the twentieth session, it had not been able to properly analyze and consult the capital on the content of the proposal. The Delegation nevertheless stated that it looked forward to discussing that proposal in future SCP sessions.

81. The Delegation of Algeria, speaking on behalf of the African Group, reiterated its concern about the lack of a precise definition of the concept of "quality of patents". From the perspective of the members of the African Group, the quality of patents was largely based on the criteria of patentability which depended essentially on the development objectives of each country. The African Group believed that the proposed initiatives would not achieve those objectives and would also result in harmonization of practices in the field of patent law, which might be prejudicial to the provisions of flexibility in national legislation on patents in various countries. The quality of patents, according to the Delegation, referred to the ability of the patent office to apply the domestic patent law effectively, as the criteria for patentability might be defined and applied differently among national patent legislations. The Delegation further referred to paragraph 49 of document SCP/20/8, which cited differences in substantive laws as the first challenge with regard to work sharing processes. The Delegation noted the proposal to develop a work program in the SCP to address how patent offices could cooperate and collaborate in conducting search and examination work in order to improve the quality of granted patents. However, in the view of the Delegation, patent quality could not be improved by simply adopting the practices of other patent offices, and harmonization of patent law might undermine the flexibilities existing in various national patent laws. The Delegation stated that it would be important for national offices to retain the discretion in determining the patentability criteria as defined in their respective national legislations. Regarding the questionnaire proposed by the Delegations of Canada and the United Kingdom (document SCP/18/7), the Delegation noted that it focused only on the issues of how national offices defined patent quality and how they measured the quality of the examination and granted patents, as well as how they utilized, or might utilize better, foreign search and examination work. In its opinion, however, the issue of patent quality was not limited to the quality of patent examination. It stated that strong and effective patent oppositions also played a significant role in ensuring a high quality patent. Referring to the proposal made by the Delegation of Spain, the Delegation recalled that the inventive step was not the only criterion that was determinative of the quality of a patent. In the view of the Delegation, it also involved the issues of novelty, industrial applicability and sufficiency of disclosure. Therefore, it was important to look at those factors in order to understand how those elements were evaluated in different countries and their impact on patent quality. However, the Delegation stated that caution needed to be exercised in discussing issues like inventive step or any other patentability criteria under the agenda item on patent quality to ensure that those discussions did not address issues of substantive harmonization. Finally, the Delegation noted the need to consider different thresholds in national patent legislations for the requirement of "sufficiency of disclosure", including the identification of practical means for addressing issues related to insufficient disclosure, as it linked to patent quality.

82. The Delegation of Spain supported the statement made by the Delegation of Greece on behalf of the European Union and its Member States. The Delegation also thanked the Secretariat for the preparation of a document concerning the issue of the re-use of work carried out by other patent offices. The Delegation noted that the re-use of work was the only item with regard to which progress had been made since the inclusion of the issue of quality of patents on the agenda of the sixteenth session of the Committee. Having looked at the latest developments concerning that issue, the Delegation highlighted the Global Patent Prosecution Highway (GPPH) pilot. The GPPH, a project in which Spain was taking part, enabled patent owners to request accelerated processing at any participating office, should their applications contain claims that had been found to be patentable by any of the other participating offices. By adopting that approach, in the view of the Delegation, Member States could avoid the need to sign bilateral PPH agreements. The Delegation believed that it was important to remember that search and/or examination work carried out by other patent offices should not be re-used in a way that was detrimental to the quality of the examination carried out by the Office of Second Filing. The Delegation noted that a number of criticisms had been leveled at the so-called PPH, one of which was based on the fact that the Office of Second Filing (or second examination, in the case of PPH Mottainai) could receive applications originating from patent offices with differing patentability criteria, for example, different requirements in terms of inventive step. Although examiners must always re-use the results

originating from the Office of First Filing, they should apply their national examination guidelines and carry out a patentability examination of sufficient quality, without being influenced by the criteria of the first office. Thus, the Delegation stated that it would be useful to supplement the study already carried out by the Secretariat with additional information on how the various laws and practices limit the potential for the work sharing and what could be done to resolve that situation at the international level. The Delegation noted that, given that patent applications and all related information were kept secret until their publication that normally occurred after 18 months from the priority date, it would also be useful to examine in greater depth those issues that arose as a result of the confidential nature of applications and to seek possible solutions in that regard. The Delegation further stated that another major problem of the patent offices, wishing to re-use of work carried out by other patent offices, was the language barrier. In the view of the Delegation, translations produced by automated systems were not of sufficient quality to allow the re-use of work carried out by other offices in a beneficial manner. In addition, the Delegation noted that document SCP/20/8 did not contain any information on PROSUR, a system covering Argentina, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Surinam and Uruguay. The main purpose of PROSUR was to facilitate data exchange between the parties and operational cooperation concerning procedures. The Delegation noted that according to the feedback received, the system was functioning extremely well. In its view, that oversight provided another reason why the scope of the study should be widened. The proposal submitted by the Delegation of the United States of America and the United Kingdom concerning the setting up by WIPO of a dedicated web portal gathering together all available information on work sharing was also of great interest to the Delegation. The Delegation considered that the web portal would be similar to that focusing on PPH agreements run by the Japan Patent Office (JPO), but would host a larger amount of contents, covering all currently existing programs. Turning to its proposal for the improvement of understanding of the requirement of inventive step (document SCP/19/5), the Delegation stated that the key factor in terms of the grant of patents of an appropriate level of quality was the proper application of the patentability requirements, including the so-called "inventive step", or "non-obviousness" as referred to in some legislations. In its opinion, that was the only way to ensure that patents were granted on inventions that warranted such protection and that the aim of the patent system i.e., encouraging innovation, was achieved. Despite the fact that there were a number of elements involved in the issue of quality of patents, the Delegation considered that the key lay in the appropriate evaluation of inventive step. It observed that, given the complex nature of the evaluation of the requirement of inventive step, work had been ongoing both through major patent offices and the case law of a number of Member States in order to develop a variety of methods designed to evaluate that requirement as objectively as possible. The Delegation expressed its firm belief that, regardless of their level of development, it was in the interest of all Member States that a detailed analysis of the various methods employed to evaluate inventive step could be performed. The Delegation stated that such a study should be carried out not with harmonization in mind, but in order to set out the advantages and disadvantages of each of the methods used, enabling the various national patent offices to decide which method they should employ, depending on the characteristics of the invention examined. The study jointly published in 2013 by the WTO, WHO and WIPO, entitled "Promoting Access to Medical Technologies and Innovation" contained a chapter focusing on pre-grant issues and, more specifically, on questions of patentability. In the said chapter, the author referred to the recommendation made by the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) of the WHO (a body established in May 2003 to examine how to improve access to medicines for diseases which affect developing countries), in which it had suggested that governments take action to avoid barriers to legitimate competition by considering developing guidelines for patent examiners on how properly to implement patentability criteria. Furthermore, that study mentioned the fact that examiners must be supported in their work through appropriate examination guidelines, with a view to ensuring high quality of granted patents. The Delegation stated that those recommendations were consonant with its proposal that a clearer understanding of the requirement of inventive step and its evaluation would facilitate the drafting of examination guidelines by patent offices. Those guidelines, according to the Delegation, would allow examiners in each office to apply the

patentability requirements in a more appropriate and uniform manner, contributing to an increase in the quality of the patents granted and, in a way, making it possible to avoid the grant of patents for inventions that did not warrant such protection. The benefits of such an approach, in the view of the Delegation, would accrue to all Member States and to society as a whole. Therefore, as was apparent to the Delegation, its proposal had also been designed to take into account the interests in terms of social and economic development. The Delegation further stated that, in the previous years, a number of Member States had implemented new patent examination guidelines with respect to the evaluation of inventive step. The Delegation believed that it could be useful to share those guidelines with the rest of the Member States. Furthermore, the Delegation observed that among the three patentability requirements traditionally applied to inventions for which a patent had been applied, it was inventive step that allowed Member States and their national patent offices the greatest room for maneuver. The Delegation noted that the process of obtaining a patent might be rendered easier or more difficult by the definition of the requirement, intervening elements and their method of evaluation, either through legislation or examination guidelines. In the view of the Delegation, a low level of inventive activity meant that exclusive rights over small improvements might be obtained at the risk of limiting the business activities of third parties. Meanwhile, a very high level of inventive activity meant that exclusive rights might not be granted on potentially deserving inventions or that only extremely limited exclusive rights might be granted, blocking investment and research. The Delegation stated that, according to a number of studies, the differences in terms of methods of evaluation of inventive step had an influence on the differing rates of grant of patents. Therefore, the Delegation considered that it was a field that warranted closer attention through the carrying out of an objective study on the different existing levels of inventive step and the factors that determined them. The Delegation stated that a study on inventive step would be of use to all those Member States in the process of amending their patent legislation and increasing the level of inventive step required. The Delegation pointed out that its proposal was consonant with recommendation 45 of the WIPO Development Agenda: "To approach intellectual property enforcement in the context of broader societal interests and especially development-oriented concerns". In the view of the Delegation, only a patent system under which protection was solely granted and maintained for deserving inventions, would contribute to the achievement of its social goals of technological innovation, technology transfer and the dissemination of technology. The Delegation noted the fact that the Committee set up to focus on the "Law of Patents" had not addressed the issue of inventive step since 2008, reflected badly on that body, and had led the Delegation to question whether it was making the best use of the only forum within which the issue of patents could be dealt with on a global scale. Consequently, the Delegation urged the Committee to treat the issue of the evaluation of inventive step as a fundamental element, be it within the context of "quality of patents" or, preferably as a separate item, as a part of the future work of the Committee. As the first step, according to the Delegation, a study could be carried out on the definition of the person skilled in the art as a key figure in the evaluation of inventive step.

83. The Delegation of the Islamic Republic of Iran thanked the Secretariat for its work in preparing for the twentieth session. It also thanked the delegations that presented proposals on that matter, and stated that it took note of their proposals. The Delegation believed that, in the framework of the SCP, any exchange of information would be beneficial to all Member States. The Delegation was of an understanding that the Committee still had no common ground regarding the term "patent quality". In the view of the Delegation, a common understanding on the definition of the term "quality of patents" was necessary in order to take further steps on that issue and before discussing a detailed work plan. The Delegation also reiterated that any future work on the quality of patents should not lead to harmonization of substantive patent law. The Delegation was of the opinion that every Member State would codify its national patent law on the basis of its requirements and on the basis of its developmental concerns. The Delegation believed that any work on patent quality should take into account the following elements: (i) the different nature and the different role of patent systems in Member States, as well as the different levels of development in IP offices; (ii) the need for capacity building and training programs for IP officers;

(iii) the relevant Development Agenda recommendations with the objective of strengthening patent offices in granting high quality patents based on their national law; and (iv) that process should be voluntary and be guided by Member States and not aimed at harmonizing patent laws. Finally, the Delegation stated that any work on the patent quality should ensure compliance with the requirements of patentability, including sufficiency of disclosure of inventions.

84. The Delegation of the United States of America expressed its support to the statement made by the Delegation of Greece on behalf of the European Union and its Member States, which supported continuing work on the questionnaire presented in the proposal by the Delegations of Canada and the United Kingdom (document SCP/18/9) and work further on the proposals by the Delegation of Denmark and by the Delegation of Spain. The Delegation also thanked the Member States that had contributed information on the topic of work sharing programs among patent offices and use of external information for search and examination. It further thanked the Secretariat for compiling that information in document SCP/20/8. The Delegation was encouraged by the interest shown by Member States on that topic and by the number and range of offices that had contributed to that document. The Delegation stated that document SCP/20/8 on work sharing programs was an excellent starting point for the Committee to work on that important aspect of the quality of patents. The current proposal that the Delegation of United States of America had submitted jointly with Japan, the Republic of Korea and the United Kingdom was built upon and was refinement of the proposal that the Delegation had set forth in document SCP/19/4, which had been presented at the previous SCP session. It was intended to address work sharing between the offices, a topic that appeared to be of importance to offices of all sizes. The Delegation believed that every Member State had an interest in improving efficiency of the patent system and granting high-quality patents as defined by their national objectives and economic considerations. Referring to document SCP/20/8, the Delegation noted that many work sharing programs were currently in place between offices of all sizes. The Delegation also noted that tangible success in harnessing improved quality and efficiency had already been seen by many offices taking part in those programs. The Delegation stated that document SCP/20/8 provided a very useful snapshot of some current work sharing and collaborative programs. However, the Delegation pointed out the need to provide up-to-date, comprehensive information on work sharing and collaborative programs that was relevant and useful for IP offices as well as for the users of the patent system. Many of those work sharing and collaborative programs, according to the Delegation, were constantly evolving and expanding. Thus, there was a real need to provide up-to-date information. For example, additional offices were joining the PPH programs, and several pilot programs had been devised to explore enhancements to the PPH system. The number and type of the work sharing programs was constantly changing, and to be useful, the information pertaining thereto needed to be updated on a regular basis. The Delegation was convinced that the website portal devoted to work sharing and collaborative programs maintained and updated by the Secretariat would be a very good way to provide such up-to-date information. The Delegation also believed that there was a need to conduct regular conferences on work sharing and collaboration between offices, designed to share national and regional experiences, as well as best practices, and to find ways to improve usefulness of those programs to IP offices, to users of the IP system and to the general public. The Delegation envisioned the content of the website would be developed by the Secretariat to maximize the usefulness to offices and to users, including, for example, descriptions of the various work sharing and cooperative programs between offices, links to the websites of those programs and statistical information pertaining to the programs. Referring to the programs accessible directly by the users, such as the PPH programs, in the view of the Delegation, instructions and/or links to instructions on how users could take advantage of those programs should be provided. The Delegation further noted that the WIPO's website already included limited information on the PCT-PPH programs. However, the proposal of the Delegation was to provide information on a wider range of work sharing and cooperative programs beyond what was currently available. Work sharing, in the opinion of the Delegation, continued to be increasingly important in the development of patent systems. For example, according to the Delegation, the PPH continued to be refined to attract participation of new offices. The Delegation observed that the PCT system,

which exemplified the oldest work sharing mechanism implemented on the international scale, had developed to a system under which Ukraine, Chile, Egypt, Brazil and 14 other offices acted as International Authorities. In concluding, the Delegation stated that its proposal well reflected the important role that work sharing and collaborative programs played in improving efficiency of the patent system in many countries around the world, and the need to increase awareness among patent offices and patent system users of existing work sharing and collaborative programs, as well as to keep that information current.

85. The Delegation of the United Kingdom thanked the Secretariat for its work in preparing the meeting. The Delegation considered that the patent quality was an important issue with potential to bring economic and social benefit to all countries. In particular, the Delegation reiterated its belief that the Committee could benefit from a questionnaire to facilitate sharing of information among Member States. The purpose of the questionnaire would be to share information between Member States so that countries could learn from each other, while maintaining their existing laws and practices. Such questionnaire, in the view of the Delegation, could contain elements of the proposals previously put forward jointly with the Delegation of Canada, as well as the proposals by the Delegations of Denmark and by the United States of America, while taking into account comments and suggestions from other Delegations. With regard to work sharing, the Delegation noted that there were a number of works sharing initiatives among offices to improve efficiency of services and reduce duplication of effort which would lead to reducing backlogs with economic benefits to users and patent offices. The Delegation thanked the Secretariat for preparing document SCP/20/8 which provided useful summary of a number of initiatives in that area. Referring to the proposal put forward by the Delegations of the Republic of Korea, the United Kingdom and the United States of America (document SCP/20/11 Rev.), the Delegation believed that providing up-to-date information on various work sharing activities in line with the proposal would improve awareness of existing initiatives and enable patent offices to collaborate more effectively.

86. The Delegation of Kenya associated itself with the statement made by the Delegation of Algeria on behalf of the African Group. The Delegation noted that Kenya regularly used external information for search and examination of patent applications. It was also stated that there were four main sources of such information that were prescribed in the Kenyan Industrial Property Act of 2001: (i) information provided by an applicant during the prosecution of the application beginning from the filing stage; (ii) information accessed by a patent examiner during searches and examination (mainly via databases such as those of WIPO, the EPO, the USPTO and IP-Australia); (iii) information provided by WIPO upon request by Kenya under the patent cooperation mechanism; and (iv) the information submitted by an applicant upon request by the Kenyan patent office. The last case applied where an application for a patent or other title of protection, relating to the same invention as that claimed in the application filed in Kenya, had been filed by the applicant with a national industrial property office of another country or with a regional industrial property office. Such information might relate to: (i) any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application; (ii) a copy of the patent or other title of protection granted on the foreign application; (iii) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application; (iv) any decision revoking or invalidating the patent or any other title of protection granted to the applicant on the basis of the foreign application; and (v) any communication received by the applicant concerning the results of any search or examination carried out in respect of any foreign application other than the one already indicated. The Delegation noted that an applicant always had the right to submit comments on the information obtained from a foreign patent office, especially under the fourth arrangement above. The Delegation expressed its appreciation for the availability of such external patent information. However, it was stated that such information, including examination reports, were not binding on the Kenyan patent examiners or Kenya as such. In particular, the Delegation clarified that the information obtained especially under the fourth arrangement merely served the purpose of

facilitating the evaluation of novelty claimed in the application filed in Kenya or in the patent granted on the basis of that application. In its opinion, such access to information, and it being not binding, availed Kenya of the opportunity to ensure the quality of patents granted within its territory, as well as to safeguard public national interest, including availing herself of the flexibilities accorded by the patent system. Therefore, the Delegation stated that continued availability of such information should be supported. However, the Delegation also stated that any further development on that matter, including work sharing initiatives, should not obligate Kenya towards automatic acceptance of the reports of the work shared, and thus any international efforts should not lead to harmonization of substantive patent law.

87. The Delegation of Japan thanked the Secretariat for its extensive work in preparing the meeting. The Delegation stated that Japan had co-sponsored the proposal regarding the establishment of a dedicated WIPO website and holding of annual conferences on work sharing (document SCP/20/11 Rev.). As a co-sponsor of the document, the Delegation associated itself with the statement made by the Delegation of the United States of America. As mentioned in document SCP/20/8, the Delegation noted that the PPH enabled an application whose claims had been determined to be patentable in the Office of First Filing (OFF) to undergo an accelerated examination in the Office of Second Filing (OSF) based on a simplified procedure, upon request from applicants. The Delegation highlighted the purpose of the PPH as follows: (i) to help applicants acquire patents as soon as possible; (ii) to promote utilization of search and examination results between and among IP offices so as to reduce workload involved with conducting examination; and (iii) to enhance the quality of examination worldwide. Those purposes of the PPH, in the view of the Delegation, did not mean automatic validation. The Delegation further stated that in aiming to make the procedures that applicants followed under the PPH more convenient, the Global Patent Prosecution Highway (GPPH) had been commenced in January 2014. In its opinion, in addition to the expansion of the GPPH framework, the PPH was expected to become a more convenient system for applicants. Further, the Delegation explained the introduction of a post-grant patent review system in Japan. It was stated that the first action pendency period had significantly reduced in Japan since 2009. That was expected to be shortened to around 11 months by the end of the fiscal year 2013. The Delegation, however, stated that it had caused an increase in the number of patents being granted without third parties being given sufficient opportunities to submit prior art information. Taking that situation into account, the Delegation noted that the Patent Systems Subcommittee had recommended that it would be appropriate to introduce a new post-grant patent review system. The Delegation recognized the need for the patent system to continually adapt, so that it was able to stay aligned with current circumstances in a timely and balanced manner, which could be achieved through discussion with stakeholders. Finally, the Delegation expressed its belief that it would be valuable for all countries to share their experiences, and reiterated its willingness to continue contributing to the discussions on those issues in the constructive manner.

88. The Delegation of Colombia stated that the work related to examination of patents had increased exponentially during the previous years due to the growing demand for industrial property services. In the view of the Delegation, that generated an overburdening of the system due to, *inter alia*, the submission of multiple applications for the same invention, so that the same patent application was often examined by patent examiners in different industrial property offices around the world. The Delegation stated that Colombia, through its industrial property office, was carrying out various projects aimed at modernization of the system for the examination of patents, taking advantage of the opportunities provided by law and through the cooperation with other industrial property offices in South America, including PROSUR, an alliance of nine offices that shared search and examination reports of patentability. The Delegation observed that it reduced the duplication of overlapping of efforts and processing times for the same patent applications submitted in the countries of the region. The Delegation expressed its firm belief that the process of cooperation and division of work among different industrial property offices was one of the best ways to reduce the duplication of efforts specifically as regards search, patentability examination,

analysis of the requirements established in patent laws of the different countries and the final decision on the right granted. The Delegation agreed with the Delegations of the United States of America and Spain with respect of establishing a better way of disseminating information on work sharing initiatives among industrial property offices. The Delegation also noted that Colombia was involved in the Pacific Alliance, a political cooperation and integration framework between Chile, Colombia, Mexico and Peru, which was officially set up on June 6, 2012, by a framework agreement. The main objective of the Pacific Alliance framework was to draw up an integration area, to achieve an effective inclusion of the other regions, particularly of Asia and the Pacific. That trade agreement included a chapter dedicated to the Working Group on Intellectual Property that opened up a little space to delve into the activities for cooperation among the intellectual property offices of the countries of the Pacific Alliance. The Delegation observed that it had contributed to the improvement of the intellectual property system and had been beneficial to the users of the system. The Delegation thanked WIPO for its cooperation with respect to the WIPO CASE that would enable intellectual property offices of the Pacific Alliance to share the information on patent applications which had been processed in Mexico, Peru, Chile and Colombia. The Delegation informed the Committee that the process for participation in WIPO CASE had been carried out in a successful manner. Furthermore, the Delegation stated that Colombia, alongside with Mexico, had been participating in the PPH since 2012. The Delegation also noted that Colombia would hold a seminar on those accelerated patent procedures in April 2014, and welcomed any information which could be provided through WIPO and the Committee. Finally, the Delegation supported the proposal made by the Delegation of Spain regarding inventive step to promote greater sharing of information and experiences of countries when analyzing those requirements. In the view of the Delegation, that proposal could be the future work benefitting all members of the SCP.

89. The Delegation of Denmark thanked the Secretariat for preparing document SCP/20/8, which was a good basis for further work on the topic of quality of patents. The Delegation endorsed the statements made by the Delegation of Greece on behalf of the European Union and its Member States and the Delegation of Japan on behalf of Group B. In its view, quality of patents was a key topic of interest to all members of the Committee. Therefore, the Delegation expressed its willingness to move forward with the questionnaire which was submitted by the Delegations of Canada and the United Kingdom. The Delegation further expressed its support to the proposal contained in document SCP/20/11 Rev. and stated that work sharing, as a means to improve efficiency and quality of patents, was a topic where much work could be further explored along the lines proposed in that document. Noting the experience of its country in participating in different work sharing programs, including the PPH, the Delegation stressed that such programs increased quality and efficiency, and that they did not lead to or intended to lead to harmonization or transfer of standards. Regarding the proposal of the Delegation of Spain concerning the inventive step requirement, the Delegation stated that the proposal had merits to study it further.

90. The Delegation of the Russian Federation stated that the proposal contained in document SCP/20/11 Rev. would be a good basis for discussion in order to develop cooperation on the international sharing of work of patent offices. It further stated that Rospatent had been involved in many international projects concerning work sharing, including the PPH and PCT-PPH. For example, the office had concluded bilateral agreements with Denmark, Finland, Japan, the Republic of Korea, Spain and the United States of America. The Delegation expressed its support to the creation of a specialized WIPO web page on that topic as well as the idea of a seminar as proposed in document SCP/20/11 Rev.

91. The Delegation of Cuba stated that there were various factors that influenced quality of patents, in particular, the responsibility of the applicant to sufficiently disclose the invention and the responsibility of the office to check the invention in light of novelty, inventive step and other requirements so as to avoid granting trivial patents. Further, the Delegation expressed its support to the proposal of the Delegation of Spain concerning the analysis of the inventive step

requirement. It also expressed support to work sharing initiatives, and noted that such initiatives would not affect each country's sovereignty and that examiners would take a final decision based on their national law, taking into account specific national circumstances. In addition, the Delegation stated that opposition procedures were favorable to offices and users and were important component to the quality of patents.

92. The Representative of TWN stated that it was important to work towards arriving at a consensus with regard to the meaning of the term "quality of patents" before launching a work program on that issue. Further, he stated that the efficiency was not a synonym for quality. In his opinion, quality of patents was related to granting a patent only to a genuine invention without prolonging the patent monopoly preventing further innovation and access to knowledge. Noting that efforts of the patent offices should be on the quality and not on the quantity of patents, the Representative stated that work sharing was not a solution to improve the quality of patents. In particular, he stated that work sharing was *de facto* leading to harmonization. In that regard, he referred to the work of Professor Peter Drahos which had supported that opinion and stated that such harmonization had compromised the policy space for developing countries with regard to the patentability. In relation to the proposal on creating a dedicated web page on work sharing programs, the Representative stated that all those work sharing arrangements lacked the legitimacy of a multilateral initiative, and that multilateral fora should not be used to legitimize them.

93. The Representative of KEI questioned how work sharing would apply when differences in laws regarding the patentability existed, and asked proponents further explanations in that regard. In particular, noting that the PPH programs were going slower than what had been anticipated partly due to the above problem, the Representative asked the proponents to share information on how those problems had been dealt with in practice. Further, referring to some of the delegations' position that a work sharing would undermine the capacity of developing countries to develop their own examination expertise, the Representative questioned about the role of developing countries in being suppliers of the work. Finally, the Representative questioned whether it would be more productive if WIPO would work towards creation of a global system for better annotation of prior art and pre-grant and post-grant disputes taking place in different jurisdictions on the issue of patentability.

94. The Representative of the ICC drew the Committee's attention to a policy statement, prepared by the ICC Commission on Intellectual Property, entitled "Cooperation between Patent Offices, Prior Arts Searching of Patent Applications" which elaborated positions taken by the ICC on the following three points: (i) to support the PCT as the preeminent vehicle for work sharing on global patent applications; (ii) to continue working with participating patent offices in the implementations of the PPH programs; and (iii) to encourage patent offices to take positive steps to achieve what was called an "early comprehensive coordinated search".

95. The Delegation of India referred to its previous statement supporting the proposal of the Delegation of Spain on the inventive step requirement. It also recalled the statements of other delegations, e.g., the Delegation of Algeria on behalf of the African Group, which had suggested studying other patentability requirements. Further, in relation to document SCP/20/11 Rev., the Delegation stated that it needed more time to reflect on that proposal, and requested information regarding its budgetary implication. The Delegation highlighted Article 29(2) of the TRIPS Agreement which allowed countries, on voluntary basis, to require patent applicants to provide information about the applicants' corresponding foreign applications and grants, and expressed its interest in further studying it. Finally, the Delegation reiterated that all those activities should be conducted on a factual basis and not with the view of doing an analysis or making a recommendation.

96. The Secretariat stated that, in relation to the budgetary implication of the proposal contained in document SCP/20/11 Rev., it would revert to the Committee later.

97. The Delegation of Algeria, speaking on behalf of the African Group, reiterated that the purpose of all the proposals made on that agenda was still not clear. Therefore, the Delegation could not agree on launching any kind of questionnaire or any other study before clarifications on the objectives of such initiatives were given. In relation to the proposal contained in document SCP/20/11 Rev., the Delegation stated that since the proposal had been submitted recently, its Group had not had time to discuss it, and therefore, the proposal should not be an element of the future work plan for the next session of the SCP.

#### **AGENDA ITEM 8: PATENTS AND HEALTH**

98. The Chair opened the sharing session on countries' use of health-related patent flexibilities.

99. The Delegation of India expressed its strong support for the proposal submitted by the Delegation of South Africa on behalf of the African Group and the DAG (document SCP/16/7). It noted that the proposed work program would seek to enhance the capacities of Member States, in particular, developing countries and LDCs, to adapt their patent regimes to make full use of the flexibilities available in the international patent system in order to promote public policy priorities related to public health. In the view of the Delegation, the components of the study and other actions proposed in the work program were most relevant and should be given due consideration by the Committee. The Delegation stated that according to paragraph 5 of the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration), each member had the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses were granted. The Doha Declaration also acknowledged that the effect of the provisions in the TRIPS Agreement that were relevant to the exhaustion of intellectual property rights was to leave each member free to establish its own regime for such exhaustion without challenge, subject to the most-favored-nation (MFN) and national treatment provisions contained in Articles 3 and 4. The Delegation further stated that the proposal for a study on compulsory licensing and exhaustion of rights was within the mandates of different international covenants and within the Development Agenda recommendations, and would assist to achieve the mandates of Millennium Development Goals (MDGs). The Delegation recalled that the United Nations, in its 2012 report on the attainment of the MDGs, had noted that availability and affordability of essential medicines still remained a challenge. The Delegation expressed its belief that the study would help developing countries in resolving the difficulties in applying compulsory and government use licenses. It further noted that such study did not necessarily mean wholesale application of compulsory license in the area of pharmaceuticals, as had been mentioned in the proposal by the Delegation of the United States of America. The Delegation continued that the Paris Convention and the TRIPS Agreement acknowledged the availability of compulsory licenses to prevent the abuse of patent rights and also in case of a national emergency, circumstances of extreme urgency or other public non-commercial use. Further, the Delegation expressed its full support to the component of a study related to assessment of the benefits of mandatory disclosure of International Nonproprietary Names (INNs) in the abstract or title of patent applications. Reiterating its comment with respect to INNs, the Delegation noted that the UNDP, in its publication "Patent Information and Transparency: A Methodology for Patent Searches on Essential Medicines in Developing Countries", available at [www.undp.org](http://www.undp.org), recognized the importance of the INNs as one of the viable options for search in determining patentability. Particularly, in the fields of incremental innovations related to such substances for which INNs were already established or were being established, the disclosure of the INNs, at the time of filing of applications or during the pendency of the application, would greatly enhance the quality of search and would reduce the uncertainty surrounding the scope of the invention. The Delegation further noted that most of the pharmaceutical compounds were complex organic molecule that were difficult to describe and that even a structurally small compound might be described in the prior art in various ways, since there was no internationally binding uniform system of nomenclature to describe a molecule, including in the system of the International Union of Pure and Applied Chemistry (IUPAC). Therefore, in its view, the disclosure

of INNs in case of incremental innovations would be extremely useful. It would not only help the examination system, but would also facilitate technology transfer as the nature of the invention would be clearer. Further, referring to the Markush claims, the Delegation explained that such claims represented one of the most difficult aspects of the patentability of organic compounds and bio-molecules. As such, claims could cover billions of compounds that involved almost all issues related to their patentability, i.e., novelty, inventive steps, industrial applicability, unity of invention, as well as sufficiency of disclosure, enablement and support. Moreover, the Delegation noted that searching Markush claims involved high costs, and such claims were capable to obfuscate the scope of the claims and had potential to hinder technology transfer. Therefore, according to the Delegation, a cost-benefit analysis of the admissibility of Markush claims, as proposed by the African Group and the DAG, was justified. Similarly, the Delegation supported the component of the proposal relating to the organization of a technical workshop on state practices involving the compulsory licensing of medical technologies, including the application of Articles 30, 31 and 44 of the TRIPS Agreement and developing a database on the patent status in WIPO Member States of relevant diagnostic tools and medicines for at least 10 non-communicable and communicable diseases. The Delegation noted, in particular, that such activities were highly justified and appropriate from the angle of public health. Further, the Delegation reiterated its opinion that competition policy, as had been recognized in the trilateral study carried out by WIPO, the WHO and WTO, was highly relevant in addressing the issue of access to medicine. It reaffirmed that the creation of a sound competitive market structure through competition law and enforcement would play an important role in enhancing both access to medical technology and fostering innovation in the pharmaceutical sector. The Delegation further expressed its full support to the component of the proposal related to technical assistance which would explain various approaches to the grant of compulsory licenses. Further, quoting the following sentence found in the proposal by the United States of America "To successfully employ a technology such as manufacturing of medicines, know-how and specialized skills are often required in addition to the detailed disclosure found, for example, in a patent", the Delegation stated that the sentence pointed to a serious deficiency of the patent system which the Delegation had been advocating since the SCP meetings had resumed after a temporary halt. The Delegation noted that it had been urging the issue of transfer of technology and the role of disclosure, not only in the SCP but almost in every forum. Noting that, ideally, a skilled person should be able to translate the knowledge into reality, after a patent was granted, the Delegation stated that, in fact, transfer of other supporting technologies in the form of trade secrets was always required. Therefore, the role of patents as a stand-alone tool in transfer of technology, independent of any trade secrecy, could be a subject matter for investigation, according to the view of the Delegation. In conclusion, referring to a study proposed by the Delegation of the United States of America, the Delegation stated that such study was uni-dimensional as it was based only on the positive role of the patent system unlike the study proposed by the Delegation of South Africa on behalf of the African Group and the DAG.

100. The Delegation of Pakistan stated that the debate on patents and health was of crucial importance for all Member States. It further stated that availability and affordability of medicines that satisfied the primary healthcare needs of the population, especially at the price an individual and a community could afford, could not be ignored. Noting that patent rights had a direct impact on the right to health, especially in developing countries, where pharmaceutical products were priced beyond the reach of poor patients, the Delegation stated that intellectual property protection should not inflate prices and put the right to health beyond the reach of developing countries. While the Delegation fully recognized that patents fostered innovation and creativity it noted, however, that patents should not trump the right to health of individuals especially in developing and least developed countries. The Delegation expressed its belief that the protection and enforcement of IPRs should be done in a manner conducive to social and economic welfare. Finally, the Delegation urged Member States to pay a special attention to and be mindful of the disparity of technological and economic development of different countries.

101. The Delegation of Japan, speaking on behalf of Group B, stated that its Group recognized the importance of agenda item 8 to developing and least developed countries. The Delegation stated that Member States should, however, fully respect the activities that had been undertaken in that context by other WIPO Committees and Geneva-based international organizations, including the trilateral study which had been carried out by WIPO, the WHO and WTO. The Delegation emphasized that patents provided an important incentive for the innovation in the pharmaceutical field, and contributed effectively to the development in that field. In its view, that important context should be taken into account when considering the relationship between patents and health. The Delegation further stated that it was important to deal with that issue at the SCP in a balanced manner, which would not shed light only to one side of the issue. In addition, it was stated that all policy making should be evidence-based. From that perspective, the Delegation looked forward to learning about objective and impartial evidence-based policy making in adopting flexibilities in a particular country during the information sharing session on countries' use of health-related patent flexibilities.

102. The Delegation of Algeria, speaking on behalf of the African Group, underlined that the agenda item on patents and health represented the highest priority for its Group. The African Group believed that WIPO must strengthen its commitment and involvement in that area, building on current activities to achieve the international goals set in that area in the future. It was within that context that the African Group and DAG jointly submitted a proposal on that subject. The proposal covered a work program which aimed at assisting Member States, particularly developing countries and LDCs, in adopting and adjusting their patent systems in order to take full advantage of the flexibilities in the international patent system to promote their policies on public health. Turning to the first element of the proposal concerning elaboration of studies to be commissioned by the WIPO Secretariat to independent experts selected in consultation with the Member States, the Delegation explained that the studies would examine the challenges and constraints faced by developing countries and LDCs in making full use of the public health-related patent flexibilities in the pre-grant and post-grant stages. It was proposed that the studies would include information on: (i) the use of compulsory and government use licenses; (ii) the use of the exhaustion doctrine to allow parallel importation of medicines; (iii) assessment of benefits of mandatory disclosure of INNs in the abstract or title of patent applications; and (iv) a cost-benefit analysis of the admissibility of Markush claims. Regarding the second element of the proposal on information exchange, the Delegation stated that the proposed activities included: (i) inviting the UN Special Rapporteur on the Right to Health to present his report to the SCP; (ii) the sharing of national experiences on the use of patent flexibilities for promoting public health objectives; (iii) holding a technical workshop on state practice involving compulsory licensing of medical technologies; and (iv) development of a database on the patent status in Member States of relevant diagnostic tools and medicines for selected non-communicable and communicable diseases. Further turning to the third element of the proposal on provision of technical assistance to Member States, the Delegation stated that one of the main aims of the proposal was to give direction to the work of WIPO on that issue. Referring to document SCP/18/5, the Delegation stated that WIPO undertook a number of activities on its own and with other international organizations, and through its technical assistance, to which Member States could provide only a limited input. While recognizing that some of those activities had been beneficial for developing countries, the Delegation expressed its concern regarding some other activities and questioned their development orientation from a public health perspective. Therefore, the Delegation reiterated that having the topic of patents and health on the agenda of the SCP would allow Member States to discuss national experiences and to provide guidance to WIPO on its work on that issue. The sharing session on countries' use of health-related patent flexibilities would offer the opportunity to exchange their experiences on the use of such flexibilities, and on the challenges to their use. The Delegation further noted that the African Group took note of the proposal by the Delegation of the United States of America and recalled that the proposal, though interesting, might guide the discussions in the SCP to issues that were not related to patents and hence were outside of the mandate of the Committee. The Delegation expressed its hope that the proposal would not depart

the discussion from its main objective, namely, to enable developing countries and LDCs to take advantage of the flexibilities in the international patent system for their need in the public health.

103. The Delegation of Czech Republic, speaking on behalf of the CEBS Group, stated that it continued to support adequate activities which might assist developing countries and LDCs in addressing their public health problems. In that respect, the CEBS Group considered sharing session on countries' use of health-related flexibilities useful. It also expressed its belief that, together with the analysis and evaluation found in the trilateral study on promoting access to medical technologies and innovation, elaborated jointly by WIPO, the WHO and the WTO, it might further contribute, in particular, to identification of the concrete patent-related issues, relevant to possible discussion in the Committee. The CEBS Group continued to share the view that any duplication of work done within WIPO relating to the topic, i.e., the CDIP, and in other international organizations, such as the WHO and WTO, should be avoided. The Delegation also continued to share the opinion that any discussion on patents and health within the Committee should be balanced, taking into account interests of all patent users and various relevant factors, including the role of the patent system to support innovation in pharmaceutical industry. Noting that evidence should be a driver of policy making, the Delegation was looking forward to the sharing session on that issue. The Delegation was expecting evidence-based justifications to be given for each policy which was implemented or being prepared.

104. The Delegation of Kenya supported the statement made by the Delegation of Algeria on behalf of the African Group and the proposal put forward by that Group and the DAG. The Delegation stated that the issue of patents and public health was a subject which was of immense importance not only to the African Group but also to other Member States. Those Member States had been keen on availing themselves of the flexibility in the substantive provisions of several bilateral, plurilateral and multilateral arrangements in order to take necessary measures to protect human, animal or plant health. Further, the Delegation introduced the approach relating to patents and health taken by the East African Community (EAC) to which Kenya was a Partner State. The EAC had adopted a regional policy related to that matter, namely, the EAC Regional Intellectual Property Policy on the Utilization of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation (EAC-TRIPS). The overall objective of the Policy was to guide the EAC Partner States on how their national intellectual property legislation should be adjusted in order to enable them to fully utilize the public health-related flexibilities contained in the TRIPS Agreement. The Policy provided a comprehensive road map of how EAC Partner States could facilitate optimization of the populations' access to health and other health-related products. It further identified the lowest common denominator of intellectual property legislation that could be approximated across all the EAC Partner States. In the Policy, EAC Partner States reaffirmed their commitment to availing themselves, in line with their respective public policies and priorities, of the public health-related flexibilities contained in the TRIPS Agreement and its related instruments in order to help them address public health problems afflicting their populations. Further, the EAC Partner States undertook to reject, both at the national, regional and international levels, any attempts which might hinder the full utilization of flexibilities. Further, turning to the Common Market for Eastern and Southern Africa (COMESA), to which Kenya was also a member, the Delegation stated that COMESA had developed, or endeavored to improve or develop, policies on intellectual property rights and public health. Further, noting that the African Union (AU) was, as well, keen on that subject matter, the Delegation expressed its hope that the work of the SCP would be supportive of the work of the EAC, COMESA and AU. Further, turning to issues specific to Kenya, the Delegation noted that its country appreciated the role of patents in facilitating solutions to public health problems. However, the Delegation continued that patent rights as private rights should be supportive of public health interests including those relating to public health. Noting that that position had been consistently pronounced in various fora held before and after the WTO Doha Declaration, including those held under WIPO, the WTO and the WHO, the Delegation recalled, among others: (i) the General Agreement on Trade and Tariffs of 1947 (GATT), and especially its general exceptions under

Article 20; (ii) the WTO Doha Declaration on the TRIPS Agreement and Public Health of 2001, and its paragraph 6-related Decision of 2003 and Protocol of 2005; (iii) the WIPO Development Agenda of 2007, and especially recommendation 17 thereof; and (iv) the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property in 2008. Further, the Delegation recalled that prior to the conclusion of the above arrangements, several studies had been undertaken to guide their negotiations. Noting that such studies had been sanctioned by a great majority of the stakeholders in the SCP process, the Delegation named the following studies as an illustration: (i) the 2002 report of the UK Commission on Intellectual Property Rights entitled "Integrating Intellectual Property Rights and Development Policy"; (ii) the 2002 WTO and WHO joint report on WTO Agreements and Public Health; (iii) the 2003 report of the WHO Commission on Intellectual Property, Innovation and Public Health (CIPIH); and (iv) the 2012 WIPO, WTO and WHO joint study on Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade. The Delegation further stated that those studies were extensive, factual, and some of them were recent. Noting further that their recommendations had been very useful for the respective processes they were to inform, as well as other related subsequent processes, the Delegation expressed its belief that the said findings and recommendations could enrich the SCP process in respect of the subject of patents and health. The Delegation suggested that the Secretariat facilitate access to such reports by the SCP stakeholders by compiling them and posting them on a website. Where necessary, the Secretariat might also summarize the reports as regards the findings and recommendations, despite most of them having executive summaries. Further, the Delegation shared the experience of its country in the use of the public health-related flexibilities. The patent law of Kenya contained provisions concerning most of the flexibilities. The legislation and the application thereof had been helpful in addressing public health problems in Kenya, including facilitating access to affordable medicines. For example, in 2001, upon coming into force of the Kenyan patent law, significant reduction of price for medicines had been witnessed. The Delegation assumed that such price reduction might be attributed to the flexibilities incorporated in the law such as international exhaustion, research exemption, compulsory licensing including governmental use, the Bolar provision, exclusions from patentability, as well as prohibition of anti-competitive practices. Further, the Delegation shared a particular case related to the use of compulsory licensing in its country. The Delegation stated that in the 2000s, a Kenyan pharmaceutical manufacturer, Cosmos Ltd, wanted to manufacture HIV-AIDS related pharmaceutical products: Lamivudine, which had been patented in Kenya by GlaxoSmithKline (GSK); Zidovudine and Stavudine, which had not been patented in Kenya; and Nevirapine, which had been patented in Kenya by Boehringer Ingelheim. It therefore had sought a voluntary licence in respect of the patented products. Cosmos had waited for over one year without a response from the patent holders before it applied for a compulsory license. Within a few weeks, visits by representatives of both companies had been received. Boehringer Ingelheim had stated that they had not known that Cosmos had existed. Eventually, a compulsory license had not been issued because both companies accorded Cosmos with voluntary licences. The Minister for Trade and Industry had witnessed the conclusion of a voluntary licence between GSK and Cosmos. Eventually, the treatment regime had been changed to a triple combination after an application for WHO prequalification by the government, following the WHO's new guidelines that had removed Stavudine from the formulation and replaced it with Zidovudine. That had completely distorted Cosmos's plan to launch the product and, as a result, the government could not purchase them from Cosmos. In the view of the Delegation, that could be seen as a challenge in the use of flexibility relating to a compulsory licensing. Thus, the Delegation concluded that despite some flexibilities working in Kenya, some challenges to their use did exist. That was why Kenya was in support of the study to unearth some of them and even propose solutions. In view of the above, the position of Kenya was that the patent system should be supportive of public health policies of Kenya – a position which Kenya sought to retain in any discussions or negotiations relating to patents and health, including those under the SCP.

105. The Delegation of China stated that the patent system was closely linked to the issue of health which was a fundamentally important issue. On the one hand, patents had to protect the

rights of patent holders, encourage innovation, and on the other hand, it should also accommodate the interests of the general public. The Paris Convention as well as the TRIPS Agreement expressly contained provisions safeguarding public interests and provided flexibilities including a compulsory license. Noting that most patent laws provided for compulsory licensing, and that some Member States had already accumulated national experiences as to its implementation, the Delegation suggested that the SCP undertake work based on the proposal made by the African Group and the DAG. The Delegation concluded by stating that patents encouraged pharmaceutical innovation and could promote national economic growth.

106. The Delegation of the Islamic Republic of Iran expressed its belief that the issues of public health and patents as well as having access to medicines at an affordable price were important issues for developing countries. Therefore, the SCP should explore practical ways to respond to existing challenges, including the use of flexibilities available under international agreements. The Delegation further welcomed document SCP/18/5 which listed the projects and activities, including their status or outcome, on patents and health in WIPO, the WHO and the WTO. In its view, that information was useful in developing a focused work plan on patents and health in the Committee. Further, the Delegation expressed its support to the proposal of the African Group and the DAG. It was of the opinion that WIPO, as a specialized agency of the United Nations, had a mandate to address the topic of patents and public health. The Delegation opposed to the idea that the proposal submitted by the African Group and the DAG would constitute duplication with other processes within or outside of WIPO. Regarding the studies, the Delegation was of the opinion 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. 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 international agreements, and WIPO should give advice to Member States on the basis of those findings in order to make appropriate revisions in their national laws to enjoy those flexibilities. Further, the Delegation stated that any work program on that issue should be balanced and based on a long-term approach. The work program of the SCP should also provide the possibility of analyzing the potential impediments and obstacles created by the system in accessing medicines such as the legal and structural impediments and capacity constraints facing developing countries and LDCs in making full use of the flexibilities and how those constraints could be removed. On the issue of the interrelation 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 stated 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. In relation to the proposal by the Delegation of the United States of America, the Delegation was of the opinion that the proposal had not observed a balanced approach and had looked at the problems from one angle. That proposal also did not share the view that the patent system could constitute a problem for accessing medicines at affordable price. Referring to the part of the proposal concerning the issue of falsified and other substandard medicines, the Delegation reiterated that that issue had no connection with patent issues and thus the SCP did not have the mandate to discuss it. The Delegation continued by stating that a patent was granted on a pharmaceutical product on the basis of whether it fulfilled the patentability criteria as provided by the national law and not on the basis of quality and safety of medicines. It observed that the topic of proliferation of poor quality medicines was within the mandate of the WHO.

107. The Delegation of Greece, speaking on behalf of the European Union and its Member States, reiterated its understanding of the concerns of developing countries and LDCs, as well as the challenges and constraints they faced in handling public health problems. In that regard, the Delegation was supportive of adequate activities which might assist those countries. The Delegation was aware of the efforts made by WIPO, the WHO and the WTO, as presented in document SCP/17/4 and in the trilateral study entitled "Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade". The

Delegation stated that the trilateral study highlighted that lack of access to medical technologies was rarely due to a single isolated factor, such as patents and other intellectual property, but included other factors such as rational selection and use of medicines, affordable prices, sustainable financing and reliable health and supply systems with quality as an underpinning element. The mere existence of IPRs on a product was neither a barrier to, nor its absence a guarantee of, access to that product. The study also highlighted that providing specific incentives to absorb the high cost and associated risks and liabilities was a central policy challenge which had been the historic role of the patent system, in particular, as applied to pharmaceuticals. Access without innovation would mean a declining capacity to meet an evolving global disease burden. Therefore, the Delegation emphasized that any further work in that area should reflect a balanced approach, taking into account the various interfaces and factors of relevance to patents and health and drawing, for instance, inspiration from the proposal by the Delegation of the United States of America.

108. The Delegation of Zimbabwe associated itself with the position of the African Group and the DAG. The Delegation stated that Zimbabwe's Patent Law, in Chapter 26, contained all the key flexibilities as provided by the TRIPS Agreement, including compulsory licenses, exhaustion of rights and parallel importation, government use, and exclusions from patentable subject matter. However, to that date, only one flexibility, namely, a compulsory license, had been utilized. The Delegation reported that Vericom, a company that had been granted a compulsory license to manufacture certain drugs, was no longer doing so as a result of a myriad of challenges. In particular, the production of first line drugs had been stopped due to viability issues. Further, since Vericom had been given the WHO prequalification certificate exclusively for first line drugs, the company had to approach the WHO to obtain the certificate for second line drugs. The Delegation stated that WHO prequalification process was a costly process, as it required the company to meet the cost of transportation and accommodation of experts who would carry out an assessment of the manufacturing plant. Hence, the Delegation concluded that challenges related to the use of flexibilities existed, and therefore, it requested a technical assistance and capacity building on how countries could best utilize those flexibilities to promote public health, including on how the government could make use of those flexibilities that were in the national legislation, but not implemented. Further, the Delegation stated that the IP office of Zimbabwe did not conduct substantive examination of all patent applications as a result of lack of expertise. That implied that all applications were literally approved and that had a serious implication on health when medical patent applications were applied for. Finally, the Delegation reiterated the need for constant technical assistance and capacity building to promote access to essential medicines at affordable prices to the population.

109. The Delegation of Brazil supported the statements delivered by the Delegations of Algeria, on behalf of the African Group, India, Pakistan and other delegations which expressed their support to the work program on patents and health contained in document SCP/16/7. In Brazil, the universal access to health was an individual right present in the constitution. To guarantee access to health to 200 million Brazilians had been a challenge faced by the Brazilian society. In the international debate, Brazil supported different initiatives and processes aimed at promoting universal access to health. The Delegation stated that the Brazilian law, in certain aspects, provided a broader protection when compared to the protection granted by multilateral treaties. Nonetheless, Brazil recognized the importance of policy space guaranteed by the TRIPS Agreement that allowed Member States to implement public policies aimed at access to medicines. Further, the Delegation stated that, at the same time, Brazil supported a balanced system that would facilitate innovation and guarantee the benefits of innovation to the society. To Brazil, those objectives were not contradictory. The Delegation observed that access to medicines was an item of interest to all countries. Further, the Delegation wished to recall that access to pharmaceuticals was an integral part of the trade-off translated in the patent system. In its opinion, it was up to WIPO Member States to engage in discussions and explore a work program on the subject. The Delegation did not agree with the argument that the SCP's work duplicated discussions in other

WIPO bodies or other organizations. It stated that different mandates of each WIPO body and of each specialized UN body reflected different perspectives adopted in the debates. In conclusion, the Delegation stated that the results of the Consultative Expert Working Group on Research and Development: Financing and Coordination of the WHO (CEWG-WHO) clearly demonstrated that the current mechanisms for financing of pharmaceutical research were not aligned to developing countries needs on health. The Delegation suggested that that issue could possibly be a subject to be discussed at the SCP.

110. The Delegation of Belarus stated that the quality and efficiency of the health system ceased to be a purely national issue and expressed its support to the work of the SCP on patents and health in view of, *inter alia*, its socio-humanitarian significance. Belarusian policy was aimed at progressive modification of national legislation in order to achieve the balance of interests of both patent holders and the general public via use of patent flexibilities. Therefore, the Delegation stated that a closer attention needed to be made to those provisions of international treaties in the field of intellectual property, which allowed to achieve more balanced protection of inventions: a system that would take into account the interests of the healthcare system and, as a consequence, of the individual. As Belarus was a socially-oriented government, access to good healthcare was one of the priorities of the government. Given the importance of the system of legal protection of the results of scientific activity, one of the directions of the state policy of Belarus was the establishment of an effective system for the protection of inventions and its continuous improvement. The patent system, which had been created more than twenty years ago, could effectively protect the results of inventive activity. At the same time, the Delegation stated that its patent law did not incorporate all the flexibilities contained in international treaties in the field of patents. Thus, while the Law of the Republic of Belarus of December 16, 2002 on "Patents for Inventions, Utility Models, Industrial Designs" contained provisions concerning compulsory licenses, exhaustion of rights, and the right of prior use, the law did not adequately reflect the specificity of issues which might arise in relation to patents in the area of health. For example, the Delegation noted that the regulatory review provision was not contained in the law. Recognizing that the system of legal protection of inventions could be more socially oriented, without diminishing the rights of patent holders, the patent law revision had been undertaken in Belarus to incorporate some of the flexibilities associated with the issue of health. Therefore, the Delegation stated that it was supportive of initiatives aimed at investigating the health-related patent flexibilities. In its view, such a study would enable countries, if necessary, to make changes and additions to the national legislation with a view to achieve a proper balance between the interests of patent holders and the public.

111. The Delegation of South Africa aligned itself with the statement made by the Delegation of Algeria, on behalf of the African Group, as well as with the statements delivered by the Delegations of Kenya, Zimbabwe, Brazil, Pakistan and India. The Delegation informed the SCP that its government had been working on the national policy on intellectual property rights which focused heavily on health reform to address the particular health challenges. The Delegation stated that the leak by the multinational pharmaceutical industry to undermine that effort was unfortunate. It was noted further that that was not the first time that South Africa had been under attack even in the face of the most devastating HIV/AIDS and TB co-morbidities. Nelson Mandela was the first respondent to the legal challenge. The Delegation continued that as South Africa moved to promoting competition, leveling the playing field and adopting an IP policy which would enable South Africa to fully utilize flexibilities provided for in the TRIPS Agreement, it would require the support and not pharmaceutical companies conspiring to undermine their efforts. The Delegation underlined that such action should be strongly condemned by all, including WIPO. Further, the Delegation stressed that it was imperative that the SCP substantively discussed the issue of patents and public health and drew up a work program which would assist countries in adapting patent laws to make full use of patent-related flexibilities in accordance with their public health needs. The Delegation was of the view that the African Group and the DAG proposal advanced

such a work program. The Delegation concluded by stating that WIPO, as a specialized agency of the United Nations, had a key role to play within its mandate to facilitate access to medicines.

112. The Delegation of Zambia supported the position taken by the African Group. It underlined that the issue was critical to Zambia which had no manufacturing capacity for special drugs, especially drugs for HIV and AIDS and other related illnesses. Further, the Delegation stated that medicines were not like any ordinary commodity. The issue of public health required a holistic approach which was practical, balanced and sustainable. That could be achieved through sharing information on national experiences on the use of flexibilities as proposed by the African Group and the DAG. Further, the Delegation stated that its experience had shown that the flexibilities were not easy to implement or utilize. For example, in 2004, Zambia had issued a compulsory license in line with its Patent Act. However, due to the requirement of predominant supply to the domestic market, the company which had been granted the license was not able to manufacture the drugs.

113. The Delegation of Colombia stated that the right to health brought together very different interests, those connected with the right to make a commercial use of a certain type of pharmaceutical information and the right to receive a certain level of medical treatment. The Delegation pointed out that the patent system did not only reward the patentee who had invested efforts and money into research in order to make medicines available to the public, but it also worked as a tool for the disclosure of technological information to public on the basis of which new therapeutic treatments could be developed for the benefit of mankind. Further, the Delegation considered important to refer to the connection that existed between competition law and patents, which had also been indicated in the trilateral study carried out by WIPO, the WTO and WHO. In particular, the Delegation stated that the competition law objectives was to guarantee: (i) market efficiency and the free choice of goods and services at different prices and qualities for the consumer; and (ii) free access by companies and their free participation in the national economy in order to ensure a fair, transparent market which was not unduly burdened by restrictive commercial or trade practices and abuses of dominant positions. Further, the Delegation stated that the relationship between competition and innovation could encourage the entry of new agents into the market. Noting that a number of market participants having a common purpose of maximizing their own profits would attempt to keep or retract consumers through various instruments, including the price of the product, its quality or novelty, the Delegation emphasized that it was precisely the last instrument, namely, the novelty, which led to innovation. The supply of innovative products and services by a successful economic agent, in its turn, would encourage the production of goods and services that were even more innovative by other agents, because they would try to increase the share of customers and influence the consumer preferences. Therefore, the Delegation explained that the competition and innovation were intimately connected. Innovation itself could lead to more competition on markets. Turning specifically to patent protection, the Delegation stated that grant of exclusive rights enabled a patentee to enjoy, during a particular period of time, the right of excluding anyone else from the economic benefits derived from his creation. In that way, the States provided inventors the possibility of return on high costs and risks involved in the inventive process, through protecting those inventions from imitations. Such a mechanism encouraged continuity and an increase in inventive processes, which would eventually promote the development of society and the general well-being of the community. The Delegation further observed that if competitors could commercialize inventions without undergoing the costs and risks run by inventors, there would be no incentive to make inventions and produce technologies. Noting that the above applied to all market players, the Delegation turned to the particular issue of pharmaceuticals. The Delegation stated that pharmaceutical companies had social responsibility to contribute to development and the well-being of a community in which they work. It therefore considered that pharmaceutical companies should conduct their activities in a transparent manner, and they should contribute to the protection of the environment. In its view, the corporate social responsibility would be a test of good practices carried out by economic agents in pursuing their commercial aims. Further, the Delegation noted that the social

responsibility of pharmaceutical companies, when it comes to patents, would be to transfer their knowledge to the community, and to ensure that creative and innovative products were on the market. If that would not occur, in the view of the Delegation, a compulsory licensing could be issued, making it possible for a third party to use the patent without the consent of the patent holder against payment. The Delegation, however, stressed that that would not imply that the States should get involved in the way in which an individual pharmaceutical company used or exploited its resources, unless there were some indications that the commercial or marketing practices infringed the law of the country concerned. Furthermore, the Delegation noted that one should not, in advance, assume misappropriation or misuse of a patent, because that would be an infringement of the principle of good faith.

114. The Delegation of Algeria stated that the Algerian legislation had taken into account the balance which should exist between the rights of the right holder and the public interest. The Order of July 2003 recognized a number of flexibilities, including, in particular, exceptions and limitations to the rights through issuance of compulsory licenses in case of health, nutrition and national security needs. Further, the Delegation stated that the patent procedure in the national patent office was applied in the same manner for all areas of technology. A compulsory license could be granted by the competent authority when a patent holder did not agree to issue a voluntary license for the product or service. The Delegation stated that they did not have any problem in implementing various flexibilities so far. While stating that some exceptions and limitations were easy to implement, the Delegation, however, noted that compulsory licenses in respect of medicines had not been used. Considering that they might use compulsory licenses in the future, the Delegation proposed that the Committee examine whether there should be a legal assistance to strengthen the human resources of offices, so that countries could better cope with the implementation of the provisions under their law.

115. The Delegation of Argentina stated that public health was of great importance for all States and was an issue that required a special attention in the implementation of the TRIPS Agreement. The Delegation stated that, in determining the requirements for patentability, the TRIPS Agreement granted Member States the power not only to define the concept of invention, but also other patentability requirements. That ability had been confirmed by the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO Ministerial Conference in November 2001. The Delegation observed that the WHO Secretariat had recognized that patents could have an influence on access to medicines, and it had encouraged the use of flexibilities under the TRIPS Agreement. The Delegation noted there was abundant literature that showed that flexibilities enabled governments to reduce negative impacts that IPRs might have on health through the adoption of appropriate legislations and regulations. Consequently, in the view of the Delegation, it was important to develop a study on flexibilities available under the TRIPS Agreement and their implementation based on the proposal made by the African Group and the DAG.

116. The Delegation of Japan expressed its hope that many new medicines would be developed, since there were many diseases all over the world, for which there was no effective treatments. Emphasizing that developing new medicines required a large amount of time and resources, the Delegation stated that there was a need to give certain incentives to inventors for the development of effective medicines. In its opinion, that was exactly what the patent protection was all about. The Delegation was of the view that denying the contributions of the patent system toward enhancing public health would prevent medicines from being developed in the future. In conclusion, the Delegation expressed its belief that the existing patent system was well-balanced and that any work should not shift that balance toward creating greater flexibilities.

117. The Delegation of the United States of America stated that patent law flexibilities in its country were used to facilitate and expedite the marketing of generic drugs. The Delegation stated that the Drug Price Competition and Patent Term Restoration Act of 1984, informally known as the Hatch-Waxman Act, demonstrated the use of patent flexibilities to incentivize the development of

new drugs by providing a mechanism to restore patent term lost due to review of the new drug applications by the U.S. Food and Drug Administration and facilitating the approval of generic drugs by simplifying the application for generic drugs and encouraging timely patent challenges. The Delegation noted that the Hatch-Waxman Act created a balanced approach to flexibilities which resulted in continued innovation in new medicines as well as strong generic drug industry in the United States of America. Further, the Delegation stated that the generic drug market entry in the United States of America had been further facilitated by the United States Code, Title 35, paragraph 271(e), which permitted use of patented inventions for testing intended to develop generic drugs for the U.S. Food and Drug Administration approval. In particular, the provision stated: "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention [...] solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products".

118. The Delegation of Chile stressed the importance of patents and inventions within the health sector. The Delegation informed the Committee about a seminar organized in Santiago by the National Institute on Industrial Property in conjunction with other public health related institutions. Turning to various proposals that had been made, the Delegation stated that, despite the differing viewpoints expressed, the activities covered in various work plans could contribute to making further headway on the issue. The Delegation further expressed its hope that they would provide specific information on implementation of health policies *vis-a-vis* the patent systems in various States, in particular, in developing countries and LDCs.

119. The Representative of KEI stated that as the SCP had been considering the relationship between patents and health, it was timely and relevant to reflect on the statement made by Marijn Dekkers, the CEO of Bayer on December 3, 2013. The drug company had been in the middle of a dispute in India over the pricing of the cancer drug, Nexavar. Bayer had set the price of Nexavar at 65,000 dollars per year in India, and in response, the Indian Government had granted a compulsory license. Due to the competition with two generic drug companies, the price of that drug had decreased 97 percent. The Representative stated that Dekkers had described the compulsory license as "essentially theft," and that she also had stated "We did not develop this medicine for Indians. We developed it for western patients who can afford it". In his view, in setting the price on a drug for a deadly disease like cancer, Bayer had determined that the company had been better off excluding nearly all patients in India. The Representative observed that that was why governments needed to have the authority to break patent monopolies – to protect health and in particular, to promote access to medicines for all, which was an obligation under 2001 Doha Declaration on the TRIPS Agreement and Public Health. Further, the Representative stated that during roughly the same period, Merck and a number of other large drug and medical device companies had proposed an extensive public relations and lobbying campaign to undermine the patent reform in South Africa. Also during the same period, Gilead had received a U.S. Food and Drug Administration approval for an important new drug that could cure hepatitis C, and had announced it would charge 1,000 USD per pill, and a total of 84,000 USD for a course of treatment. Noting that concerns about patents and health were not only a developing country issue, the Representative stated that since 2011, drug companies had registered a record number of new cancer drugs with the U.S. Food and Drug Administration, and that most of the new cancer drugs were priced at more than 60,000 USD per year. More than ten were priced more than 100,000 USD per year, and some were nearly 400,000 USD. Doctors, reimbursement authorities, patients and employers in high income countries had been shocked at those aggressive prices, and had been struggling to control costs and provide access. The Representative further stated that Greece and Spain were considering the use of compulsory licenses on patents for expensive cancer drugs. Germany, the United States of America, Belgium, Canada and France had all issued or considered issuing compulsory licenses on patents for medical devices and diagnostics. In the view of the Representative, in considering the work program on health and patents, the SCP needed to identify specific activities that were relevant to

the challenges faced by the governments, including those with aging populations, budget deficits and escalating healthcare costs. The African Group and the DAG had proposed a series of studies, meetings, research projects and technical assistance activities which collectively strengthen the ability of States to negotiate and manage some of the challenges directly relating to patents and health. Noting that some delegations had intended to block any work that could weaken drug company monopolies, the Representative stated that that was wrong for developing countries, and also wrong for countries with developed economies. Referring further to the proposal by the United States of America (document SCP/17/11), the Representative stated that the proposal was a defense of the worst abuses of the patent system in the field of health, as even courts in that country had issued compulsory licenses on at least four medical devices in recent years and recently denied patents on certain gene patents. In addition, the Representative noted that the Congress had created an automatic compulsory licensing program for undisclosed patents on biologic drugs as part of the Affordable Care Act. Therefore, the Representative suggested that the proposal by the United States of America be abandoned, and that delegations negotiate a work program based on, as a starting point, the African Group and the DAG proposal. The Representative concluded that if the patent system was going to survive and thrive, it would have to be seen as an instrument to benefit society, and not as a weapon of mass destruction. In its opinion, reforms that would moderate the worst abuses of the patent system were good for the patent system, because those reforms would protect the patent system's legitimacy and its role in promoting social welfare.

120. The Representative of TWN took the opportunity to congratulate the African Group and the DAG for submitting the proposal on patents and public health. The Representative fully supported that proposal and urged Member States to initiate a work program as found in the proposal. He further stated that access to medicine was one of the critical elements to ensure the enjoyment of the right to health. The 23<sup>rd</sup> session of the Human Rights Council had adopted a resolution on access to medicines. The recently concluded session of the WHO Executive Board had also approved a resolution of access to essential medicines. The Representative observed that both resolutions contained operational paragraphs which encouraged Member States to use the TRIPS flexibilities to ensure access to medicines. Similarly, the Representative noted that discussions in the context of the Development Agenda, as well as deliberations on sustainable development goals also flagged access to medicines as an important issue. In his opinion, in the absence of access to affordable medicines, global efforts on universal health coverage would fall apart. The Representative further stated that even though access to affordable medicines depended on many factors such as domestic production, public procurement, efficient distribution etc., patent rights could play an adverse role by limiting the competition in pharmaceutical market. The Representative observed that, unlike those other factors, there was a limited policy space for Member States to address the barriers posed by patents on access to medicines. Therefore, in the view of the Representative, it was timely for WIPO to move forward on that issue. Failure to do so would affect WIPO's credibility as an organization promoting the right to health. Noting that while more and more countries were taking measures to amend their national laws to optimize the scope of flexibilities to meet the access to medicine needs, the Representative noted that there were efforts from pharmaceutical multinational corporations and their associations to block such efforts. In his opinion, the leaks in South African media showed that there was a collective effort by pharmaceutical companies to unleash a campaign against the South African government's legitimate efforts to address public health concerns. Recent press reports from India with regards to the statement made by the CEO of Bayer also showed the disregard placed by pharmaceutical companies on ensuring access to medicines in developing countries. Further, he stated that, similarly in 2013, the Pharmaceutical Manufacturers Association of America had lobbied the US political leadership to mount political pressure on India against the use of TRIPS flexibilities. That lobbying had resulted in an investigation against Indian generic manufacturers by the International Trade Commission, a government body of the United States of America. The Representative further urged the Director General of WIPO to either not engage or to disengage from pharmaceutical companies and their associations who were involved in the efforts to block use of

flexibilities. He also urged the Member States to condemn the efforts of the pharmaceutical industry to undermine the use of TRIPS flexibilities and their disregard to human rights. The Representative expressed its hope that the deliberations should identify the constraints faced by developing countries to effective and efficient use of flexibilities in their patent laws to ensure access to medicines. Finally, the Representative urged that Member States put people's health above profits.

121. The Representative of MSF welcomed a discussion on patents and health, as it provided an opportunity for sharing countries' experiences in using TRIPS flexibilities to promote public health. However, the Representative expressed her concern about the slowness of WIPO in providing technical assistance to countries in order to enable them to design and reform patent laws through the use of public health flexibilities. MSF also remained concerned that developing countries continued to face difficult challenges in balancing intellectual property, public health and access to medicines in their national patent laws. The Representative stated that the recent events in South Africa had demonstrated the willingness of multinational pharmaceutical companies to secretly undermine a legitimate patent law reform process – the very sort of reform that WIPO should support – leading to the improvement of generic competition and promotion of access to medicines. The Representative observed that South Africa was facing one of the world's most acute HIV and TB epidemics, where price for medicines could be 35 times higher than countries with more robust generic competition. While those revelations had triggered the intensive discussions at the previous WHO Executive Board meeting, with many countries expressing their solidarity and support for South Africa, the Representative considered that the current SCP session on patents and health was a particularly appropriate forum to address the issues under discussion in South Africa from a technical standpoint. MSF further urged Member States to grasp the pressing need for WIPO to play an appropriate role to support patent law reform that could improve public health. Firstly, MSF urged the SCP to take concrete steps in adopting African Group and the DAG proposal contained in document SCP/16/7, with a clear implementation plan. The Representative noted that the proposal outlined the technical needs of developing countries, and a road map to apply WIPO's technical abilities in supporting countries to understand the impeding impact of patents on access to medicines, and incorporating technical solutions in their national patent systems to mitigate such effects. Further, noting that WIPO needed to collaborate with the WHO to implement the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, the Representative stated that the proposal was a positive step forward to fulfill WIPO's mandate. Secondly, MSF encouraged Member States of developing countries to increase information sharing and technical support to one another in the context of patent law reform that promoted public health. MSF also urged the Secretariat to facilitate such exchanges as an extension of the sharing exercise that was underway at the Committee. Further, the Delegation stated that, in recent years, debates and policy decisions regarding the intersection of intellectual property, public health and access to medicines had been reflected in a number of patent law reform processes, for example, in Brazil and India. However, the Representative noted that those efforts diverged greatly from South Africa which, in lacking substantive examination capacity, had granted nearly 2,500 patents on pharmaceuticals in 2008 alone without an adequate assessment of the quality of patent applications. By contrast, Brazil had granted only 273 patents in the five-year period up to 2008. The Representative was of the opinion that those divergent experiences could be mitigated in part by encouraging governments to work more closely with each other to ensure that best practices could be adopted. Thirdly, the Representative stated that there was a need to ensure a consistent application of public health concerns across the agenda items under consideration at the SCP. The Representative noted that, for example, delegations had debated over the ambiguity and absence of a shared definition of quality of patents. The Representative continued that, in the context of public health, second use patents could significantly restrict access and hinder innovation, especially the development of fixed dose combinations and other formulations of medical products that could be beneficial in resource-limited settings. In the view of the Representative, identifying public health-friendly patentability criteria in national patent laws could be a positive step to promote innovation and access. In addition, it was stated that any

discussions on patent opposition systems as well as exceptions and limitations must ensure the inclusion of the public health considerations. Noting that such analysis had been done elsewhere many times over the last decade, the Representative expressed its belief that it was long overdue for the Committee to integrate such perspectives into its work now and in the future. The Representative considered that failure to do so would mean that those discussions would not reflect the challenges and realities facing developing countries.

122. The Secretariat informed the Committee that, pursuant to the decision of the SCP at its nineteenth session, a summary of the sharing session on countries' use of health-related patent flexibilities would be available before the end of the twentieth session of the Committee.

#### **AGENDA ITEM 9: CONFIDENTIALITY OF COMMUNICATIONS BETWEEN CLIENTS AND THEIR PATENT ADVISORS**

123. The Secretariat introduced document SCP/20/9.

124. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, thanked the Secretariat for preparing document SCP/20/9 containing a compilation of laws and practices on experiences relating to the issue of confidentiality of communications between clients and their patent advisors, and for the interesting presentation made on the subject. The Delegation expressed its strong interest in continuing discussion, in particular, in relation to the cross-border aspects of the issue. The Delegation was of the opinion that the discussion was still necessary, since it was closely related to quality of the international patent system. Taking into account different approaches of national laws of Member States and different practical solutions, the Delegation continued to believe that developing non-binding principles or guidelines to address the topic would be an appropriate way forward. The CEBS Group was of the view that soft law approach would be appropriate and useful, enabling and avoiding any need to amend national legislation or change judicial systems. Such approach, according to the view of the Delegation, would benefit all and, therefore, should be acceptable to all WIPO Member States.

125. The Delegation of India reaffirmed its stand on the issue of client-attorney privilege as it had taken in the previous sessions. In particular, the Delegation stated that there was no provision in the India's Patents Act of 1970 with respect to patent agents who were required to be science graduates. It also wished to reiterate that neither the Paris Convention nor the TRIPS Agreement provided any such privilege. Noting that the issue was of substantive nature, the Delegation stated that, in its view, harmonizing the client-attorney privilege would imply harmonizing the exceptions to the disclosure. In India, persons who graduated in science or engineering might be qualified for practicing as a patent agent, even without having a law degree. The lawyers were protected from discovery proceedings by the Indian Evidence Act. However, a patent agent, being a person of scientific background, did not fall under such protection under the Indian law. In addition, the Delegation stated that, since such disclosure might help the court in the final determination of the substantive issues such as the novelty and inventive step, such privilege might cause detriment to the patent system. Therefore, the Delegation reiterated that any attempt to harmonize the cross-border aspects of the issue was not compatible with its perspective.

126. The Delegation of Japan, speaking on behalf of Group B, thanked the Secretariat for the preparation of document SCP/20/9. In its view, the document provided useful information about laws, practices and experiences relating to confidentiality of communications between clients and their patent advisors. It was also found that information in the document was valuable in considering laws and practices that reflected Member States national circumstances. In its view, such information should be effectively disseminated, for example, by putting it in a more accessible and user friendly format, such as through a dedicated WIPO web page. It further considered that regular updates, including the court cases, would enhance the value of the information. In addition,

the Delegation stated that such efforts could also be implemented by a possible seminar involving the users who had practical experiences to share. The Delegation stressed the importance of the cross-border recognition of foreign privilege, as its absence complicated business environment and could prevent core investment. Therefore, the Delegation considered that a greater cooperation to address that problem could bring benefits to all countries, irrespective of the level of development, through the enhancement of the credibility, reliability and certainty of the business environment. Noting that Group B continued to support further work on that issue, the Delegation suggested that solutions be found at the global level. In that regard, the Delegation was of the opinion that the SCP was the right forum to continue to deal with the issue. Consequently, it stated that guidelines or any other soft law approach, based on non-binding minimum standards, should be further considered as a possible solution. In its opinion, such an approach was appropriate, since each country could adopt its own measures, taking into account its specific legal situation.

127. The Delegation of Australia thanked the Secretariat for its continued work in preparing meetings and the papers for the SCP. In particular, the Delegation expressed its appreciation for the preparation of document SCP/20/9 and the related summary document. The Delegation expressed its belief that free and frank communication between clients and their patent advisors was essential to clearly articulated patent applications and to the prosecution of inventions throughout the world. The Delegation stated that that applied regardless of the status of the country, and the issue was relevant to all developed, developing and least developed countries. The Delegation further stated that the bulk of Australian patent applications originated from overseas, and in order to encourage technological importation into Australia, it sought to ensure that any advice provided to a client overseas would be privileged within Australia. The Delegation explained that before the amendment of its legislation, opposite had occurred - a privileged piece of information that had been discussed with an overseas patent attorney had not been privileged in Australia, and the substantive rights of that client had been prejudiced within the Australian borders. In order to rectify such situation, in April 2013, Australia had implemented legislation to provide a clear and specific privilege that had been extended to communications to patent agents and patent advisors outside of Australia. The Delegation was of the view that the new legislation would lead to better defined specifications for patents and to greater certainty of validity of those patents, and also allow frank and free disclosures to client advisors which clients needed to undertake. The Delegation further red out the revised subsection 200(2) of the Patents Act, which stated that a communication made for the dominant purpose of a registered patent attorney providing intellectual property advice to a client was privileged in the same way, and to the same extent, as a communication made for the dominant purpose of a legal practitioner providing legal advice to a client. The Delegation noted that a similar paragraph was provided regarding the documents that were prepared in providing legal advice, as well as another paragraph which provided a definition of a registered patent attorney. The Delegation stated that that was not a particularly complicated piece of legislation and that it set out a premise that a court could use in order to provide privilege in any particular situation. The Delegation further expressed its hope that the Committee would move forward on that issue. It stressed that the protection and preservation of confidentiality in relation to IP professional advice was the common principle that applied both in civil and common law nations. However, the Delegation observed that the problems of the lack or loss of protection remained, given that there were jurisdictions where the protection was not provided. The Delegation further stated that, based on that principle, the problems of client-attorney privilege could be resolved by some form of an agreement between nations that they mutually recognize confidentiality on the advice. However, the Delegation added that, before proposing such an agreement, there was a need to conduct another study or information gathering by the Secretariat with a view of finding out from Member States what limitations or difficulties they might have in their particular jurisdiction in order to provide a reciprocal client-attorney privilege.

128. The Delegation of Pakistan thanked the Secretariat for the presentation and the document that had been prepared on the subject. Further, it stated that client-attorney privilege was a sensitive topic considering the diversity in national laws of Member States. The Delegation

stressed that there was a considerable variation in national laws, marked by a widespread lack of uniformity of protection and difference in opinion about the extent and scope of recognition of privilege both locally and internationally. Similarly, the Delegation noted that application of privilege showed a wide diversity, extending from lawyers to IP advisors, who may or may not be legal attorneys. The Delegation stated that the matter was further complicated by the fact that it fell in the domain of private law and regulation of professional services. In its opinion, the topic therefore reflected an issue which was not purely technical but also legal. The Delegation expressed its strong belief that further studies looking into possible adverse implications of having uniform legal standards on client-attorney privilege were required. In conclusion, the Delegation stated that it supported positive engagement and information sharing as long as it was not contrary to national legislations of Member States.

129. The Delegation of Kenya thanked the Secretariat for the preparation of document SCP/20/9. Further, it stated that in Kenya patent advisors were called patent agents, and in order to be qualified to practice as a patent agent in that country, the person needed to be a citizen of Kenya who would be practicing and residing in Kenya. That person could be a lawyer or a scientist or someone having a technical background. The Delegation stated that would mean that, in Kenya, foreign patent advisors or agents were not allowed to practice. Therefore, the Delegation was not yet convinced that those discussions were very encouraging in the SCP.

130. The Delegation of Montenegro fully supported the statement made by the Delegation of the Czech Republic on behalf of the CEBS Group. The Delegation expressed its belief that the confidentiality of communication between clients and patent advisors, in particular, in relation to the cross-border aspects, was of great significance. The Delegation stated that guidelines or non-binding principles would be the right direction for future work on that issue without the necessity of changing national patent laws or judicial systems in the respective Member States.

131. The Delegation of Greece, speaking on behalf of the European Union and its Member States, thanked the Secretariat for the preparation of the compilation of laws and practices in relation to confidentiality of communications between clients and their patent advisors, contained in document SCP/20/9, and the accompanying presentation. The European Union and its Member States remained convinced that the convergence of existing diverse systems in the area of confidentiality of communications between clients and patent advisors among WIPO Member States would be beneficial for users of the patent system, irrespective of the level of development of individual WIPO Member States. In the view of the Delegation, time was ripe to consider concrete mechanisms to address the recognition of foreign patent advisors' privilege. The Delegation suggested that in order to avoid the need to amend national legislation or change national judicial systems, a soft law approach be considered, whereby WIPO Member States would adopt non-binding principles that could be applied at the national level. It urged delegations, particularly those countries who had stated that they did not have any provisions on confidentiality of communications, and that any attempt to establish minimum standards would undermine national legislations, to take a constructive approach.

132. The Delegation of Japan thanked the Secretariat for its extensive work in preparing the informative document SCP/20/9 and the presentation. The Delegation informed the SCP that, at the Patent Attorney System Subcommittee in Japan, the issue of attorney-client privilege had been discussed as one of the subject related to the revision of the patent attorney system. As a result of that discussion, it was considered that international negotiations should be pursued as a way to advance the issue. The Delegation stated that, as mentioned in document SCP/20/9, the respective national measures were not effective globally, in particular, in countries which had categorically denied the privilege to foreign-based patent advisors. In that context, the Delegation of Japan expressed its belief that a soft law approach, based on non-binding minimum standard, should be considered at WIPO as a viable approach so that the attorney-client privilege could be globally recognized by the judicial authorities. On that note, the Delegation associated itself with

the position taken by Group B on the issue and expressed its strong support for the dedicated WIPO web page and a possible seminar.

133. The Delegation of Canada thanked the Secretariat for its work in compiling the information contained in document SCP/20/9. The Delegation was of the view that the Secretariat should go further into details on the prevalence and severity of problems caused by a lack of privilege for non-lawyer agents as well as the remedies available. The Delegation stated that studies prepared by the Secretariat had provided examples of clear credible cases where the lack of privilege had been problematic. Therefore, in the view of the Delegation, it might be worthwhile to study the extent to which problems caused by a lack of privilege were systemic and widespread. The Delegation considered that information gathered from the Member States on their experience on that issue, in particular, on how countries' change of the regime to provide client-attorney privilege had benefitted them, could be a worthwhile exercise.

134. The Delegation of Zambia thanked the Secretariat for the preparation of document SCP/20/9, and stated that in its country, the issue of client-attorney privilege was governed by the Legal Practitioners Act which established who was entitled to practice, the privileges, restrictions and offenses in connection with the practice. In addition, the Patent Act provided for who could be qualified as a patent agent, their functions, qualifications, privileges and entitlement. Further, the Delegation underlined that a person wishing to become a patent agent or attorney must be a resident in Zambia and must be registered in accordance with the Legal Practitioners Act. In view of the above, in its opinion, no universal system on the issue of cross-border communications between clients and patent advisors should be applied. Noting the variation of approaches on the issue in various jurisdictions, the Delegation stated that the cross-border aspect should be looked at in a very critical manner and holistically. Consequently, the Delegation concluded that setting standards on the issue required a further study.

135. The Delegation of South Africa, speaking on behalf of the African Group, stated that its Group was of the view that the issue of client-attorney privilege was a matter that fell within the purview of private law and the regulation of professional services and hence fell outside of the mandate of WIPO. The Delegation also noted that in many countries, the issue of privilege was the subject of the law of evidence, and that it was not a substantive patent law issue. The African Group was of the firm view that it was up to each Member State to decide how to handle the issue within its national law.

136. The Delegation of Guatemala stated that, according to the legislation of its country, in case of cross-border IP issues, a legal representative had to be appointed who was of a Guatemalan national. Therefore, the issue was a subject to the professional code of lawyers in Guatemala. Further, the Delegation stated that Article 5 of that code provided that the professional secrecy shall be maintained, and it was a duty and a right of the attorney towards his clients to preserve the professional secrecy before the judges and the other authorities even after the termination of his services. In view of the Delegation, there was a need to include such a provision in legislation on patents as well as a provision on the confidentiality of information contained in the patent applications.

137. The Delegation of Switzerland congratulated and thanked the Secretariat for the preparation of the comprehensive document SCP/20/9 and stated that the issue of client-attorney privilege affected patent practitioners and courts all over the world and therefore should be further pursued. The Delegation stated that, in addition to the measures proposed by Group B, a possible next step for the Committee could be a non-binding recommendation which would contain general definitions of key terms such as, for instance, patent advisor, privileged information and a minimum standard of the privilege. In its view, those non-binding soft law definitions could serve as a common point of departure for future all-inclusive discussions about client-attorney privilege and would not entail an amendment of national laws or judiciaries whatsoever.

138. The Delegation of Belarus thanked the Secretariat for the document prepared on confidentiality of communications between clients and their patent advisors, and supported those delegations which stressed the importance of examining the issue at the Committee. Noting the various nature of work that patent advisors handled, the Delegation underlined the urgency of the problem and the need to study the issue further in order to examine possible approaches to solving the problem at the Committee.

139. The Representative of the ICC drew the attention of Member States to the public interest implications of the issue. In particular, the Representative stated that privilege against disclosure of client-advisor communications played a key role in the transparency of the IP system. In his opinion, it helped to ensure respect for national laws and to achieve just and efficient outcomes for all parties, including right holders and those confronted by IP rights of others.

140. The Representative of TWN stated that one of the key reasons for granting patent monopoly was to facilitate disclosure of the invention in the public domain. Therefore, in his opinion, there should not be any legal protection which would protect against full disclosure. Further considering the implications of patent monopoly on people's life, patents should be granted only to genuine inventions which would satisfy the patent applicability criteria. In his view, any kind of privilege on communication between the patent attorney and the client would provide the legal protection to cover up information from the patent Office in order to obtain patents. Therefore, the Representative argued that, contrary to setting a protection, there should be legal requirements to reveal all such communications and to ensure the granting of patents of the highest standard.

141. The Representative of JPAA expressed its strong support for the continuation of the discussion of the issue at the SCP. The Representative noted that, after the six-year discussion at the SCP, the understanding of the issue by Member States had been deepened. The Representative expressed his belief that the SCP would be able to reach a good conclusion on the issue. The Representative stated that JPAA had been trying to introduce the privilege to the Japanese Patent Attorney's Law by seizing the opportunity of the revision of that law. Finally, the Representative expressed his strong support for a soft law approach on the issue and the adoption of a minimum standard.

142. The Representative of AIPPI thanked the Secretariat for the preparation and presentation of document SCP/20/9. He noted that the study of the protection of client-IP advisor confidential communications had made substantial progress since it had started in 2009 and had led to the recognition that the problems identified could not be solved by national laws alone – an international remedy was required. The Representative stated that the problems were generally two fold. The first was the lack of adequate protection in some nations. The second was the risk, and actual loss, of whatever protection which had been provided in particular nation when disclosure of advice was required cross-border. Noting that an element shared by both common law and civil law jurisdictions in relation to the needs of clients to be protected from forcible disclosure of their advice was the confidentiality of that advice, the Representative stated that the remedy for the problems identified could be based on that common element of confidentiality. He further stated that the protection from forced disclosure of confidential advice given by IP lawyers had been recognized for centuries both in the common and civil law regimes. Where the protection existed, it flew from the public policy that clients needed to be protected from forcible disclosure so that they could get correct legal advice, namely full, fair and frank advice from their IP advisor. The extension of that public policy to non-lawyer IP advisors was simply a reflection of the modern reality where many advisors were not lawyers, but individuals with advanced technical or scientific degrees. In relation to any proposed remedy, the Representative clarified that the protection would apply only to communications relating to the instructions and advice itself, and did not provide protection against disclosure of facts material to determining intellectual property rights such as the existence of relevant prior art. Such protection also did not serve to avoid the disclosure

requirements imposed upon patent applicants by national patent offices and patent legislations. The Representative further stated that the past SCP process had been enriched by its inclusiveness of all Member States, regardless of their particular position taken on the issue. AIPPI urged the Member States to continue working that way. AIPPI drew the attention of the SCP to AIPPI's work on the issue since the 19<sup>th</sup> session of the SCP and the development of the international remedy which AIPPI proposed for the consideration by the Member States. The Representative stated that part of that work had been the further development of AIPPI's proposed remedy. That proposal had been peer reviewed by lawyers, patent attorneys and government representatives in a colloquium conducted by the AIPLA, AIPPI and FICPI with government representatives of Australia, Germany, Japan, Switzerland, the United States of America and others, in Paris in May 2013. Responding to the suggestions made in the SCP by developing countries and others that any remedy needed to make clear that knowledge of prior art was not compromised by the remedy proposed by AIPPI, the AIPPI proposal had been specifically amended to make clear that the protection did not extend to facts or relevant documents such as prior art. The proposal had also been amended to account for national exceptions that might reasonably apply. Further, the Representative wished to note that its proposal was consistent with the approach taken in Europe in respect of the Unified Patent Court (UPC) and its Rules of Procedure. In particular, he stated that those Rules included the provision for the establishment and preservation of confidentiality in communications relating to intellectual property advice in respect of proceedings before the UPC. In closing, the AIPPI congratulated the SCP on the work to date on the issue and encouraged the SCP to take advantage of that good work by continuing to consider the issue and the existing unknowns, including the investigation of the difficulties or problems that Member States might encounter in implementing a solution to the problem.

143. The Representative of APAA stated that APAA, being a representative of patent attorneys in private practice in the Asian region, had passed a resolution on client-patent advisor privilege issue in 2009. The Representative noted that during the 13<sup>th</sup> session of the SCP, APAA had made a statement supporting an international consensus on setting minimum standard or any other possible measures to protect client-patent advisor privilege against forcible disclosure. In consideration of the facts that a number of cross-border IP disputes had been increasing, in order to protect clients from being exposed to a high risk of forcible disclosure, thereby potentially undermining a client's potential to obtaining suitable legal advice on IP matter, APAA continued to support taking further steps for studying the feasibility of setting a minimum international standard on the issue in an accelerated manner.

144. The Representative of FICPI thanked the Secretariat for the compilation of document SCP/20/9 and for the very clear summary presentation of that document. The Representative stated that members of FICPI were professionals active in prosecution, litigation as well as in legal and technical advice with respect to IP rights such as patents, trademarks and designs. FICPI had over 5,000 members in 86 countries throughout the world, and it carried the views of those professionals with their diversity and practical experience. In view of that practical experience, FICPI considered confidentiality of communications between clients and their IP advisors as a very important topic. In fact, FICPI had been standing for many years for the recognition of client-attorney privilege for IP practitioners in private practice. Over the years, it had been carefully watching the developments on the topic at the SCP and had made written and verbal efforts to have the issue better understood by the Member States. Referring to the colloquium conducted by the AIPLA, AIPPI and FICPI on confidentiality in Paris in 2013, the Representative stated that the colloquium had confirmed the importance of the topic and allowed practitioners from around the world to realize once again that its appreciation could be diverse in different jurisdictions. Noting that one of the drivers for that colloquium had been the continued discussion at the SCP, the Representative stated that that discussion had indeed allowed identifying a different situation with respect to confidentiality of communications between clients and their IP advisors. Further, the Representative stated that IP was by nature international, and IP right holders were exposed to situations involving IP rights in jurisdictions all over the world. FICPI considered that it was

essential for every client willing to explore a project involving IP to be able to communicate with an IP advisor without being exposed to unpredictable legal consequences, including those in foreign jurisdictions. The Representative observed that current legal situation with respect to confidentiality of communication was governed by provisions which differed significantly across jurisdictions, which created some strong uncertainty. Further, the Representative recalled that confidentiality of communication between clients and their IP advisors was not in any manner a means to retain facts such as, for example, prior art. He explained that confidentiality of communications provided protection on communications, which meant that communication between a client and its advisor could freely include exploration on every option concerning IP rights. The Representative noted that such open and unlimited communication was important, as it was a necessary condition for a good understanding on efficient exchange between a client and his IP advisor. He further stated that such confidentiality was a key to the IP advisor gaining a complete and unlimited understanding of his client's technology, which in turn allowed the drafting of good quality patents with a description of the invention as complete as possible. Therefore, in his opinion, confidentiality was a driver of quality of patent applications. In conclusion, the Representative reiterated its strong support for future work on that important topic.

145. The Representative of CEIPI reiterated its support for the continuation of the study of the issue under discussion.

#### **AGENDA ITEM 10: TRANSFER OF TECHNOLOGY**

146. Discussions were based on document SCP/20/10.

147. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, thanked the Secretariat for having prepared document SCP/20/10, summarizing the information received from some members and observers of the Committee. The Delegation stated that the document, together with the previous document on the same subject, confirmed the complexity of transfer of technology, which was an issue affected by various factors, including the absorptive capacity of national industries and of the recipient party. The Delegation stressed that the issue of transfer of technology went beyond the patent system. In its opinion, a high quality of patents and well-functioning of the PCT system were essential elements for a patent system to fulfill its objectives in terms of supporting innovation and transfer of technology. The CEBS Group continued to maintain its position that it was necessary to avoid any potential duplication of work with the CDIP projects related to transfer of technology. As an example, the Delegation named the project "Intellectual Property and Technology Transfer: Common Challenges – Building Solutions", and stated that results of the specific projects related to transfer of technology should be analyzed before any new steps concerning transfer of technology could be envisaged in the SCP.

148. The Delegation of Japan, speaking on behalf of Group B, thanked the Secretariat for its preparation of document SCP/20/10 on practical examples and experiences relating to patents and transfer of technology. The Delegation stated that the document included initiatives and measures that Member States had adopted to promote technology transfer under the framework of the existing patent system. The Delegation also noted the absence of any conclusive example that suggested that the patent system was impediment to technology transfer. The Delegation continued that, as had been noted by its Group at the previous session of the SCP, technology transfer was affected by a range of elements. In its opinion, among those elements, the SCP could deal with factors which had a direct relationship to its core mandate. In particular, the Delegation stated that enhanced quality of patents would give a greater certainty, which was an essential part of the environment which could accommodate technology transfer. Further noting that there were other projects on the topic, as reported in paragraph 29 of document SCP/20/10, the Delegation stated that Group B was of the view that further work on the issue should be considered only after the whole picture of the issue was clearly presented.

149. The Delegation of Greece, speaking on behalf of the European Union and its Member States, thanked the Secretariat for preparing document SCP/20/10 expanding the study on patent-related incentives and impediments to the transfer of technology through practical examples and experiences. In particular, the Delegation expressed its satisfaction with the systematic approach and objectivity shown in the document, listing various activities on the transfer of technology undertaken by WIPO and its Member States. In addition, the Delegation noted that the Secretariat had difficulty in identifying cases in which patents had been an impediment to technology transfer. In its view, it demonstrated that all efforts to improve the patent system would have a positive impact on technology transfer. The Delegation further stated that document SCP/20/10 built on the findings of document SCP/18/8 suggesting that high quality of granted patents, sufficient disclosure of inventions in patent applications, an adequate scope of patent protection and the well-functioning PCT system were essential elements for a patent system to fulfill its objectives in terms of innovation and transfer of technology. In particular, document SCP/20/10 highlighted that better awareness of the patent system and the encouragement of private sector also played an important role in supporting technology transfer. As regards the WIPO Development Agenda and the CDIP projects concerning transfer of technology, the Delegation noted that the Project on Intellectual Property and Technology Transfer: Common Challenges – Building Solutions was due to report by the following session of the CDIP in May 2014. The Delegation, therefore, reiterated that, until completion of that Project and its follow up analysis, it was not in favor of launching new initiatives on transfer of technology within the Committee.

150. The Delegation of India stated that, from the public interest aspect, transfer of technology was 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 further stated that since the discussion in the SCP resumed at the 12<sup>th</sup> session, India and other developing countries had been pressing for discussion on the issue of sufficiency of disclosure and transfer of technology. The Delegation pointed out that a patent would become a social burden if a skilled person in the country where application was filed failed to translate the patented invention into a workable reality without the aid of other secret technologies outside the coverage of the patent; also such failure posed a serious challenge to the very *raison d'être* of the patent system in that country. The Delegation continued that the role of the patent system, as a stand-alone system, and transfer of technologies effected by the patent system, independent of any know-how or show-how, had not been firmly established. In its view, under an ideal situation, a patent should contain all necessary information for transfer of specific technological knowledge. The Delegation further stated that practical examples, as provided in document SCP/20/10, showed the difficulty of transfer of technology faced by a developing country; which indicated that the patent system was yet to earn its credibility as an efficient tool for technology transfer, free from hidden conditions. Further, regarding the idea of compilation of information on the national/regional regulations, guidelines, practices and jurisprudence regarding voluntary licensing agreements, including anti-competitive patent licensing practices, contained in paragraph 27 of document SCP/20/10, the Delegation welcomed that idea and expressed its readiness to meaningfully participate in that regard.

151. The Delegation of China stated that document SCP/20/10 reflected the practices and experiences from many countries, which could be useful for people to learn from them and to explore how to carry out technology transfer. Further, the Delegation noted that there were two basic functions of the patent system. First, it was through granting patents that the innovation and invention was encouraged and protected legally. Second, the system also had to disseminate the use of the technology. Therefore, the Delegation stated that the patent system had a lot to do with the technology transfer, and should continue carrying out the relevant work in that field.

152. The Delegation of Colombia expressed its appreciation to the Secretariat for the preparation of document SCP/20/10 on patents and transfer of technology. The Delegation wished to share with the Committee some experience that they had had with respect to the transfer of knowledge on the basis of patent documents. The Delegation stated that they had received a strong support from WIPO on the creation of a network called "Shared Services on IP" (SECOP), whereby universities and research centers would carry out research in the area of industry, energy and health in Colombia. On the basis of that cooperation, networks for the handling of intellectual property was set up. One important aspect of development of those networks, the Delegation noted, was that over 70% of the total number of patent applications filed in Colombia every year were filed by nationals and residents came through that particular initiative. Further, the Delegation stated that another experience they had had in relation to the topic under discussion was the production of publications known as "technological bulletins". The technological bulletins were publications which provided structured patent information on developments at national and international levels in various areas of technology. They served to help in creating greater understanding among people about the organizational strategies being followed by companies and enterprises. The Delegation noted that, in its view, there had not been much use of the patent system in developing countries and LDCs, particularly, in relation to the information that was available through the system. According to the Delegation, that could be the result of the fact that citizens of those countries did not know well about the industrial property system. The Delegation drew the attention of the Committee to the fact that patent applicants might not be providing all the technical or technological information necessary for a third party consulting the patent document to be able to make legitimate use of it. It stressed the importance of that aspect when it came to access to information.

153. The Delegation of Brazil thanked the Secretariat for the preparation of document SCP/20/10, which was an improvement of the document presented to the SCP at its previous session. The Delegation stated that the analysis of the issue of transfer of technology should take into account also the capacity of Member States to absorb and reproduce technologies. The Delegation wished to highlight further the importance of discussing the anti-competitive practices found in licensing agreements in relation to the transfer of technology. Further, stressing that the important aspect of the patent system lied in the transfer of technology, the Delegation stated that the SCP should maintain working on that subject. Turning specifically to document SCP/20/10, the Delegation stated that lessons could be learnt not only from success cases but also failures and their causes. Therefore, the Delegation encouraged the Secretariat to further investigate that aspect of transfer of technology, especially regarding LDCs.

154. The Delegation of Japan stated that it did not share the view that the existing system which was designed to protect intellectual property constituted a barrier to technology transfer. It expressed its firm belief that adequate protection of intellectual property created a stable foundation that induced direct investment and technology transfer. That was, in turn, expected to lead to the development and transfer of technology. The Delegation noted that "WIPO GREEN", an industry-driven initiative in which Japanese industry was actively involved, was designed to offer opportunities for both "technology providers" and "technology seekers" to find partners through a free online database that enabled them to transfer Environmentally Sound Technologies (ESTs). The online database included information not only on patented technologies but also on the knowledge and technical expertise that the technology providers might want to transfer. On the other hand, technology seekers could register their specific EST needs in the WIPO GREEN Database. The Delegation stressed the importance of encouraging industry to contribute to addressing the global environmental issues on a voluntary basis.

155. The Delegation of the Russian Federation thanked the Secretariat for preparation of the excellent document SCP/20/10. In particular, the Delegation stated that the document was

detailed and beneficial to understand the issue. The Delegation stated that in the Russian Federation, their main strategy was to overhaul the Russian economy in such a way as to put it in the fine grade of technological development. That meant, among others, making sure that the Rospatent was able to increase the amount of knowledge and understanding of the IP system and to engage more actively in creative activities. The Delegation noted that in September 2011, through a memorandum of understanding between the Rospatent and WIPO, they had started to implement a project setting up centers to support innovation and technological development. Based on that project, 80 centers had been set up throughout the territory of the Russian Federation. Their purpose was to increase access to up-to-date useful and full technological and technical information to those who were engaged in the creation of inventions. The Delegation explained that they had also been creating networks between the centers, which they hoped would make it easier to implement the innovation strategy in the Russian Federation and to ensure that the Government's overall IP strategy could be carried out with 100% effectiveness. Noting further efforts to develop those networks in Russia as well as abroad, the Delegation stated that they would continue its work on that issue, and WIPO continuing the discussion of the topic as well.

156. The Delegation of Kenya thanked the Secretariat for the preparation of the document under discussion. It underlined the fact that transfer of technology was essential to an intellectual property system and especially the patent system. The Kenya Industrial Property Institute (KIPI) had undertaken two functions which would lead to the transfer of technology. One was that KIPI had been mandated to seek technology transfer agreements and licenses. In addition, the Office had been mandated to provide to the public intellectual property information for technological and economic development. Further, the Delegation noted that the patent law contained a number of provisions on how technology transfer should take place in Kenya. Therefore, the Delegation encouraged further discussions on the subject in the SCP.

157. The Delegation of Algeria, speaking on behalf of the African Group, stated that the issue of technology transfer was very important to its Group. In its view, the documents submitted by the Secretariat on the activities of WIPO in the context of technology transfer enabled the SCP to undertake concrete actions in that area. The Delegation considered that it was essential that the issue be discussed substantially by the Committee which primarily dealt with patents and innovation, and suggested the continuation of further studies on the issue of technology transfer. Noting that the Secretariat had been unable to access adequate information regarding failures in technology transfer due to impediments from the patent system, the Delegation considered that the Committee could identify flexibilities and measures available in the TRIPS Agreement concerning technology transfer, improve an understanding of developing countries' policy makers on the role of IPRs in technology transfer, learn from the experiences of developed countries in acquiring technology and building technological base, collate information on R&D policies of developed countries and identify appropriate policies that could be implemented by developed country governments and entities to facilitate technology transfer to entities in developing countries.

158. The Representative of TWN stated that transfer of technology was a critical component of industrial development. Before the establishment of the global IP regime through the TRIPS Agreement, the policy space in the patent system had allowed developing countries to facilitate the framing of national patent regimes which had promoted technology catch-up. He further stated that the history showed that all the developed countries followed the same technology catch-up pathway to achieve technological self-sufficiency. The Representative noted that towards that purpose, developed countries had had a very low level of patent protection to facilitate the imitation of technology. In his view, however, through the TRIPS Agreement, developed countries denied the pathway they had used in the early stages of development. In other words, developed countries had kicked away the ladder which they had used to move up the technology value chain. The Representative stressed that TWN attached utmost importance to the topic of technology transfer and patents. In his view, the patent regime was an important barrier to technology transfer. He stated that that had been recognized by UNCTAD in the early 60s and even WIPO

had concurred with that view. He further noted that there was a very limited space available for developing countries to negotiate the barriers created by patents. Hence, it was important that the SCP focused its work on patents and technology transfer. The Representative recalled that, in 1975, there had been a report prepared by the United Nations Department of Economic and Social Affairs (UN DESA), UNCTAD and the International Bureau of WIPO on the role of the patent system and the transfer of technology to developing countries. The Representative stated that 40 years had passed since the publication of the report and almost 20 years since the establishment of the patent regime. Reiterating that the TRIPS Agreement had taken away the policy space of developing countries with regard to patent law and policy, the Representative stated that that had not only affected the technology catch-up process but also denied the treatment of millions of people in developing countries and in instances pushed them to death. Therefore, he considered that it was timely to examine the barriers created by patents on technology transfer. He further expressed his full support to the proposal of the DAG for the establishment of independent commission of experts to examine technology transfer and patents. After various revisions of the study by the Secretariat, the study was still not informing the Member States or the public on the exact barriers posed by patents on technology transfer. Therefore, he stated that the study should be further revised to include concrete cases of denial of technology to developing country governments and entrepreneurs. Towards that purpose, the Secretariat should examine the voluntary licenses granted by patent holders to developing countries entrepreneurs. The Representative wished to cite two concrete examples. First, he stated that the Energy Research Institute in 2009 had looked at technology transfer issues pertaining to climate change in five Asian countries, namely China, India, Indonesia, Malaysia and Thailand, and had concluded that there had been important patents in the hands of a few dominate players which had created a monopolistic situation where dissemination of knowledge had been restricted due to limited access and higher prices of climate friendly technology. It had also mentioned the case of Chinese IGCC demonstration power plants where Chinese companies had failed to get technology from foreign companies due to high cost and reluctances to transfer key technologies on the part of patent holders. After the prolonged negotiations, the project had finally been stopped. The Representative stated that Zuan, in 2011, had highlighted some of the IP-related problems that were faced by wind power equipment companies in China in a study which specifically made the following findings: there had been a major boom in China in companies that had manufactured wind power equipment. However, to produce a piece of complete wind power equipment, China had to buy foreign designed technologies, such as gear boxes, which generally contributed to the largest part of the price. The requirements for China to access patented wind energy technologies were also very strict. The Representative stated further that Zuan had cited a survey that an average Chinese company had to pay high licensing fees for the technology and 5% royalties per piece of equipment when the final product had been sold domestically. However, higher royalty fees had usually been applied when the final product incorporating foreign patents had been exported. Most importantly, Chinese innovation had been discouraged because R&D activities relating to the patent were only possible after agreement of the licensor. Further, Representative considered that the CDIP project on technology transfer should not be used as an argument to prevent further work in that area at the SCP. For example, the Representative noted that discussions on work sharing programs were also under discussion within the PCT Working Group. Stressing the importance of continued discussion on transfer of technology within the SCP, the Representative urged Member States not to further block discussions on that issue.

159. The Representative of the ICC stated that companies used patents and other IP rights to facilitate the development and delivery of new and useful products and services to their customers such as governments, individuals and other companies. They also used patents to protect their competitive advantage *vis-à-vis* their competitors, and relied on a strong patent system that attracted investment. Noting that private sector actors accounted for the bulk of investment, the Representative stated that, for instance, transactions between companies and their customers including sales, joint R&D or licensing were important drivers of technology diffusion across sectors over time. Patents helped to facilitate and structure those transactions. The Representative

further stated that, in general, patents did not constitute a barrier to technology diffusion even in the fields of technology with significant patenting activity. As an example, the Representative cited the case of mobile phones. He stated, in particular, that there had been 6.8 billion individual wireless connections in the world. Mobile phones had been becoming more widely available and cheaper even as their functionality had been increasing exponentially. It was well known that players in that field used patents intensively to protect their competitive advantage. Further, the Representative stated that it was important to note the role of know-how in technology diffusion. Even in jurisdictions where a technology solution was not protected by a patent, local companies approached a technology provider for a license if they needed additional technical input to develop a solution. They did so in order to work with that company to obtain a deeper understanding of possible solutions and to identify what might work best in their environment. Regarding what know-how exactly was, the Representative stated that it could be, for instance, a deep familiarity with a technology among the members of a team that had developed it over many years. He explained that know-how was not necessarily secret, but it could be hard to acquire precisely because it was gleaned from experience. It could not be simply transferred in an instant and its transfer could not be forced, but it was routinely shared in many ways. The Representative continued that that required trust among partners in the business environment, and use of IP rights and contracts by the technology provider to ensure that its valuable know-how would not leak to its competitors. The Representative explained that IP rights were part of frameworks for collaboration, providing clarity as to each party's rights and responsibilities. In his opinion, by facilitating collaboration and sharing, patents could facilitate technology transfer. The Representative further noted that the sharing of know-how and technology required adequate absorptive capacity. At the same time, such exchanges would enhance existing absorptive capacity at the firm or the macro level over time. He stressed that many factors influenced where technology and investments would flow. The Representative stated that legal certainty, which was quite important for businesses, was provided in part by predictable IP systems that could deliver high quality and enforceable rights.

#### **AGENDA ITEM 11: CONTRIBUTION OF THE SCP TO THE IMPLEMENTATION OF THE RESPECTIVE DEVELOPMENT AGENDA RECOMMENDATIONS**

160. The Delegation of Egypt, speaking on behalf of the DAG, attached great importance to the coordination mechanisms developed for the implementation of the Development Agenda. It considered that the Committee was entitled to contribute to the Development Agenda recommendations, as it had done in 2012 and 2013. Therefore, in its view, that agenda item should become a standing item on the agenda of the SCP, which would enable the Committee to set up recommendations. The Delegation observed that, since the Development Agenda had been adopted, the Committee had made efforts in that area by tackling with a number of important subjects for Member States and guaranteeing a balanced implementation of the recommendations involving every Member State. In its opinion, the consideration of all national legislations, avoiding any marginalization and working with a common focus, would make it possible to get good results. The Delegation expressed its belief that those were the underlying principles for the work of the Committee, in accordance with recommendation 17 of the Development Agenda. The Delegation further stated that the work on quality of patents was connected with recommendations 8, 10 and 17, and that strengthening of the IP infrastructure and increasing quality could lead to the implementation of those recommendations. The Delegation was of the opinion that the Committee had been able to achieve progress in the area of technology transfer and the implementation of the recommendations of the Development Agenda. However, it considered that it was necessary to make more efforts to implement them. The Delegation explained that its Group was in the process of adopting recommendations for the implementation of other recommendations under the Development Agenda and expressed its willingness to cooperate with all Member States in the SCP.

161. The Delegation of South Africa, speaking on behalf of the African Group, noted that the Committee was taking stock of how it had contributed to the mainstreaming of the Development Agenda in its areas of work. It underscored that the patent system was a key in the IP framework that directly impacted national socio-economic development and societal welfare. It noted that there was a growing recognition that the current IP system was focusing heavily on ensuring rights to IP holders, without adequately ensuring that the public interest was taken into account. Subsequently, that was leading to the thought of the Delegation that the IP system was not working as it was originally intended. While the Delegation recognized that there had not been a discussion in the Committee on some of those aspects, it emphasized that it was necessary to have a more open and frank discussion about some of the current inefficiencies of the system. It considered that such discussion could only happen if there was a willingness and commitment to improving the system, where needed, both for the benefit of Member States and the future viability of the system itself. To that end, the Delegation welcomed the discussions that had taken place in the Committee on a wide range of issues, including exceptions and limitations to patent rights and patents and health. However, it noted that the Committee had to go beyond the theoretical debate to address issues that were the subject of intense debate outside WIPO but had not yet been addressed in the Committee. The Committee, therefore, should not be afraid of discussing and better understanding how patents were used in the market, and how those uses promoted or hindered innovation, technological growth and development. It considered that only through frank discussions, the Committee could be expected to generate the collective will and actions needed to improve the system. It stated that, similarly, more tangible discussions were needed on how patents could better contribute to addressing the challenges humanity was facing in the areas such as food, energy, security, environment, disaster management, climate change and education. It hoped that there would be an open and constructive engagement on those important issues in the Committee. It considered that the long prevalent and naive assumption that providing patent holders with stronger rights would by itself foster innovation and attract investments had presently been rejected in light of global economic realities and experience. In its opinion, so far, there had only been an academic discussion in the Committee on how countries could optimally calibrate the level of protection of IP rights, using exceptions and limitations, as well as other flexibilities. The Delegation, therefore, considered the establishment of an analysis on that issue would allow WIPO to play its dual role, in assisting countries and in establishing evolving and tailor-made IP policies. Noting that the SCP had started an important and necessary discussion on various development-related aspects of the patent system, the Delegation welcomed that positive step and looked forward to a meaningful translation of those discussions into concrete elements of a work program. It reminded the Committee that many critical issues had not yet been addressed and could become the subject of honest and constructive consideration leading to their integration in a holistic, development-oriented and balanced work program for the SCP.

162. The Delegation of the United States of America did not support the proposal of including the agenda item as a standing item in the agenda of the SCP. It stated that it should be continued to be treated as a temporary agenda item.

163. The Delegation of Japan, speaking on behalf of Group B, endorsed the statement made by the Delegation of the United States of America. In its understanding, that item was not a standing agenda item but a provisional one.

164. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, supported the statements made by the Delegations of the United States of America and Japan on behalf of Group B.

165. The Representative of the TWN supported the statement made by the Delegation of South Africa on behalf of the African Group.

## INFORMATION ON THE PATENT-RELATED ACTIVITIES OF THE IP GLOBAL CHALLENGES PROGRAM (PROGRAM 18)

166. The Secretariat from the IP and Global Challenges Program (Program 18) reported on its patent-related activities, and distributed a comprehensive document and materials related to its activities. The Secretariat stated that intellectual property was a tool used for socio-economic purposes – to encourage innovation and creative activities, to facilitate the distribution of innovative products, and to structure partnerships and technology transfer. Referring to the agreement that WIPO had concluded with the United Nations in 1974, the Secretariat noted that promoting innovation and creativity as well as facilitating transfer of technology in order to accelerate economic, social and cultural development had been WIPO's obligations since it had joined the UN system. As the issues relating to global challenges, such as climate change, global health and food security, predominantly affected the poorest populations in the world, they inherently brought a development aspect with them. Further, the Secretariat observed that it had been widely believed that innovation and technology could play a key role in addressing those global challenges. Therefore, the Secretariat considered that intellectual property had a role to play as a means to develop new technologies and to facilitate their transfer and diffusion. In 2008, WIPO had decided to become involved in that somewhat politicized area, i.e., climate change, global health and to a lesser extent, food security, where there had been important international discussions on how to address those challenges. WIPO's involvement, however, had been neither to further politicize the debate nor to push a specific agenda, nor to participate as a party in the negotiations, nor to lead and advocate changes to the existing system. Rather, WIPO had been involved in the discussions as a resource, making available its specific expertise and abilities. The Secretariat therefore stated that the areas in which WIPO could make a difference were those already identified in the agreement between the UN and WIPO, mainly intellectual property and transfer of technology. Referring to the Program and Budget 2012/2013, the Secretariat noted that the Program had published fact-based analytical studies and provided a forum for discussion, such as seminars, symposia and conferences. He stated that, most importantly, the task of WIPO over the last few years had been focused on platforms and projects that had the possibility to achieve tangible results to make a constructive contribution to finding ways of addressing issues regarding climate change and global health. Those platforms were: (i) WIPO Re: Search, which was an open innovation consortium launched in 2011 to address research and development in the area of neglected tropical diseases, malaria and tuberculosis; and (ii) WIPO GREEN which facilitated the use and transfer of green technologies. With those tools and platforms, Program 18 was trying to use WIPO's specific expertise in innovation, technology and knowledge transfer, and its specific ability to bring together multi-stakeholder partnerships. The Secretariat noted in that context that it had enjoyed good relationships not only with Member States, intergovernmental organizations and non-governmental organizations but also with the private sector that had traditionally been a user of the services which WIPO had offered in other areas. The Secretariat further elaborated on its principal patent-related activities, including: (i) a patent review of DNA fragments of influenza viruses upon a request by the WHO; (ii) collaborative activities with the WHO and WTO, such as organizing joint symposia and publishing a joint publication "*Promoting Access to Medical Technologies and Innovation – Intersections between Public Health, Intellectual Property and Trade*"; (iii) WIPO Re: Search; (iv) WIPO GREEN; and (v) a project ongoing in Tanzania related to intellectual property and food security in the area of wheat production. The Secretariat reiterated that WIPO had got involved in global challenges issues because it had expertise in intellectual property, innovation and technology transfer, which could be used productively to address those challenges, together with other partners. As a way for Member States to become involved, in particular, in those platforms, the Secretariat requested Member States to reach out to research institutions or companies that might be able to either contribute to the platforms or profit from information which were available from such platforms. The Secretariat further encouraged Member States' contributions through providing funds in trust.

167. The Delegation of Brazil expressed its appreciation to the Secretariat for the information

provided on the patent-related activities of Program 18. The Delegation expressed its understanding that, due to the lack of sufficient time between the Assemblies in December 2013 and the twentieth session of the SCP, the Secretariat had not been able to prepare a written information document in a timely manner, enabling Member States to evaluate the document prior to the meeting by experts in the capitals. However, the Delegation requested that, for the report of Program 18 on its development-related activities at the next CDIP session, a written information document be circulated to Member States in a timely manner. It stressed the importance of improving the transparency of WIPO activities. The Delegation expressed its agreement with the Secretariat that WIPO should not interfere in the debates currently taking place in specialized fora on climate change, food security or global health. With respect to discussions on climate change, the Delegation stated that the United Nations Framework Convention on Climate Change (UNFCCC) was the appropriate forum for discussion, especially when referring to the definition and modalities of transfer of environmentally sound technologies. Further, noting that WIPO activities on the subject were voluntary and not binding Member States, the Delegation requested that material developed by the Program include a disclaimer stating that it had been developed by the Secretariat and that it did not express the opinions of WIPO Member States.

168. The Representative of TWN asked why the royalty free license mechanism under the WIPO Re: Search initiative was limited to LDCs only, although neglected tropical diseases cut across the countries other than LDCs. Further, in relation to the collaboration with the WHO, noting that the WHO was working on various models of research and development, addressing the cost of R&D and the price of medicines, she requested clarification on the role of the Global Challenges Division on that particular issue, since in her view, there could be ways and means of doing research without holding any kind of intellectual property rights.

169. The Secretariat clarified that, regarding the WIPO Re: Search licensing conditions, WIPO Re: Search was looking at gaps in technologies, basically, in medical products, vaccines and diagnostics, that were simply not in existence yet. Therefore, as a first step, material information had to be gathered in order to boost the development of those technologies. Such information was free of charge for everybody, all over the world, and research and development of relevant products was free of charge. The only distinction came into play when a product that had been developed was marketable and then introduced in various markets. At that point, any licensing agreement under WIPO Re: Search would stipulate that the sale of products would be royalty free in LDCs. Members also agreed to negotiate in good faith access to all developing countries, taking into consideration the burden of disease and the economic development of the populations most in need. While the WIPO Re: Search initiative recognized the disease burden in various countries and the need to make those products available on preferential terms, it could not currently decide what those terms were, since a product to be developed and the situation in the respective country were not known at that time. The Secretariat therefore noted that it was more a declaration of goodwill than a firm contract. He also clarified that if parties agreed, they could go beyond the minimum terms and understanding of all partners who participated in WIPO Re: Search, and agree on preferential terms. On the relationship with the WHO, the Secretariat stressed the importance of the WHO being on board from the outset and of close collaboration with them, since WIPO did not have expertise and a mandate specifically on global health. The Secretariat referred to the WIPO Re: Search launch event, during which the Director General of the WHO had expressed her strong support on the project, stating that it had been one mechanism of approaching and addressing neglected tropical diseases, malaria and tuberculosis. No one said that it was the only way, and it did not limit, and was not aimed at limiting, the discussions which had taken place among experts within the WHO. It was meant to provide a one answer and one model of facilitating innovation in an area that for far too long had been neglected. Further, the Secretariat observed that there was no conflict between WIPO Re: Search and the different funding mechanisms discussed at the WHO. It explained that WIPO Re: Search enabled new research to jump start and for ongoing R&D to be accelerated by being able to benefit from tremendous intellectual property and knowledge that had been generated by 70 plus billion dollars of R&D

spent in the public and private sector for health. Therefore, WIPO Re: Search was a type of indirect funding and a complementary contribution in an area where WIPO had a comparative advantage, namely to bring intellectual property assets to positively contribute to addressing global challenges, particularly in the area of neglected tropical diseases, malaria and tuberculosis.

## **AGENDA ITEM 12: FUTURE WORK**

170. The Delegation of Japan, speaking on behalf of Group B, stated that the future work program had to be balanced as a whole, and at the same time, balanced in the context of each item. With regard to exceptions and limitations, the Delegation noted that a half day seminar on the remaining five exceptions and limitations had already been agreed and scheduled for the following session of the SCP. It stated that further work on that issue should be considered only after the seminar at the following session would have taken place, taking account of its outcome. The Delegation recognized the significant merit of the work on quality of patents and attached great importance to it. Referring to several proposals on the table under that agenda item, in order to respond to concerns expressed by some Member States and to share the common direction to proceed, the Delegation clarified the objectives and the benefits of those proposals. As for the questionnaire proposed by the Delegation of Canada, Denmark and the United Kingdom (SCP/18/9), the Delegation explained that the objectives were: (i) to identify what the term "quality" meant to each Member State; (ii) sharing of knowledge to allow patent offices to learn from each other and improve practices; (iii) to build capacity of patent offices at varying stages of development; and (iv) better provision of technical assistance to patent offices. The first objective was to completely respond to the concern expressed by some Member States which stated that there was no common definition of "quality" of patents. The one of the purposes of that questionnaire was the gathering of materials in order to discuss what quality of patents was. Such discussion could include various aspects, for example, to what extent such definitions were diverged depending on countries and how the Committee could find common ground upon which it could further cooperate on that issue. Therefore, in its view, the fact that there was no common definition of quality of patents in front of the Committee justified the objective of that questionnaire, rather than preventing its launching. The Delegation further stated that other objectives of the questionnaire were clearly beneficial for all countries, especially developing countries, for self-explanatory reasons. The Delegation explained that the questionnaire included the question "What definition/s of 'quality of patents' is used within your national jurisdiction?" as Q.1, corresponding to the first objective, and the subsequent Sections (1) to (3) of the questionnaire corresponding to respective objectives mentioned above. The Delegation clarified that the purpose of that questionnaire was not to establish the unified definition of quality of patents, rather, to know the whole picture of the concept of quality of patents with respecting the right of Member States to interpret that concept, taking account of the respective domestic circumstances. If other Member States had other concerns, the Delegation expressed its willingness to include other questions that reflected those concerns. With regard to the work sharing proposals by the Delegations of Japan, the Republic of Korea, the United Kingdom and the United States of America (document SCP/20/11 Rev.) and by the United States of America (document SCP/19/4), the Delegation underlined that the sovereign right of respective countries to make a decision to grant a patent or not was completely preserved under those work sharing initiatives. As the Delegation of India had pointed out, Article 29.2 of the TRIPS Agreement prescribed that members might require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants. In its understanding, the work sharing programs such as the PPH provided incentives to applicants to embody the provision of information prescribed in that Article voluntarily. The Delegation drew the attention of the Committee to the fact that there were two types of work sharing programs. One was applicant-driven such as the PPH, and the other was IP offices-driven. As for the latter, in its opinion, it was important to understand that work sharing was just the simple reality of life, reflecting the necessity for the offices to collect useful information for examiners. The Delegation expressed its strong belief that a dedicated home page could provide a whole picture of work

sharing programs and it could contribute to actual understanding on the nature of the programs. It considered that the establishment of a home page was a transformation of existing information into accessible format, and it could be done through the expansion of the existing website of WIPO on the PCT-PPH. Furthermore, the Delegation stated that an annual conference, as initially suggested in document SCP/19/4, could be used as a venue to discuss whether work sharing program influenced the right to make a decision of respective countries or not in an evidence-based manner. It clarified that one of the purposes of that proposal was to promote actual understanding of the programs. In that regard, the Delegation considered that the study proposed by the Delegation of Greece on behalf of the European Union and its Member States on how different laws and practices limited the potential for work sharing and what voluntary measures could be put in place to address any problems at the international level, could also clarify the fundamental nature of work sharing programs. Furthermore, the Delegation stated that the objective of the proposal by the Delegation of Spain on inventive step (SCP/19/5) was not harmonization of that concept but improvement of knowledge about that requirement. The proposal was made up of three studies. The first one would be a fact finding survey about the definition of the person skilled in the art in legislation, examination guidelines, and case law worldwide. The second one would be a similar fact finding survey about methods employed worldwide to assess inventive step. In the opinion of the Delegation, the improvement of the knowledge on inventive step, for example, knowledge such as differences in terms of the level of inventive step would be useful for all offices and users irrespective of the level of development. As inventive step was the last hurdle to overcome to get patents, in its view, that patentability requirement was critical for quality of patents. The Delegation considered that, by improving knowledge about inventive step, countries would be able to grant patents only on inventions that comply with patentability requirements. In addition to quality of patent, the Delegation stated that Group B also attached the importance to further work on confidentiality of communications between clients and patent advisors. In its opinion, the Committee should take substantive steps to the concrete mechanisms to address the recognition of foreign patent advisors' privilege, based on soft law approach. In that regard, the Delegation supported the proposal by the Delegation of Australia on the study by the Secretariat about the problems which limited or prevented the implementation of attorney's privilege. The Delegation was of the opinion that those steps would also be complemented by the establishment of a dedicated WIPO web page which could disseminate useful information obtained through the Secretariat's activities so far and by a possible seminar involving observers who had practical experiences to be shared. With regard to patents and health, the Delegation reiterated that the Committee should adopt a balanced approach even within an agenda item. It noted that there were two aspects on the relationship between patents and health, namely, access and innovation. The Delegation observed that the Committee had dealt with the first aspect at the twentieth session by holding a sharing session on countries' use of health-related patent flexibilities. Therefore, at the forthcoming session, the delegation was of the opinion that delegations should turn their eyes to the other aspect, innovation in the context of patent and health. The Delegation supported the proposal by the Delegation of the United States of America (document SCP/17/11), which shed light to the innovation aspect of patents and health, as a possible element of the future work program at the 21<sup>st</sup> session of the SCP. Finally, regarding technology transfer, the Delegation reiterated that further work on that issue should be considered only after the whole picture of the issue would be clearly presented, following the completion of the work by the CDIP.

171. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, expressed its belief that the Committee could put together a balanced program. The Delegation considered that the objective of delegations was to build upon existing working program and to improve it further in order to enhance and develop a common better understanding of all relevant aspects. The Delegation stated that the CEBS Group remained committed to continuing discussions on all current topics. It however stressed that its priority was to continue discussion particularly on the issues of quality of patents and confidentiality of communication between clients and their patent advisors. As regards the quality of patents, the Delegation supported launching a questionnaire

proposed by the Delegations of Canada and the United Kingdom as well as by the Delegation of Denmark (SCP/18/9). The Delegation further expressed its continued support for the proposal by the Delegation of Spain (document SCP/19/5), and considered that it would be useful to launch a comparative study dealing with the inventive step concept. Moreover, the CEBS Group also considered that gathering information on work sharing programs among patent offices would be useful for the discussions concerning quality of patents, namely, patent search and patent examination. In that light, the Delegation endorsed the proposal made by the Delegations of Japan, the Republic of Korea, United Kingdom and the United States of America (document SCP/20/11 Rev). It strongly believed that both the dedicated web page and the annual conference could contribute to a better understanding of the nature and benefits of the programs. The Delegation also shared the view that the study proposed by the Delegation of Greece on behalf of the European Union and its Member States on how different laws and practices limit the potential for work sharing and what voluntary measures could be put in place to address any problems at the international level, might also contribute to clarifying the nature of work sharing programs. Concerning further work on confidentiality of communications between clients and patent advisors, the Delegation expressed its interest in developing nonbinding principles based on a soft law approach, which would not in any case have an effect on the sovereignty of WIPO Member States. The CEBS Group also supported the idea of establishing a dedicated web page providing information about the situations in Member States on that issue. Furthermore, in its opinion, a seminar should be organized by the Secretariat, involving observers, with the aim of sharing practical experiences in that area. The Delegation considered that all those steps would be an appropriate way forward. As regards the topic of exceptions and limitations to patent rights, the Delegation noted that the Committee should take into account the fact that a seminar on the remaining five exceptions and limitations during the next session of SCP had already been scheduled. It was of the view that further work on that issue should be discussed only after the seminar at the following session would have taken place. With regard to patents and health, the Delegation stated that further discussion should be balanced, taking into account the role of the patent system to support innovations in pharmaceutical industry. The proposal by the Delegation of the United States of America (SCP/17/11) that focused on the innovation aspect of patents and health might contribute to such balanced approach. Finally, concerning technology transfer, the Delegation was of the opinion that the results of the CDIP projects related to transfer of technology should be analysed before any new steps concerning transfer of technology were envisaged in the SCP. The Delegation expressed its belief that an agreement on the Committee's future work would be reached successfully.

172. The Delegation of Greece, speaking on behalf of the European Union and its Member States, stated that, in discussing future work, a balanced program should be reached. In reference to quality of patents, it stated that a work program should be established based on the proposals made by the Delegations of Canada and the United Kingdom (document SCP/17/8), the Delegation of Denmark (document SCP/17/7), the Delegation of the United States of America (document SCP/17/10) and the Delegation of Spain (document SCP/19/5). As a next step, the Delegation expressed its willingness to launch a questionnaire containing the elements of all the proposals by the Delegations of Canada and the United Kingdom, Denmark and the United States of America. Furthermore, the Delegation considered that a study on inventive step and the evaluation methods used in the WIPO Member States, as proposed by the Delegation of Spain, would allow for the improvement of understanding of that requirement. As regards opposition systems, the Delegation suggested that the Committee consider elaboration of a compilation of models of opposition systems and other administrative revocation and invalidation mechanisms, in a non-exhaustive manner. On work sharing programs, in its view, a dedicated page on the WIPO website for work sharing activities would improve awareness of existing initiatives and enable patent offices to collaborate more effectively. In addition, it was of the view that annual conferences on the margins of the SCP sessions would allow for the sharing 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 considered that a

study by the WIPO Secretariat on how different laws and practices limited the potential for work sharing and what voluntary measures could be put in place to address any problems at the international level, could identify areas where initiatives could be undertaken to improve the efficiency of the patent system. Given the optional nature of the schemes endeavored, in its opinion, any efforts to improve the quality and efficiency of the patent system should not be hindered. As regards the topic of patents and health, while understanding the concerns of developing and least developed countries in handling public health problems, the Delegation stressed that the mere existence of IPRs on a product was not a barrier to, nor its absence a guarantee of, access to that product. It stated that elements of the proposal made by the Delegation of the United States of America could be considered in discussing further work. In relation to confidentiality of communications between clients and their patent advisors, the Delegation noted that concrete mechanisms should be considered to address the recognition of foreign patent advisors' privilege. It stated that a soft law approach, whereby WIPO Member States would adopt non-binding principles that could be applied at the national level, would allow for the convergence of existing systems to the benefit of users of the patent system, irrespective of the level of development of individual WIPO Member States. On the topic of transfer of technology, noting that a report on the Project on Intellectual Property and Technology Transfer: Common Challenges – Building Solutions was due by the next session of the CDIP in May 2014, the Delegation stated that it was not in favor of launching new initiatives within the SCP until the completion of that Project and its follow-up analysis. Finally, as regards exceptions and limitations, the Delegation noted that a document covering the remaining exceptions and limitations to patent rights had already been mandated and was expected to be presented by the Secretariat in the next session of the SCP. The Delegation stated that it looked forward to a constructive discussion and remained committed to participate towards establishing a well-balanced work program.

173. The Chair submitted his suggestions on future work of the SCP in writing, which was discussed by the Committee.

174. The Delegation of Japan, speaking on behalf of Group B, noted inconsistency between the terms "feasibility study" and "confined to fact-finding", and invited the Secretary to provide an explanation on those terms for the record.

175. The Secretariat clarified that the issue was the relationship between the term "feasibility study" and the associated phrase "confined to fact-finding". It was the position and the understanding of the Secretariat that the term "feasibility study", standing on itself being a kind of ambiguous term, could nevertheless be read consistently with the phrase "confined to fact-finding" in that the ultimate word "study" would be controlled by the phrase "confined to fact-finding". The Secretariat explained that it would provide a full explanation of the context and identify and explore possibilities in that study, without engaging in evaluations and recommendations.

176. The Delegation of Algeria, speaking on behalf of the African Group, reiterated that it was looking forward to more substantial work under patents and health. The Delegation stated its understanding and hope that a study on exhaustion of rights would be carried out at the twenty-second session, even if the Committee still had to agree upon that. Further, the Delegation reiterated the African Group's concern that the work under the agenda item "quality of patents" might lead to harmonization to which it could not agree.

177. After some discussion, the Committee agreed that the non-exhaustive list of issues would remain open for further elaboration and discussion at the next session of the SCP.

178. Further, without prejudice to the mandate of the SCP, the Committee agreed that its work for the next session (SCP/21) be confined to fact-finding and not lead to harmonization at this stage, and would be carried out as follows:

(1) Exceptions and Limitations to Patent Rights

- (i) The Secretariat will prepare a document, based on input received from Member States, on how the following exceptions and limitations are implemented in Member States, without evaluating the effectiveness of those exceptions and limitations: acts for obtaining regulatory approval from authorities; exhaustion of patent rights; compulsory licensing and/or government use; and exceptions and limitations relating to farmers' and/or breeders' use of patented inventions. The document should also cover practical challenges encountered by Member States in implementing them.
- (ii) A 1/2 day seminar as proposed in document SCP/19/6 will be organized during SCP/21 on the above exceptions or limitations.

(2) Quality of Patents, including Opposition Systems

- (i) The following two studies will be prepared by the Secretariat and submitted to SCP/22. They will be based on the information provided by Member States, and will be a collection of factual information without analysis or recommendation:
  - (a) a study on inventive step that contains the following elements: the definition of the person skilled in the art, methodologies employed for evaluating an inventive step and the level of the inventive step; and
  - (b) a study on sufficiency of disclosure that contains the following elements: the enabling disclosure requirement, support requirement and written description requirement.
- (ii) The Committee will have an information sharing session during SCP/21 among Member States regarding experiences on international work sharing and collaboration. The Committee shared the understanding that discussions on work sharing and collaboration do not imply any automatic acceptance of work sharing products and do not prejudice the sovereign rights of Member States in processing patent applications and patents in accordance with the applicable law.
- (iii) Document SCP/20/11 Rev. will be added to the working documents listed in the agenda of the next session of the SCP.
- (iv) The Secretariat will improve the WIPO webpage (PCT-PPH) on work sharing initiatives.

(3) Patents and Health

- (i) The Secretariat, in collaboration, to the extent possible, with the WHO and WTO, will carry out, for SCP/21, a feasibility study on the disclosure of International Nonproprietary Names (INNs) in patent applications and/or patents.
- (ii) The Secretariat will prepare, for the next session of the SCP, a study on the role of patent systems in promoting innovative medicines, and in fostering the technology transfer necessary to make generic and patented medicines available in developing countries/least developed countries.

- (iii) At SCP/21, the potential of a study on the implementation of flexibilities concerning different types of exhaustion of rights in Member States and its contents will be discussed.
- (4) Confidentiality of communications between clients and their patent advisors
  - (i) The Secretariat will publish the information contained in document SCP/20/9 on the SCP electronic forum website in more accessible and user-friendly format, and update regularly.
  - (ii) The Committee will conduct, at the next session, a half-day seminar on the confidentiality of advice from patent advisors and practical experiences of clients as well as patent advisors.
  - (iii) Member States are invited to submit proposals on this topic.
- (5) Transfer of Technology
  - (i) The Secretariat will collect further practical examples and experiences on patent-related incentives and impediments to transfer of technology from members and observers of the SCP, in particular from least developed countries, taking into account the dimension of absorptive capacity in technology transfer.
  - (ii) Member States are invited to submit proposals on this topic.

#### **AGENDA ITEM 13: SUMMARY BY THE CHAIR**

- 179. The Chair introduced the Summary by the Chair (document SCP/20/12).
- 180. The Secretariat informed the SCP that its twenty-first session would tentatively be held from November 3 to 7, 2014 in Geneva.
- 181. The Summary by the Chair was noted.
- 182. 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.
- 183. The Chair closed the session.

*184. The Committee is invited to adopt this draft report.*

[Annex follows]

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