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Standing Committee on the Law of Patents

Nineteenth Session
Geneva, February 25 to 28, 2013

REPORT

adopted by the Standing Committee

INTRODUCTION

1. The Standing Committee on the Law of Patents ("the Committee" or "the SCP") held its nineteenth session in Geneva from February 25 to 28, 2013.

2. The following States members of WIPO and/or the Paris Union were represented: Algeria, Argentina, Australia, Bangladesh, Belarus, Belgium, Benin, Botswana, Brazil, Burkina Faso, Burundi, Canada, Chile, China, Colombia, Congo, Costa Rica, Côte d'Ivoire, Czech Republic, Denmark, Dominican Republic, Egypt, El Salvador, Estonia, Ethiopia, Finland, France, Germany, Ghana, Greece, Honduras, Hungary, India, Indonesia, Iran (Islamic Republic of), Ireland, Italy, Japan, Jordan, Libya, Lithuania, Luxembourg, Madagascar, Malaysia, Mali, Mexico, Montenegro, Morocco, Myanmar, Namibia, Nepal, Netherlands, Nigeria, Norway, Pakistan, Panama, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Senegal, Serbia, Singapore, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Tajikistan, The former Yugoslav Republic of Macedonia, Trinidad and Tobago, Tunisia, Turkey, Ukraine, United Kingdom, United States of America, Uganda, Venezuela (Bolivarian Republic of), Viet Nam, Zambia and Zimbabwe (85).

3. Representatives of the African Intellectual Property Organization (OAPI), the African Union (AU), the Eurasian Patent Office (EAPO), the European Patent Office (EPO), the European Union (EU), South Centre (SC), the World Health Organization (WHO) and the World Trade Organization (WTO) took part in the meeting in an observer capacity (8).

4. Representatives of the following non-governmental organizations took part in the meeting in an observer capacity: American Intellectual Property Law Association (AIPLA), Asian Patent

Attorneys Association (APAA), Cámara Industrial de Laboratorios Farmacéuticos Argentinos (CILFA), CropLife International (CropLife), European Law Students' Association (ELSA International), International Association for the Protection of Intellectual Property (AIPPI), International Centre for Trade and Sustainable Development (ICTSD), International Chamber of Commerce (ICC), International Federation of Industrial Property Attorneys (FICPI), International Federation of Pharmaceutical Manufacturers Association (IFPMA), International Intellectual Property Institute (IIPI), Japan Patent Attorneys Association (JPAA), Knowledge Ecology International, Inc. (KEI), Latin American Association of Pharmaceutical Industries (ALIFAR), Max Planck Institute for Intellectual Property and Competition Law (MPI), Medicines Patent Pool (MPP) and Médecins sans Frontières (MSF) (17).

5. The 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: "Report on the International Patent System: revised Annex II of document SCP/12/3 Rev.2" (SCP/19/2); "Addendum to the Report on the International Patent System" (SCP/19/3); "Proposal by the Delegation of the United States of America regarding Efficiencies of the Patent System" (SCP/19/4); and "Proposal of the Delegation of Spain for the improvement of understanding of the requirement of inventive step" (SCP/19/5); "Proposal by the Delegation of Brazil regarding exceptions and limitations to patent rights" (SCP/19/6).

7. In addition, the following documents prepared by the Secretariat were also considered by the Committee: "Report on the International Patent System" (SCP/12/3 Rev.2); "Addendum to the Report on the International Patent System" (SCP/12/3 Rev.2 Add.); "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 from Brazil" (SCP/14/7); "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); "Quality of Patents: Comments received from Members and Observers of the Standing Committee on the Law of Patents (SCP)" (SCP/18/INF/2); "Addendum to Quality of Patents: Comments received from Member and Observers of the SCP" (SCP/18/INF/2 Add.); "Patents and Health: Comments received from Members and Observers of the Standing Committee on the Law of Patents (SCP)" (SCP/18/INF/3); "Addendum to Patents and Health: Comments received from Members and Observers of the Standing Committee on the Law of Patents (SCP)" (SCP/18/INF/3 Add.); "Overview of the Responses to the Questionnaire on Exceptions and Limitations to Patent Rights" (SCP/18/3); "Opposition Systems and other Administrative Revocation and Invalidation Mechanisms" (SCP/18/4); "Projects and Activities on Patents and Health in WIPO, WHO and the WTO" (SCP/18/5); "Approaches and Possible Remedies to Cross-border Aspects of Confidentiality of Communications between Clients and Patent Advisors" (SCP/18/6); "WIPO's Activities on Transfer of Technology" (SCP/18/7); and "Patents and Transfer of Technology: Examples and Experiences" (SCP/18/8).

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 nineteenth session of the Standing Committee on the Law of Patents (SCP) was opened by the Director General, Mr. Francis Gurry, who welcomed the participants and underlined the importance of the SCP as a multilateral forum for discussing substantive issues regarding patents. Recognizing the difficulties in the past to advance the work of the Committee, the Director General made a plea to Member States to identify issues where there was a need for some form of normative action which could improve the patent system. The session was chaired by Mr. Vittorio Ragonesi (Italy). Mr. Philippe Baechtold (WIPO) acted as Secretary.

AGENDA ITEM 2: ADOPTION OF THE DRAFT AGENDA

10. The Delegation of Brazil, speaking on behalf of the Development Agenda Group (DAG), proposed the addition of a new agenda item regarding the SCP's contribution to the implementation of the Development Agenda.

11. The Delegation of Belgium, speaking on behalf of Group B, stated that it could support the proposal made by the Delegation of Brazil on behalf of the DAG, with the understanding that the new item would not be a standing agenda item.

12. The Chair stated that there was a consensus about introducing a new agenda item 10 "Contribution of the SCP to the implementation of the respective Development Agenda recommendations", provided that it would not be a standing agenda item.

13. The SCP adopted the revised draft agenda (SCP/19/1 Prov.) with the addition of a new agenda item 10: Contribution of the SCP to the implementation of the respective Development Agenda recommendations (SCP/19/1).

AGENDA ITEM 3: ADOPTION OF THE DRAFT REPORT OF THE EIGHTEENTH SESSION

14. The Committee adopted the draft report of its eighteenth session (document SCP/18/12 Prov.2) as proposed.

AGENDA ITEM 4: REPORT ON THE INTERNATIONAL PATENT SYSTEM

15. Discussions were based on documents SCP/12/3 Rev.2, SCP/12/3 Rev.2 Add., SCP/19/2 and 3.

16. The Chair noted that, with respect to Annex II of document SCP/12/3 Rev.2, it had received updated information concerning certain aspects of national patent laws from the following Member States: Australia, Mexico and Zambia. He further stated that the information, available on the website of the SCP electronic forum, would be updated based on the submissions by Member States.

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

GENERAL DECLARATIONS

18. The Delegation of the Dominican Republic, speaking on behalf of the Group of Countries of Latin America and the Caribbean (GRULAC) reiterated its willingness to fully support the work of the Committee in respect of the substantive issues regarding the progressive development of patent law as provided under its mandate. Regarding the Report of the International Patent System, the Delegation stated that it should be open for future revisions so that any legal modifications that would take place in different countries could be incorporated. As regards the topic of exceptions and limitations to patent rights, the Delegation expressed its appreciation to the Secretariat for document SCP/18/3 which provided an overview of the responses to the questionnaire on exceptions and limitations to patent rights. In relation to the term "quality of patents", the Delegation was of the view that it needed to be clearly defined by the SCP. It further noted the importance for the patent offices to have access to various databases to ensure the quality of granted patents. In relation to the issue of opposition procedures, the Delegation stated that such procedures would have a positive effect if they were undertaken prior to the granting of patents. However, it stressed the importance of having some provisions in the applicable law which would ensure that the system would not be abused. In relation to the issue of patents and health, the Delegation reiterated its support for the continuation of the work in that area. Further, recognizing the complexity of the issue of confidentiality of communications between clients and their patent advisors and the difficulty of making the system homogeneous when it was dependent upon different legal systems, the Delegation expressed its belief that the best way to deal with that issue would be under national legislation. The Delegation welcomed the publication of the study entitled "Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade" (the trilateral study). The Delegation noted that that was the first time that WIPO, the World Health Organization (WHO) and the World Trade Organization (WTO) had worked together in a coordinated matter on intellectual property, health and trade. The Delegation further welcomed the proposals submitted by the Delegation of the United States of America, contained in document SCP/19/4, regarding the efficiencies of the patent system. It looked forward to the discussions on the proposal by the Delegation of Spain for improving the understanding of the requirement of inventive step and the proposal by the Delegation of Brazil regarding exceptions and limitations to patent rights, contained in documents SCP/19/5 and SCP/19/6, respectively. Finally, noting that despite no agreement had been reached on future work in the previous session of the SCP, the Delegation stated that the SCP needed to take the necessary steps to ensure that two meetings would be held annually, as had been the practice in WIPO before, to have sufficient time to pursue its work in the area of patents.

19. The Delegation of Belgium, speaking on behalf of Group B, thanked the Secretariat for its timely preparation of documents and facilitation of the SCP discussions. It further expressed its regret that the eighteenth session of the SCP had not resulted in a balanced program for future work. However, it was convinced of the importance of the SCP and of the possibilities of making progress during the current session, and expressed its willingness to find a well-balanced way forward towards further work on substantive patent law. Group B, therefore, expressed its readiness to discuss issues, such as quality of patents, including opposition systems, exceptions and limitations to patents rights, confidentiality of communications between clients and their patent advisors, patents and health and transfer of technology. The Delegation expressed its belief that it was important that all Member States showed flexibility in the discussions over the next few days, including how the SCP could build on the comprehensive WIPO, WHO and WTO study entitled "Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade". The Delegation expressed its eagerness to work further on the issues of quality of patents, including opposition systems and confidentiality of communications between clients and their patent advisors. In that regard, Group B welcomed the opportunity to further elaborate existing proposals and supported the two new proposals submitted by the Delegations of Spain and the United States of America, contained in documents SCP/19/5 and SCP/19/4, respectively. It further stated that both proposals complemented earlier proposals on quality of patents and further defined the debate. Referring to other topics of the agenda, the

Delegation expressed its readiness to discuss them further, and underlined the importance of finding a balanced approach that would avoid duplication of work.

20. The Delegation of Algeria, speaking on behalf of the African Group, expressed its appreciation to the Chair's informal consultations held before the nineteenth session of the SCP in order to move the work of the Committee forward. The Delegation stated that the African Group would fully support the work of the Committee. Referring to the agenda of the nineteenth session, the Delegation stated that some issues were of particular importance to the African Group. It further stated that since patent rights had an effect on social development and innovation, the African patent systems were being reformed in order to base them on innovation and knowledge as a motor for development. The rules, institutions and agreements which affected the dissemination and protection of knowledge were critical for the growth of those economies. It was therefore increasingly important for the African Group to strengthen the link between the interests of the public and the holders of rights, particularly patents holders' rights to facilitate dissemination and technology transfer in order to ensure that patent law contributed to development and innovation. The Delegation further stated that the questions of exceptions and limitations and transfer of technology were illustrations of the challenges faced by developing countries. In its view, those topics would allow the Committee to understand better how to adjust the patent system in order to respond to the needs of development. The Delegation expressed its interest in discussing the issue of exceptions and limitations to patent rights which allowed for a margin of maneuver within the area. It recognized that national patent legislations, in particular exceptions and limitations, must be adapted to the economic and social development of countries. Consequently, the African Group expressed its hope that the SCP would contribute to a better understanding and implementation of exceptions and limitations on the basis of the proposal submitted by the Delegation of Brazil. As to the topic of quality of patents, the Delegation reiterated its concern regarding the lack of a precise definition of that concept. The Delegation stated that, without such a definition, it was difficult to understand the proposals submitted on that issue. In its view, the quality of patents was based on the patentability criteria stipulated in the patent law of each country. It further stated that the harmonization of patent systems would be problematic for some developing countries. In addition, the Delegation noted that activities relating to achieving the goals of transfer of technology must be supported. Referring to the proposal submitted by the Delegation of South Africa on behalf of the African Group and the DAG in respect of a work program on patents and health, the Delegation stated that the proposal would assist countries in adapting their patent regimes and make full use of patent flexibilities. With respect to the proposal made by the Delegation of the United States of America on patents and health, the Delegation expressed its hope that the proposal would not distance the SCP from its purpose of supporting the least-developed and developing countries in that area and of undertaking concrete actions for the purpose of transfer of technology. In the African Group's view, it was critical that transfer of technology continued to be addressed within the Committee in order to contribute to industrial and economic development. Finally, noting the importance of patents for development, the Delegation expressed the concern of its Group regarding Member States' inability to reach a consensus on future work at the last session of the SCP. The Delegation expressed its hope that, at the current session of the SCP, an agreement on the key issues would be reached and that the SCP would work towards the establishment of a more balanced patent system. The Delegation noted that the success of the session would depend on the willingness of the Committee to reach consensus.

21. The Delegation of Brazil, speaking on behalf of the DAG, thanked the Chair for his efforts in consulting Member States, which ensured the Committee of its cooperative spirit. It expressed its hope that the current session would accomplish concrete progress for the future work of the SCP. The Delegation stated that the nineteenth session of the SCP was taking place after its postponement in late 2012 due to lack of agreement among Member States. Recognizing the differing views on the subject of patents, the Delegation expressed its belief that such differences were positive for the system, since they gathered contributions from many members and helped to address the matter in its complexity. The Delegation further stated that, nevertheless, some areas

of existing convergence should be explored, such as the positive effects on innovation brought by a balanced patent system in which patent offices provided high quality services regarding the examination of patent applications. Another area of agreement was the need of balance between the interests of right holders and those of society regarding socio-economic development. In order that progress be achieved, the SCP had maintained a step-by-step approach, where members selected subjects from the non-exhaustive list for further discussions. In the view of the Delegation, that process had brought interesting information for members and had stressed the different views on the complex subjects. In addition, the DAG observed that the Development Agenda began to be part of the debate since the proposals tabled by members from the regional groups had underlined their adherence to the principles of the Development Agenda. The Delegation noted that that was a welcome change to the discussions in the Committee. Nevertheless, the previous session of the SCP had been disappointing and contentious wherein some members attempted to exclude issues which were paramount for other members, such as health, from the future work of the Committee. The Delegation therefore expressed its hope that other delegations should exercise flexibility when deciding on the future work of the Committee. In the last session, some members seemed to advance the understanding that the mandate of the Committee should necessarily progress the harmonization of patent laws. Referring to paragraph 3 of document SCP/1/2 which stated that the SCP would serve as a "forum to discuss issues, facilitate coordination and provide guidance concerning the progressive international development of the law of patents, including the harmonization of national laws and procedures", the Delegation expressed the understanding of the DAG that the international development of the law of patents might or might not include such harmonization. In some areas, the Delegation continued, that might be deemed useful as had been the case with the Patent Law Treaty. However, in other areas, an agreement might not be reached regarding its desirability. DAG was of the view that harmonization of substantive patent law was far from an agreement and should not be addressed by the Committee in the ongoing session. Furthermore, the Delegation wished to reiterate the DAG's view that intellectual property could and must be used to assist developing countries to overcome their difficulties and thus provide social and economic security for their citizens. Referring to the Development Agenda recommendations, the Delegation stated that recommendation for the work of the ongoing session included, but was not limited to, recommendation 11 regarding assistance to Member States to strengthen national capacity for protection of domestic creations, innovations and inventions, and recommendation 12, which requested the mainstreaming the development considerations into WIPO's substantive activities and debates.

22. The Delegation of Poland, speaking on behalf of the Group of Central European and Baltic States (CEBS), expressed its appreciation for the efforts, involvement and commitment of the Chair and the coordinators of the regional groups to make it possible for the Committee to resume its work and continue discussions on many important issues which it had failed to successfully complete in the previous session. The Delegation expressed its belief that the Committee would be able to advance negotiations on the topics in the agenda and agree on a well-balanced program for future work. The Delegation was convinced that it was in the interest of all members of the Committee to reach consensus over the most controversial issues and to move forward the work mandated to the SCP, aimed at strengthening the functioning of the international patent system. The Delegation stated that it attached particular importance to the work of the SCP on quality of patents and was interested in continuing discussions on the basis of the proposals submitted by the Delegations of Canada and the United Kingdom, Denmark, the United States of America and Spain. The Delegation expressed its hope that during the ongoing session, the SCP would finally be in a position to issue the questionnaire proposed by the Delegations of Canada and the United Kingdom contained in document SCP/18/9. The Delegation also considered it useful to prepare studies that included inventive step concept as proposed by the Delegation of Spain in document SCP/19/5. The Delegation further stated that another issue of particular interest to CEBS was confidentiality of communications between clients and their patent advisors. In that respect, CEBS maintained its opinion that the adoption of a voluntary approach in which WIPO would set out non-binding principles that could be applied at the national level could be a

way forward in the Committee's further work. The Delegation noted that its Group was also ready to continue discussions on the other topics of the agenda, namely exceptions and limitations to patent rights, patents and health and transfer of technology. As regards exceptions and limitations, the Delegation expressed it belief that in the case of any exclusion from patentability and of any exceptions or limitations to patent rights, the appropriate balance should be maintained between the interests of the right holders and the general public. As far as the issue of patents and public health was concerned, the Delegation welcomed the trilateral study prepared jointly by WIPO, the WHO and the WTO. The CEBS shared the opinion of some other groups that careful consideration of all ongoing projects and initiatives undertaken in other WIPO bodies and organizations would help the Committee to take a decision on further work in that area while avoiding the duplication of work in WIPO or other international organizations. Finally, the Delegation expressed its hope that during the ongoing session of the Committee, a balanced work program based on the non-exhaustive topics selected by the Committee would be agreed upon so that it would enable the SCP to achieve its primary objective of working towards the international harmonization of substantive patent law.

23. The Delegation of Ireland, speaking on behalf of the European Union and its 27 Member States, expressed its regret that the eighteenth session of the Committee had not been able to agree on a well-balanced program for its future work. Nevertheless, the Delegation noted that it remained fully committed to the work of the SCP, and looked forward to a constructive, efficient and fruitful session. The Delegation also thanked the WIPO Secretariat for its extensive work in preparing for the meeting. It noted that, during the ongoing session, the SCP would continue discussions on a number of important 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. The Delegation noted that the discussions were aimed at getting a more efficient and accessible patent system. In particular, the Delegation attached considerable importance to advancing work on the issue of quality of patents outlined in the proposal by the Delegations of Canada and the United Kingdom, Denmark, the United States of America and Spain. The Delegation expressed its commitment to continue the work on issues such as opposition systems and confidentiality of communication between clients and their patent advisors, which were of benefit to users of the patent system. It also expressed its readiness to continue discussions on exceptions and limitations to patent rights and on possible further steps regarding that topic. In that context, the Delegation, however, emphasized the utmost importance of striking an appropriate balance between work on exceptions and limitations to patent rights and on corresponding legal standards used to determine whether an invention was patentable, as those two topics were closely interlinked. The Delegation further stated that, given the importance of the issue of patents and health for tackling public health problems in developing and least developed countries, it fully understood the interest of those countries to include that topic in the future work of the SCP. However, taking into account the great number of ongoing projects, work programs and other activities, in particular within WIPO, the WHO and the WTO, and the recent publication of the trilateral study on promoting access to medical technologies and innovation, the Delegation was of the view that any possible initiative of the SCP in that area should be carefully considered to avoid duplication of work either by WIPO or other international organizations. Similarly, in its view, further possible activities of the Committee in relation to the transfer of technology should be considered after the completion of work under the CDIP project on Intellectual Property and Technology Transfer: Common Challenges - Building Solutions and its follow-up analysis. The Delegation stated that a balanced work program of the Committee enabling fruitful discussions on technical issues concerning patent law should be promptly established. It expressed its hope that that would lead to working towards a long-term goal of discussions on the international harmonization of substantive patent law to which the European Union and its 27 Member States were strongly committed.

24. The Delegation of the United States of America expressed its appreciation for the detailed studies and documents prepared by the Secretariat that would guide the SCP's work in addressing

important questions of the current international patent system. The Delegation remained committed to an ongoing, balanced work program of the SCP. It looked forward to engaging in rich and constructive discussions on all the issues before the Committee. In particular, the Delegation expressed its hope that discussions could be undertaken in a manner that sought to improve the quality, functioning and effectiveness of the patent system as a tool to deliver economic progress. To that end, the Delegation was pleased to present its proposal on efficiencies of the patent system (document SCP/19/4) to be discussed under agenda item 6: quality of patents, including opposition systems. The Delegation further expressed its wish to take the opportunity to provide Member States a brief update on the implementation of the Leahy-Smith America Invents Act (AIA), which was passed by the Congress of the United States of America in September 2011 and proceeding on a timely basis. The Delegation noted that innovators seeking patent protection in the United States of America benefit from that legislation. Most of the provisions of the AIA had been implemented within the time frame prescribed by the Act. The remaining provisions (first-inventor-to-file, fee-setting and micro-entity) would be implemented as planned in March 2013. Several of the AIA provisions, such as first-inventor-to-file, continued to align the law of the United States of America with the laws of many of its global partners. Other provisions contributed to form a more cost-effective administrative challenge mechanism to granted patents, including *inter partes* and post-grant reviews. Other provisions were aimed at improving the quality of issued patents, for example, the third party pre-issuance submissions system. The Delegation continued that, in addition to the AIA implementation, the United States Patent and Trademark Office (USPTO) had been engaged in a number of initiatives aimed at improving the quality and efficiency of the patent examination process. In collaboration with a number of other countries, it continued to actively pursue ways to make use of previous examination results from partner offices under the Patent Prosecution Highway (PPH), PCT-PPH and PPH2.0 programs. Noting that it had 25 PPH partners, the Delegation hoped that the list would continue to grow. The USPTO had also been engaged in promoting patenting of technologies used in humanitarian endeavors and in helping to move important innovations to the marketplace more rapidly. The Delegation stated that, for instance, the USPTO had recently announced the Patents for Humanity pilot program, a voluntary program which encouraged patent owners to address humanitarian needs with their patented technology. The program advanced the global development agenda of the President of the United States of America by rewarding companies who brought life-saving technologies to underserved people of the world, while showing how patents were an integral part of tackling the world's challenges. Winners would receive a certificate for accelerated processing of selected patent matters. The program created a powerful tool for businesses to expedite handling of their most important inventions and helped validate technology in the market – leading to quicker and more efficient investment decisions. The Delegation further stated that another important program was a partnership between the USPTO and Cornell University in New York City (NYC) that had been announced in October 2012. The USPTO had placed a permanent staff member at Cornell's NYC Tech campus in order to bring its resources to the university community, helping students and faculty with intellectual property strategies, export assistance tools, government grants, and connecting with academic partners and early-stage investors. In conclusion, the Delegation expressed its hope that under the able guidance of the Chair, the nineteenth session of the SCP would be productive and would achieve progress on the important issues before the Committee.

25. The Delegation of China expressed its belief that the SCP was an important platform for countries to discuss the development of the patent system and to promote international cooperation. The Delegation stated that, during the past five years, the SCP had updated the report on the international patent system, drafted a non-exhaustive list of issues for future discussions and submitted a number of preliminary studies on the issues relating to the patent system, including a special work project on exceptions and limitations to patent rights. In its view, the SCP provided a sound platform for countries in the world to exchange information and to share views and experiences relating to the patent system. The Delegation stated that the three main items currently under discussion, namely, exceptions and limitations to patent rights, quality of patents and patents and health, were very important. In particular, the Delegation noted that in the current state of global public health environment, the exceptions and limitations study had a very

important significance. Further, in the view of the Delegation, raising the quality of patents was very important to enable the SCP to play its functions. In its view, the quality of patents had a broad scope as it had close relationship with countries' innovation and development level and policy objectives. The Delegation considered that raising the capacity level of patent offices would ensure high quality of granted patents and promote the understanding of countries' patent quality. The Delegation noted that while the primary objective of the patent system was to encourage innovation, the end-goal of the system was for the well-being of society. Noting that life and health were the forms of the fundamental for the well-being of mankind, the Delegation stated that a balanced patent system should encourage R&D of new drugs. Therefore, the SCP should carry out comprehensive and objective studies as regards the relationship between health and the patent system. In relation to the future work of the Committee, the Delegation was of the view that work should be carried out on the exceptions and limitations to patent rights and patents and health.

26. The Delegation of India aligned itself with the statement made by the Delegation of Brazil on behalf of the DAG. It further wished to reaffirm its view expressed in the previous session of the SCP on issues related to transfer of technology, quality of patents and opposition systems, confidentiality of communications between clients and their patent advisors, international patent system and patents and health. The Delegation stated that the evergreening policies for incremental innovations without substantial improvement would have an adverse impact on the delivery of healthcare services. The Delegation further noted with concern that the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS)-plus harmonization was being pushed in the Committee. The Delegation stated that under the provision of Sections 6 and 8 of the Indian Patent Act, the Patent Office of India could freely use the relevant search and examination reports of other countries as well as information regarding foreign prosecution history from the applicant during the process of examination of applications. In the view of the Delegation, each office had freedom to conduct whatever work was considered necessary to determine whether the specific requirements of its national law, in particular those relating to patentability, had been met by applicants. The Delegation was of the opinion that each Member State should be free to adopt any policy, taking into account their level of resources and capacity. Therefore, the Delegation expressed its concerns over formulating any norms for such work in the future. As regards the quality of patents, the Delegation expressed its firm belief that patent offices alone would not be able to maintain the quality of patents without maintaining the standards of search and examination. Most of the patent offices in developing countries were in the transition phase and needed to upgrade their systems, in particular, those related to prior art search and human resource development. Therefore, the Delegation was of the opinion that sharing work with other offices was not the remedy for improving the quality of patents, but rather, such exercise could weaken the examination process in developing countries. The Delegation reiterated its view that steps should be taken to build the capacity of intellectual property offices of developing countries to enable them to carry out their *quasi* judicial functions in the best manner possible. The Delegation further stated that understanding and evaluating the inventive step was one of the important tasks of patent examiners. In its opinion, it was the last and final gatekeeper of the patent system. Therefore, it was pertinent for the Delegation to mention that the TRIPS Agreement defined neither the term "inventive step" nor "a skilled person", thereby providing sufficient flexibility to the members to define those terms, depending upon the technical development of the respective country. Therefore, in the view of the Delegation, any attempt to understand and analyze the level of inventive step and the person skilled in the art implemented by the Member States and formulating the norms through the SCP would be beneficial neither to the patent system nor to Member States, especially to developing countries. In that regard, the Delegation took note of the proposal made by the Delegation of Spain for the improvement of understanding of the requirement of inventive step, and stated that it would take part in further deliberations on that issue. The Delegation further reminded the Committee that it had urged the Secretariat in the past to prepare a study on the practices being adopted by companies across Member States concerning voluntary licensing of patents and whether those policies were in line with the principle of competition in order to enable Member States to make certain policy interventions at the national

level to address that issue. The Delegation expressed its hope that the Secretariat would take a positive note of its view and take the necessary action in that regard. In conclusion, the Delegation expressed its support for the proposals of the Delegation of Brazil on exceptions and limitations to patent rights, and of the African Group and the DAG on patents and health.

27. The Representative of IIPI stated that inventive and creative peoples lived in all countries, not only in those that had enjoyed greater economic development. As an example, the Representative brought the case of the Philippines. He stated that in 2010, IIPI had reviewed over 1,000 articles published by researchers in Philippine universities. It had been found that 27 per cent of those articles had contained potentially patentable inventions. However, because none of the researchers had filed patent applications, they had failed to fully benefit from their ingenuity. In the view of the Representative, instead of questioning whether the international patent system should exist, the question to be asked was how the advantage of the opportunities that the system created should be taken. The Representative further stated that, in the Philippines, like in many other developing countries, they were concerned with the low number of patent filings. In that regard, IIPI had been working to strengthen the research infrastructure in the Philippines and teaching the researchers how to identify and commercialize their inventions. The Representative noted that the United States of America had significantly contributed to complementary projects, such as the innovation opportunities program between the IIPI, USPTO and the Intellectual Property Office of the Philippines. In his opinion, the current imbalances in the global patent system could be corrected, but only if Member States fulfilled their obligations to each other. On the one hand, developing countries should respect and protect patents. But on the other hand, they should insist in realizing their potential through technical assistance and capacity building efforts as mandated by Article 67 of the TRIPS Agreement. The Representative noted that, unfortunately, the focus of the technical assistance and capacity building programs on intellectual property were often only related to small components of a larger development system package. That, according to his view, needed to be changed. In addition, he stated that WIPO, the World Bank, the Inter-American Development Bank, the Asian Development Bank, to mention some, and the United States Agency for International Development should devote more resources to activities that would promote innovation in developing countries. Otherwise, the Representative concluded, human potential would be wasted and the progress facilitated by the international patent system would be endangered.

AGENDA ITEM 5: EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

28. The Delegation of Brazil, speaking on behalf of the DAG, noted that the discussions on exceptions and limitations had a long history in the Committee. The Delegation recalled that in the twelfth session of the SCP, held in June 2008, the Secretariat had been requested to elaborate a preliminary study on the issue of exclusions from patentable subject matter and exceptions and limitations to patent rights. In the following thirteenth session, the Committee had approved a request that a study be commissioned to external experts regarding exclusions, exceptions and limitations, focused on, but not limited to, issues suggested by Member States, such as public health, education, research and experimentation and patentability of life forms, including from a public policy, socio-economic development perspective, bearing in mind the level of economic development. The study had provided relevant information useful for policymakers' intent on calibrating their patent system. In the fourteenth session, the Delegation of Brazil had tabled a proposal of a work program on exceptions and limitations divided in the following three phases: (i) an exchange of detailed information on all provisions of exceptions and limitations in national or regional legislation, as well as on the experience of implementation of such provisions, including jurisprudence; (ii) an investigation of what exceptions or limitations were effective to address development concerns and what were the conditions for their implementation, including how national institutional capacities affected the use of exceptions and limitations; and (iii) the elaboration of an exceptions and limitations manual, in a non-exhaustive manner, to serve as a reference for WIPO Member States. The Delegation was of the opinion that its proposal had

received widespread support, thus attesting the importance attached by Member States to the subject. In the subsequent session of the SCP, Member States had agreed on a questionnaire regarding the subject. Seventy-two Member States had replied to the questionnaire issued by the Secretariat and shared their experiences on exceptions and limitations to patent rights, expressing different views and attesting the importance given to the matter. Considering the time spent for the discussion on the issue and the amount of input provided through the questionnaire, the Delegation expressed its belief that it was the right time to resume work on the subject. Therefore, DAG supported the proposal of the Delegation of Brazil contained in document SCP/19/6. The Delegation further stated that exceptions and limitations to patent rights were relevant to an adequate and balanced patent system, and Member States had developed different approaches for their implementation. In its view, a flexible policy space was necessary in order to allow Member States to develop and adapt a set of exceptions and limitations relevant to their national patent system. The Delegation was of the view that the simple existence of exceptions or limitations was not sufficient by itself in order to evaluate its benefits or obstacles faced by its implementation. That was the reasoning that underpinned the second phase of the proposal made by the Delegation of Brazil, aiming at investigating which exceptions or limitations were more effective to address development concerns and what were the conditions for Member States to enjoy it to the fullest, since national capacities would obviously affect the capacity for using exceptions and limitations. The Delegation further stated that the use of exceptions and limitations by Member States to improve their IP protection system in place was a core value of the Development Agenda. It was explicitly mentioned in recommendation 22 of the Development Agenda, while it was directly related to recommendations 3, 10, 11, 12 and 14, among others. With that in mind, the Delegation urged the SCP to continue the work on the subject which was paramount to improve the understanding by Member States and which had been continuously discussed for almost five years in the Committee alone. The Delegation further stated that the arguments on duplication of work did not seem to take into account the different perspectives adopted by the Committees for the discussions.

29. The Delegation of Brazil, in its national capacity, referred to its proposal contained in document SCP/19/6. The proposal contained two elements that were closely interlinked. The first element was to ask the Secretariat to prepare an analysis of exceptions and limitations which were most commonly used by Member States in each of the ten clusters of the questionnaire. That document should take into account public policy objectives and society needs as a whole, including, *inter alia*, development needs, public health goals and competition. It should also consider the obstacles Member States found when implementing such exceptions and limitations. The second element was a one-day seminar to be held at the following session of the SCP. The seminar would have three segments, as follows: (i) a presentation by the Secretariat of the findings of the above-mentioned analysis; (ii) a presentation by the Chief Economist plus two experts from different backgrounds on, *inter alia*, the effectiveness of exceptions and limitations when addressing development concerns and how national capacities affect the use of exceptions and limitations; and (iii) presentations by Member States of case studies on the implementation of exceptions and limitations. The Delegation noted that the last segment would be an opportunity for Member States to share their experience, focusing on the conditions for the implementation of exceptions and limitations, the actual difficulties they had faced, and the solutions to overcome those difficulties. The Delegation stated that Brazil volunteered to make a presentation and share its experience in that field. It further explained that the outcome of the analysis by the Secretariat and of the discussions of the seminar would become additional materials for the continuation of the work program contained in document SCP/14/7.

30. The Delegation of the Russian Federation recalled that, in its statement given at the eighteenth session of the Committee, it had proposed to conduct, during the second stage of the work program proposed by the Delegation of Brazil, appropriate subject-based research aimed at systematizing forms of exceptions and limitations to patent rights and assessing their legal foundations, as well as assessing the consequences of introducing those or other exceptions and limitations, having illustrated the subject-based research by means of specific situations regarding

application of limitations and exceptions at the national level, including healthcare. In that regard, in the opinion of the Delegation, the results of subject-based research could be of practical use when proposing recommendations on the rational application of one or other form of limitations by Member States which had positive experiences in resolving those issues in terms of their national legislation. The Delegation noted that, in accordance with the report prepared by the Secretariat in document SCP/18/3, a large amount of material relating to theoretical aspects of exceptions and limitations had been presented. In other words, Member States had displayed the possibilities of using the limitations and exceptions provided for in their national laws. The Delegation was of the view that the material gathered was sufficient for conducting the second stage of the proposal by the Delegation of Brazil, in particular for beginning to systematize the forms of exceptions and limitations to patent rights and the assessment of the legal foundations of their introduction in national laws. The Delegation stated that, in addition, in order to provide a full picture covering also the practical aspect of applying exceptions and limitations, it was essential to obtain and study additional information in relation to law-enforcement practices in Member States. The Delegation explained that the proposed approach corresponded to the proposal reflected in paragraph 36 of document SCP/18/2 Prov. 2, concerning the provision of information on the application of exceptions and limitations to patent rights which would have practical significance to national legislation. Such information could also be provided by other Member States, and consequently, the Secretariat could gather that information which could be used when proposing recommendations on the rational use of the corresponding exceptions and limitations. In its view, the reflection in the recommendations of the theoretical as well as practical aspects of applying exceptions and limitations would provide the possibility of mutli-faceted assessment of the problems of applying exceptions and limitations and the ways in which to resolve them. Having consulted document SCP/19/6, in which the Delegation of Brazil requested the Secretariat to conduct further analysis of the exceptions and limitations which were most frequently used by Member States in each of the ten categories presented in the questionnaire, the Delegation stated that the proposal made by the Delegation of Brazil was in line with the proposal made by the Delegation of the Russian Federation concerning the timeliness of carrying out further subject-based research in relation to the analytical material contained in the questionnaire. The Delegation supported the position of the Delegation of Brazil regarding the focus of the proposed research directed towards meeting the needs of society as a whole, including development concerns and the aims of public health care and competition. In addition, the Delegation also considered that the identification of the most significant exceptions and limitations to patent rights, from the point of view of the State policy and satisfying the needs of society, was insufficient in terms of the practical use of the results of research in national practice. In that connection, the Delegation was of the view that the greatest interest lied in the analysis of the obstacles which Member States encountered when implementing such exceptions and limitations. Moreover, in the opinion of the Delegation, the recommended approaches on the assessment of exceptions to patent rights and the practical application of limitations to patent rights were essential, taking into account the practice of Member States which had developed positive dynamics in resolving those issues in terms of national laws. In conclusion, the Delegation stated that the results of analysis of the above described aspects could be used as a basis for recommendations (or guidelines), as it had proposed on several previous sessions.

31. The Delegation of Chile agreed with the Director General on the point raised in his opening speech that the SCP was the only multilateral forum where Member States could discuss the substantive issues regarding patents, and urged members to continue such discussions in that forum. On the issue of exceptions and limitations, the Delegation referred to its statement made at the previous session of the SCP, stated in paragraph 37 of document SCP/18/12. As regards the proposal made by the Delegation of Brazil contained in document SCP/14/7, the Delegation stated that it was in favor of an exchange of information on exceptions and limitations, and supported the second phase as set forth in the proposal. In relation to document SCP/19/6, the Delegation stated that some of the elements included in the document were worthy of consideration for the future work of the Committee.

32. The Delegation of Poland, speaking on behalf of the CEBS, reiterated its Group's position. The Delegation stated that the information gathered from 73 responses to the questionnaire had increased the knowledge of the SCP about the national and regional frameworks regarding that issue and constituted a good basis for further works in that respect. The Delegation recalled its statement made at the previous session in which it had requested additional clarifications as to the proposal of the Delegation of Brazil. In that context, the Delegation thanked the Delegation of Brazil for submitting the proposal contained in document SCP/19/6 concerning the second stage of its proposal. Noting that the document had been published only a few days ago, the Delegation stated that it had not had sufficient time to discuss it within its Group. However, the preliminary remark of the Delegation as regards the proposed analysis was that it should be more balanced by reflecting also the positive aspects of implementing exceptions and limitations. Regarding the proposed seminar, the Delegation considered that it should not be held during the session of the SCP, but rather on the margin of the session, particularly after its closure, in order to focus on the regular work of the Committee. The Delegation further stated that the terms of reference of the study and the seminar should be carefully elaborated, balanced and the scope of the future work should include all Member States. As regards future work on that issue, the Delegation maintained its opinion that the appropriate balance between the interests of right holders and that of the general public should be maintained. Therefore, exclusions from patentability and exceptions and limitations to patent rights should be discussed with due consideration, which was also given to other substantive issues of patentability, such as the definition of prior art, novelty, inventive step and disclosure requirements.

33. The Delegation of Ireland, speaking on behalf of the European Union and its 27 Member States, stated that while the European Union and its 27 Member States recognized the importance attached to the issue of exceptions and limitations to patent rights, as evidenced by the 20 responses submitted by the EU Member States on the questionnaire, further work on that topic should maintain an appropriate balance between the interests of right 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 is patentable, such as novelty, inventive step and industrial applicability. The Delegation further stated that it did not consider it appropriate for the Secretariat to apply value judgments as to the efficacy of exceptions and limitations operating at the national level, as suggested in document SCP/14/7. Noting that much data had been collected by the questionnaire, summarized in document SCP/18/3, the Delegation expressed its belief that further statistical analysis of such data would be a useful first step in deciding future work. The Delegation concluded that any further study on that topic had to be absolutely objective.

34. The Delegation of Argentina thanked the Delegation of Brazil for its proposal contained in document SCP/19/6. The Delegation stated that the proposal was intended to contribute to the review of exceptions and limitations to patent rights, an issue which was closely related to fundamental matters pertaining to development. It noted that exceptions and limitations to patent rights was a very important issue, because they enabled States to envisage an adequate and balanced system for innovation and promotion of use of existing inventions, and to have a space in which their patent legislation could be adopted, taking into account national characteristics. In its view, that would provide Member States with the possibility of amending their legislation as well as obtaining better benefits from their own IP system in order to meet public welfare or policy objectives. The patentability criteria and exclusions of certain inventions were important instruments that countries could make use of in order to avoid the continuing stagnant situations and to ensure that patents could be useful in pharmaceutical sectors, since those factors would determine the patentability of new and existing formulas. The Delegation further expressed its support for the proposal on the work program that was put forward by the Delegation of Brazil in document SCP/19/6. In its view, the proposal would enable Member States to know how other Member States had used exceptions and limitations. It would thus be an important contribution that would enable the Committee to identify difficulties encountered when making use of such exceptions and limitations.

35. The Delegation of the United States of America stated that the two proposals made by the Delegation of Brazil raised several questions, in particular with respect to phase II of the proposal. The Delegation sought clarification as to how it was possible to define the "effectiveness" of exceptions and limitations to address development concerns of 185 distinct and sovereign WIPO Member States; how the "effectiveness" could be measured; what the indicators were; and how other factors could be controlled. Further, the Delegation questioned whether it was within WIPO's competence to attempt to measure the so-called "effectiveness of a flexibility" against other developmental factors for which WIPO had no competence. With respect to the specific elements of phase II found in the proposal of the Delegation of Brazil contained in document SCP/19/6, the Delegation noted that it was beyond the Secretariat's competency to draw conclusions on the effectiveness of exceptions and limitations in reaching "public policy objectives and society needs as a whole". In its view, such analysis would entail an enormous amount of work, since every Member State had different "public policy objectives and society needs" and a different strategy in achieving those. The Delegation stated that since development needs and goals differed among Member States and were up to each Member State to decide, a "one size fits all" approach was contrary to the spirit of the Development Agenda. In the opinion of the Delegation, the Secretariat should be neutral and objective and should not offer generic advice on when a country should use a particular flexibility. The Delegation continued that each Member State was sovereign and should make its own policy decisions, which might include the adoption of stronger intellectual property rights provisions to attract foreign direct investment. Member States might, in fact, believe that providing reliable incentives for innovation through the patent system was the best method to achieve developmental and public policy objectives. The Delegation noted that there was enough evidence to show that the patent system was a key component in the industrial development for many countries. In conclusion, the Delegation stated that WIPO should not be placed in the position of making qualitative judgments or criticizing other international agreements on the ground that they could be viewed as "constraints" or "obstacles" in the implementation of the TRIPS Agreement flexibilities. The Delegation, therefore, was not able to support phase II of the Brazilian proposal for such a study. However, the Delegation stated that it would be able to support a one-day seminar to be held during the next session of the SCP, where Member States would be presenting case studies on the implementation of exceptions and limitations.

36. The Delegation of Algeria, speaking on behalf of the African Group, underlined the particular importance of the issue of exceptions and limitations to its Group and expressed its belief that the Brazilian proposal would enable countries to better adapt their national patent legislations to their own realities in setting up their own intellectual property systems. Therefore, the Delegation expressed its particular support to the first element of the second phase of the Brazilian proposal, which was to have the Secretariat prepare an analysis of the exceptions and limitations most commonly used by Member States in each of the ten clusters of the questionnaire.

37. The Delegation of Brazil clarified that it was not against Member States bringing positive effects or positive use of exceptions and limitations, but rather according to its experience, for the most part, developing countries faced obstacles. As an example of an obstacle that countries might face, the reference was made by the Delegation to paragraph 6 of the Doha Declaration where it had been detected that members with insufficient or no manufacturing capacity in the pharmaceutical sector could not make full use of the exceptions regarding compulsory licenses. The Delegation explained that its intention was to focus on such obstacles.

38. The Delegation of India reminded the Committee that it had already expressed its support to the Brazilian proposal on exceptions and limitations to patent rights, contained in documents SCP/14/7 and SCP/19/6. In its view, the analysis proposed in those documents would be extremely helpful to enrich the experience of Member States and other stakeholders in the utilization of the patent system. Such analysis could focus on the subjects that were considered important from the perspective of the accessibility and affordability of medicines, such as compulsory licensing, parallel imports, government use and Bolar exceptions.

39. The Delegation of Egypt supported the statement made by the Delegation of Algeria on behalf of the African Group, and the statement made by the Delegation of Brazil on behalf of the DAG, as well as the proposal made by the Delegation of Brazil contained in document SCP/19/6. The Delegation noted that the study to be carried out by the Secretariat as described in the proposal could be very useful, since the Secretariat could present statistics and analyze the information based on the information gathered from Member States, and countries themselves could also analyze the results of the study.

AGENDA ITEM 6: QUALITY OF PATENTS, INCLUDING OPPOSITION SYSTEMS

40. The Delegation of Belgium, speaking on behalf of Group B, reemphasized the importance it attached to further work with regard to the issue of quality of patents, including opposition systems. Noting that the Committee had considered, during previous sessions, several proposals put forward by the Delegations of Canada, Denmark, the United Kingdom and the United States of America, the Delegation expressed its support to the new proposals tabled by the Delegation of Spain with regard to the improvement of understanding the requirements of inventive step, and by the Delegation of the United States of America regarding efficiencies of the patent systems. The Delegation noted that both proposals embodied the issue of quality of patents and complemented earlier proposals and thus refined the debates. Group B was therefore convinced that the Committee was in a position to establish a work program on quality of patents. In that regard, the launch of a questionnaire containing the elements of all the proposals could be a way forward. With regard to the issue of opposition systems and invalidation mechanisms, the Delegation underscored that irrespective of further discussions and/or work on that topic, Member States' flexibility in deciding not to introduce such procedures should be respected. However, the Delegation welcomed the compilation of the models of opposition systems, other administrative revocation and invalidation systems, and other similar mechanisms.

41. The Delegation of Spain introduced its proposal contained in document SCP/19/5. The Delegation explained that the proposal aimed at improving the understanding of the requirement of the inventive step within the broader framework of the proposal of the Delegations of Canada and the United Kingdom contained in document SCP/16/5, under the topic "process improvement" which stated that "process improvement is intended to identify ways offices can improve their patent granting processes to ensure an appropriate degree of quality". In the view of the Delegation, the key factor for granting patents with an adequate level of quality was a correct application of the patentability principles, such as "inventive step", also known as "non-obviousness" under some legal systems, which meant that patents could be properly granted for certain inventions in order to fulfill the objective of the patent system to encourage innovation. The Delegation was convinced that, of all the different criteria of patentability, inventive step was the most difficult one in its evaluation. In all the different elements which were necessary for that evaluation, it could be considered that the "person skilled in the art" was a key element. Once the state of the art was established, the patent examiner had to take the position of that hypothetical person, known as the "person skilled in the art". The result of the patentability examination and the granting of patent rights greatly depended on the definition of such person. That was the reason why one of the studies proposed by the Delegation would cover the definition of a "person skilled in the art" in different Member States, be it in legislation, in guidelines or in case law. In view of the complexity of the evaluation of the inventive step, a number of countries had aimed in establishing methods to evaluate that element as objectively as possible. The Delegation expressed its belief that a detailed analysis of the different methods applied in the evaluation of inventive step, without any intent of harmonization, could identify the advantages and disadvantages of each different system, with the aim of putting national patent offices in a position to decide which method or methods to apply, based on the characteristics of each invention, would be of interest for every Member State, independently of their level of development. As a recent example highlighting the importance of adequate evaluation of the patentability criteria, in particular, the inventive step, in order to obtain acceptable quality of granted patents, the Delegation quoted the trilateral study

which had been carried out by WIPO, the WHO and WTO. That study, within the chapter dedicated to pre-grant issues and, in particular, the questions of patentability, made a reference to a recommendation of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) of the WHO which suggested that governments should take actions to remove obstacles to legitimate competition by developing guidelines for patent examiners on how to apply the patentability criteria properly and, if appropriate, considering changes to national patent legislation. Further, it was stated in the document that in order to ensure quality of granted patents, it was important to support the work of examiners with appropriate patent examination guidelines. The Delegation explained that its proposal was to have a better understanding of the requirement of inventive step and its evaluation so as to facilitate the establishment of guidelines for patent offices, which would make it possible for patent examiners to apply the requirements of patentability more correctly and in a homogenous manner, thereby contributing to a higher quality of granted patents which would be of benefit for all Member States and society at large. Consequently, the Delegation considered that its proposal was also intended to cover the interest of social and economic development. Therefore, the Delegation was of the opinion that the criterion of inventive step could, through the definition or through related elements and methods of evaluation of those elements either in legislation or examination guidelines, facilitate or create obstacles to the granting of patents. Further, the Delegation stated that low requirements for the criterion of inventive step would result in the granting of exclusive rights on small improvements with the risk of limiting industrial activity of third parties, while high requirements for the inventive step might have the consequence that inventions which might deserve protection would not be covered by exclusive patent rights or would be covered by very limited exclusive rights, which would further create obstacles to investment and research. The Delegation noted that it was obvious that patent applications that belonged to the same family and had the same subject matter resulted in the grant of a patent in some Member States and not in others, due to various factors, *inter alia*, different results of the evaluation of the criterion of inventive step. In that context, the Delegation quoted a study undertaken in 2005 by the University of Melbourne, the Melbourne Institute of Applied Economic and Social Research and the Intellectual Property Research Institute of Australia, in which the fate of 70,000 patents which had belonged to the same families and had been submitted to the USPTO, Japan Patent Office (JPO) and the EPO, known as the trilateral patents, had been examined. One of the results of that study was that of all the patents granted in the United States of America, 14.6 per cent had been denied by the JPO and 3.8 per cent had been rejected by the EPO. The Delegation further stated that, according to that study, differences in the methods of evaluating the concept of inventive step had influenced the different grant rates. In its opinion, that was an area that should be looked at in greater detail in order to identify the different levels of inventive step and the different factors which influenced the evaluation of inventive step. The Delegation therefore suggested to consider that a study be undertaken in this context, and that the Committee decide whether a questionnaire should be prepared. The Delegation reiterated that its intent was merely to obtain objective information which would be available to the registries and patent offices of Member States with the objective of improving the quality of granted patents.

42. The Delegation of Ireland, speaking on behalf the European Union and its 27 Member States, reiterated its support for advancing work on quality of patents 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 that those proposals were fully complementary, fell under the mandate of the Committee and took into account a number of the Development Agenda recommendations. The Delegation noted that some 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, and encouraged a broader range of members to do the same. The European Union and its 27 Member States were of the view that the Committee should establish a work programme on quality of patents. As to the next steps to be taken by the Committee, the Delegation was in favour of launching a questionnaire containing

the elements of all the proposals of the Delegations of Canada and the United Kingdom, Denmark and the United States of America. Furthermore, in relation to the third component of the work programme proposed by the Delegations of Canada and the United Kingdom, namely, 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 all Member States.

43. The Delegation of Canada thanked the Delegation of the United Kingdom for its continued collaboration on the agenda item as well as other delegations who had expressed their support for furthering work on that item. The Delegation stated that the Delegation of Canada and the United Kingdom proposed moving forward by developing a questionnaire to facilitate the sharing of information between Member States and patent experts from national and regional intellectual property offices. The Delegation reiterated that the intention of the questionnaire was not to lead to a benchmarking exercise, but rather, to advance knowledge and best practice. As identified in document SCP/17/8, the Delegations of Canada and the United Kingdom had attempted to provide a definition of patent quality in response to concerns expressed by some delegations. Recognizing that quality of patents encompassed many different components and that it could have different meanings for different patent offices, for different countries, or for different stakeholders, the Delegation supported the view that to prescribe a harmonized, one-size-fits-all definition was not in the best interest of all Member States and recommended that, as part of the proposed information gathering exercise, Member States be asked to provide a definition of quality that was utilized in their respective national or regional patent offices. Noting that some Member States had expressed their discomfort with the notion of quality and feared that some might seek to rank the practices of offices based on some arbitrary quality ideal, the Delegation reassured the Committee that that was neither their goal nor intention. The Delegation expressed its belief that patent quality was an individual standard that reflected the objectives of the Member States' domestic patent policy. The objective of their proposal was to learn from other Member States in the hope of obtaining valuable information that could help them improve their own practices. With respect to the proposal made by the Delegation of Spain, the Delegation expressed its belief that a study of the requirements of the inventive step could result in an excellent information exchange that could benefit Member States when reviewing their own standards. The Delegation informed the Committee about the decisions of the Supreme Court of Canada on the concept of obviousness, including the cases where an invention may be "obvious to try". Finally, with respect to the proposal made by the Delegation of Denmark, the Delegation was of the view that the proposal had identified a practical and helpful tool in improving the quality of patents granted by national and regional intellectual property offices.

44. The Delegation of the Russian Federation stated that issues relating to harmonization of substantive patent law standards remained topical, since harmonization was able to effectively reduce expenditure relating to the filing and prosecution of an application, enhance the quality of the substantive examination and reduce the length of such an examination, i.e., something in which patent system users throughout the world were interested. The Delegation further stated that the issue of quality of patents was very important and was of interest not only to patent offices, but also to inventors trying to protect their inventions. The Delegation noted that inventors were interested in obtaining a patent with the broadest scope of rights, while patent offices were keen to reduce labor costs and, at the same time, enhance the quality of processes at all stages of prosecution of applications and grant of patents. Taking into account the above, the Delegation expressed its willingness to participate actively in the discussion of the agenda item relating to quality of patents. The Delegation stated that, at the previous session of the Committee, during the discussion of the proposal of the Delegation of Denmark (document SCP/17/7), it had provided the Secretariat with detailed information regarding the use by the Russian Patent Office (Rospatent) of the results of prior art search conducted by foreign patent offices on "corresponding" applications which were used both when examining convention applications filed with Rospatent and also in the process of examining applications according to the procedure of accelerated patent prosecution (as part of the PPH program) and PCT international applications that had entered the national phase with Rospatent. The Delegation agreed with the point of view of the Delegation of Denmark

that the aim of using the results of prior art search carried out by foreign patent offices was to enhance the quality of one's own search work and of examinations by the national patent office, which in turn led to the grant of high-quality patents. Taking into consideration that the issue of enhancing the quality of search and examination of national applications using the results of search and examination by foreign offices was of interest for Rospatent, as part of the research into the problem of enhancing the quality of patents, the Delegation put forward the proposal reflected in paragraph 68 of document SCP/18/12 Prov. 2, i.e., to continue work on collecting information regarding the use by national patent offices of the results of prior art search, since the exchange of information on the quality of patents was an important element in the development of national patent systems. Further, the Delegation stated that there was no doubt that the past decade had been characterized by the routine "spiral" in the development of the various forms of international cooperation in the sphere of patent examination, carried out both as part of the systems which had already functioned for a long time under the aegis of WIPO, for example the PCT, and also as part of relatively new projects, in particular the PPH program. In its view, the PPH program was essentially based on international division of labor, which eliminated duplication of work in offices and improved the quality of patent examination. The Delegation noted that Rospatent was playing a role in the implementation of international projects, among which particular attention was devoted to the programs of accelerated patent prosecution (PPH and PCT-PPH). Rospatent had concluded bilateral agreements on the PPH program with the Patent Offices of China, Denmark, Finland, Japan, the Republic of Korea, Spain and the United States of America. In its opinion, that was a witness to the manifestation of mutual interest by patent offices carrying out a patent search and examination, in the establishment of bilateral cooperation. Further, referring to the proposal made by the Delegation of the United States of America contained in document SCP/19/4, the Delegation expressed its support for the idea aimed at studying the experience relating to the distribution of work, joint projects and common practice, which would allow the quality of granted patents to be improved and, as a result, would enhance the effectiveness of the patent systems of Member States. The Delegation considered that the proposed program of work may be a basis for discussion on the development of mutually-beneficial cooperation in order to implement a number of programs on the international division of labor between patent offices. The Delegation stated that the task of enhancing the effectiveness of the PPH system was resolved by means of cooperation between patent offices participating in the program. In its view, the main efforts must be directed to standardizing requirements which must be applied to applications and, in particular, the claims. In the view of the Delegation, the development of unified requirements and procedures applied in each patent office would allow the effectiveness of protectable patent rights to be enhanced throughout the world, as well as reduce the workload of examiners. In order to guarantee the effectiveness of cooperation between patent offices, monitoring of such activities and their results should be conducted. Taking into account the above, the Delegation proposed that the International Bureau expand and restructure the section of the website of WIPO devoted to the PPH program. The Delegation considered it expedient to supplement the portal with sections such as "PPH-MOTTAINAI" and the "Plurilateral PPH Program" in order to facilitate understanding of the process by which they were used. Also, the Delegation fully supported the idea of holding seminars to promote the PPH and PCT-PPH. In its view, studying experience and exchanging information in relation to ensuring the quality of patents was an important component which defined the development of national patent systems. Having supported the proposal of the Delegations of Canada and the United Kingdom on the questionnaire concerning the quality of patents (document SCP/18/9), the Delegation pointed out that it had already submitted answers to that particular questionnaire and considered that it fit the proposal of the Delegation of the United States of America contained in document SCP/17/10 (the comments by the Russian Federation on that document had been included in document SCP/18/INF/2), since the exchange of experience and information facilitated the improvement of quality of patents. In view of the above, the Delegation expressed its willingness to participate actively in the discussion of the subject of quality of patents, in accordance with the proposals of the Delegations of Denmark, Canada, the United Kingdom and the United States of America. As regards the proposal made by the Delegation of Spain for the improvement of the understanding of the requirement of inventive step contained in document SCP/19/5, the Delegation supported the

proposal on the whole, and proposed undertaking analysis according to the following themes: (i) determination of the person skilled in the art as a key figure in the assessment of inventive step; (ii) methods used to evaluate the inventive step; and (iii) differences in the required degree of inventive step. However, the Delegation considered it appropriate not to analyze all the subjects at the same time, but to begin with a particular aspect of the proposed issues, for example, the study of the methods of evaluation of the inventive step. In its opinion, the evaluation methods must be closely related to particular sectors of technology, for example, chemistry, medicine, pharmaceutics and computer-implemented inventions, since the application of a general approach may be fraught with peculiarities resulting from the nature of subject matter. The Delegation continued that, as regards the first and third themes, it should be assumed that they were mutually related. The Delegation suggested that a person skilled in the art in a particular area of technology be taken into account in evaluating the "degree of inventive step", i.e., the quality of assessment of the inventive contribution. As part of the proposed research in that particular area, the Delegation expressed its interest in the following issues: (i) evaluation of the inventive step of inventions expressed by the Markush formula; and (ii) establishment of inventions characterized with the application of a range of values of computer-implemented inventions. Further, of interest to the Delegation also were the methods of evaluating inventive step with respect to the following factors: (i) satisfaction of a long-existing demand; (ii) complexity of a task to be resolved; (iii) introduction of substantive improvements to technical progress; (iv) overcoming mistrust and skepticism on the part of specialists; continuity of research leading to a positive result; (v) simplicity of a claimed invention resolving a long-standing problem bearing witness to the originality of an invention; (vi) essential economic significance of an invention; (vii) use by an examiner of a host of different references relating to different periods of time and/or various fields of technology; and (viii) the pioneering nature of an invention. The Delegation noted that its interest in the proposed analysis arose, since within Rospatent, there was no established practice on the above factors when assessing inventive step, although those factors were taken into account in examining inventions by, for example, the EPO, EAPO and USPTO. Moreover, in connection with the proposal by the Delegation of Spain, the Delegation expressed its belief that the issue relating to confirmation of the possibility of achieving a technical result could also be examined. In conclusion, the Delegation supported the initiative to devise a questionnaire on those particular issues.

45. The Delegation of Poland, speaking on behalf of the CEBS, reiterated the importance of continuing the discussion on the quality of patents on the basis of the proposals put forward by the Delegation of Canada and the United Kingdom, Denmark and the United States of America. The Delegation expressed its hope that during the current session of the Committee, Member States would finally decide on establishing a work program on quality of patents by way of addressing the questionnaire of the Delegations of Canada and the United Kingdom contained in document SCP/18/9. CEBS welcomed the proposal submitted by the Delegation of Spain in document SCP/19/5 and considered that it was useful to launch studies that included the inventive step concept, the definition of the person skilled in the art and the method of evaluating inventive step used in the WIPO Member States. The Delegation expressed its belief that the comparative study on that issue and gathering information on different existing concepts of inventive step applied by Member States would increase the knowledge of the Committee in that respect, and would help further work on quality of patents.

46. The Delegation of Switzerland, in line with the statements made by other delegations, considered the issue of quality of patents an important one, and supported the discussion of that issue within the Committee. Thanking the Delegations of the United States of America and Spain for their proposals submitted to the nineteenth session of the Committee, the Delegation stated that those additional proposals described the way to move ahead in that area. In addition, the Delegation expressed its support for the continuation of the work as proposed by the Delegations of Canada and the United Kingdom. With respect to opposition procedures, re-examination systems, systems of submission of third party information as well as administrative procedures for annulling patents, the Delegation stated that such systems also played a role in ensuring the credibility and the quality of patents. Even if they differed widely, they nonetheless showed the fact

that such mechanisms could function well in providing a rapid, simple and economical way to test patents and, hence, to enhance their quality. Noting that it was essential to continue working on that issue during the ongoing session of the SCP, the Delegation proposed a compilation of all the various mechanisms that were contained in the document SCP/18/4 so that each country could make use of that information in order to either improve its system or to introduce such a system if it so wished. The Delegation was convinced that such a compilation would benefit all Member States.

47. The Delegation of the United Kingdom supported the statement made by the Delegation of Canada on the topic of patent quality and thanked it for its continued collaboration on that subject as well as other delegations who had commented on those proposals. The Delegation expressed its belief that patent quality was an area which would benefit all countries and would allow them to share knowledge and to learn from each other. The Delegation associated itself with the statement made by the Delegation of Canada, and reassured the Committee that the intention of that work was not to lead to a benchmarking exercise, but to advance knowledge and best practice on that issue. In addition, the Delegation supported the proposals of the Delegations of Denmark, Spain and the United States of America under the same agenda item.

48. The Delegation of the Republic of Korea expressed its appreciation to the Delegation of Spain for its proposal contained in document SCP/19/5. The Delegation agreed that the study was needed in relation to the requirement of inventive step as described in paragraphs 20 to 22 of that proposal. Noting that the inventive step requirement was one of the most controversial aspects of the patentability, the Delegation stated that studying that issue would advance its understanding and improve the quality of granted patents. However, the Delegation noted that the study should be implemented in a practical way, for instance, by collecting information on inventive step and analyzing examination cases and results, and not by taking a more complex approach, such as the harmonization of patent laws.

49. The Delegation of Brazil, speaking on behalf of the DAG, stated that it was clear that patents of high quality were paramount for attaining the goals of the patent system. Therefore, the Delegation deemed that it was useful to engage in a discussion on that important issue as a contribution to the improvement of the patent system, including therein the search and examination of patents and the evaluation of the workflow. The Delegation expressed its belief that patents of high quality were key to reach the objectives of patent protection, that was, to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. With regard to the proposals submitted on that issue, the Delegation stated that the discussion on the national goals of a patent system, as proposed by the Delegation of the United States of America in document SCP/17/10 reflected the debates undertaken in WIPO since the Development Agenda had been approved. In its view, the underlying assumption of the “one-size-fits-all” approach with respect to national goals of a patent system was not adequate, as the high-level goals varied from country to country and were affected by many factors, including national industrial policies and the capacity of Member States to absorb technology. In the opinion of the Delegation, that also implied that a common definition for substantive patenting criteria would reduce policy space and thus affect the capacity of Member States to adapt their patent system according to the changes in the concrete reality. The Delegation noted that the discussion of the requirement of inventive step tabled by the Delegation of Spain was handled with great care by the DAG. In its view, that subject was directly related to the calibration of the patent system, since it provided more flexibility for Member States to analyze patent applications, and ideally, the precise definition of that requirement took into account the industrial policy’s goals of each country. With that in mind, the Delegation expressed its belief that the Development Agenda provided a useful framework for starting to address the matter, in particular, recommendation 17 regarding the flexibilities in international intellectual property agreements; recommendation 11 which urged WIPO to assist Member States to strengthen national capacity for protection of domestic creations, innovations and inventions and to

support development of national scientific and technological infrastructure; recommendation 12 regarding mainstreaming of development considerations into WIPO's activities and debates; recommendation 20 which stated that WIPO should promote norm-setting activities that support a robust public domain; and recommendation 22 stating that WIPO's norm-setting activities should be supportive of the development goals agreed within the United Nations system. Considering that the proposal had been circulated only recently, the Delegation stated that that was a preliminary reaction of the DAG to the Spanish proposal, and other positions could be stated as the debates continued. The DAG expressed the view that a first step could be the exchange of information regarding access to patent databases, in light of the shared objective of continuously raising patent quality. Some patent offices, including the National Institute of Industrial Property of Brazil, already made available search and examination documents on their websites. Access to such information was helpful in order to enable examiners to carry out search and examination with adequate quality, as long as the flexibility for the access and use of the databases was maintained. Nevertheless, the Delegation noted that some countries had faced obstacles in accessing those databases and it would be useful to explore the reasons behind such difficulties. Finally, the Delegation expressed its belief that initiatives of work-sharing should remain strictly voluntary and that the undertaking of such programs be guided by national developmental and public policy objectives.

50. The Delegation of Chile, recognizing the value and importance of the discussion on quality of patents, stated that the correct functioning of the patent system was essential for ensuring patent quality. With regard to the issue of opposition systems, the Delegation noted that the opposition systems, a pre-grant opposition system in the case of Chile, made it possible to further the objective of high quality patents by providing legal security for rights holders and the system as a whole. The Delegation referred to its comments made on that issue in previous sessions of the Committee. Regarding the proposal of the Delegations of Canada and the United Kingdom, the Delegation reiterated the importance of looking at the various items linked to the development of technical infrastructure, exchange of information and access to databases in enhancing the quality of patents. The Delegation stated that the proposal of a questionnaire contained in document SCP/18/9 could be a very good way of gathering information directly from Member States, making it possible to further enhance the discussions. In its view, that would be a good starting point, especially with the understanding that the objective of the questionnaire was not to affect the decisions by IP offices at the national level. The Delegation thanked the Delegation of Spain for submitting the proposal, which was currently being reviewed by the Delegation of Chile. The Delegation stated that it was important to look at the possibility of carrying out a study in the area of inventive step. Concerning future work, the Delegation considered that it was important to bear in mind all the documents that had been submitted in the area of quality, and expressed its willingness to deepen that discussion. However, in order to bring those proposals forward, the Delegation reiterated that there should be a balance between the interest of that item and the various other items on the agenda.

51. The Delegation of Japan supported the proposal made by the Delegation of Spain on improving the understanding of the requirement of inventive step concerning the issue of quality of patents, including opposition systems. It highlighted that many court cases related to the issues of how to judge patentability requirements, such as, novelty or inventive step, which were common to the legal systems of many countries and regions. Therefore, in its view, it would be useful to consider how each country implemented their patent requirements from a practical perspective for discussions on patent quality. The Delegation considered that such consideration would increase the Committee's knowledge about the requirements of inventive step in each Member State. The Delegation also supported the proposal of the Delegation of the United States of America on the efficiencies of the patent system (document SCP/19/4). It observed that through the recent globalization of patent filings, duplication of work among IP offices had been increasing. In that regard, the Delegation noted that it was meaningful to conduct work-sharing among offices, not only for themselves but also for users of the patent system and the public. The Delegation pointed out that there were work-sharing programs that maintained the sovereignty of offices and pursued

reasonable cooperation, such as the PPH programs. As the Delegation of the United States of America had proposed, the Delegation considered that evaluating those programs would increase their usefulness from the viewpoint of providing opportunities for work-sharing programs to be conducted among Member States.

52. The Delegation of the United States of America stated that it remained committed to achieving a balanced work program for the SCP. The Delegation supported the proposal made by the Delegation of Spain contained in document SCP/19/5 in relation to study the aspects of inventive step, also known as non-obviousness. The Delegation noted that the proposed study of the definition of the person skilled in the art, methods of evaluation of inventive step and differences in the level of inventive step required was very important, because the determination of inventive step/non-obviousness was essential to the patentability decisions made by various national offices. The Delegation further introduced its proposal on work-sharing between patent offices, which may interest patent offices. The Delegation expressed its belief that every Member State had an interest in improving the efficiency of the patent system and in granting high quality patents, as defined by their national objectives and economic considerations. The Delegation observed that many programs of that type were currently in place, both in developed and developing countries, and stated that tangible successes in harnessing improved quality and efficiency had already been seen by many patent offices that had been taking part in those programs. As an example, a number of South American countries, namely Argentina, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Suriname and Uruguay, were members of PROSUR, a regional cooperation mechanism which aimed at improving services to users of the IP system by voluntary cooperation as well as creating databases, a common portal and work-sharing. The PCT system exemplified the oldest work-sharing system implemented on an international scale. The Delegation noted that Chile had recently joined Egypt, Brazil and 14 other offices as an international authority under the PCT system. Other examples of international work-sharing were the various PPH programs taking place among national patent offices. The USPTO alone had PPH arrangements with 25 offices, representing countries of all levels of economic development, and more offices were added on a regular basis. In the opinion of the Delegation, it was apparent that work-sharing held benefits that could appeal to patent offices. In view of the improvements demonstrated obtained by work-sharing programs, the Delegation proposed that Member States collaborate in the following activities: (i) carry out an inventory of work-sharing programs that were or had been taking place between offices bilaterally, multilaterally, and regionally, and evaluate their benefits for IP offices, for users of the IP system and for the general public; (ii) explore ways to further refine and increase the usefulness of those programs, for example, by determining best practices, that could be adopted by participating offices on a voluntary basis; (iii) explore the tools that could facilitate effective work-sharing programs between participating offices; and (iv) conduct workshops on how work-sharing programs could be effectively implemented.

53. The Delegation of Algeria, speaking on behalf of the African Group, thanked delegations who had submitted proposals with respect to patent quality, including the proposals made by the Delegations of Spain and the United States of America. In general, the Delegation reiterated the African Group’s concern about the absence of a precise definition of the concept of patent quality. In the absence of such a definition, the African Group stated that it would not be ready to go a step further in the activities of the Committee. The Delegation expressed its hope that a proposal or at least broader information regarding Member States' understanding of patent quality would be received. The Delegation stressed that the African Group was strictly against any idea of harmonization with regard to the quality of patents, be it on the basis of patentability requirements or on any other criterion having to do with substantive patent law. The Delegation considered that every Member State had to draft its own national patent law on the basis of its own requirements and on the basis of its developmental concerns. In its view, it would be impossible to define common grounds for all Member States on that particular matter. The African Group took note of the proposals made by the Delegations of Spain and the United States of America without making any final statement on it. It highlighted that in the framework of the SCP, any exchange of information had to be beneficial to all Member States. The Delegation, however, stated that most

of the African countries who only examined the formality aspects of patents would be excluded from a debate if the Committee only considered the needs of those countries facing difficulties with regard to substantive examination. Therefore, the Delegation suggested that the exchange of information should focus on the way in which information contained in patent applications was disclosed so as to enhance access of African countries to that information. It stated that such an exchange of information should also look into technical assistance provided by WIPO to Member States in order to improve the patent systems. In its view, the exchange of information should have the purpose of strengthening the role of public policy as determined by governments within the framework of the patent systems.

54. The Delegation of the Dominican Republic, speaking on behalf of GRULAC, supported the proposal made by the Delegation of Spain contained in document SCP/19/5. It considered that the proposed study would be useful for Member States, since inventive step was a very subjective criterion, in particular, with regard to the important definition of a “person skilled in the art". The Delegation stressed the importance of examining the issue of patent quality in the SCP.

55. The Delegation of Ghana thanked the Member States for their proposals and the comments made so far on the topic of quality of patents and the opposition systems. The Delegation expressed its interest in the quality of patents which had an effect within its jurisdiction. In that regard, the Delegation supported the proposals of the Delegations of Denmark, Spain, Canada and the United Kingdom, and other proposals from other Member States. It sought to obtain information from Member States regarding the quality of patents as long as the information obtained would only create a platform for sharing experiences and exchanging views of mutual consideration. It considered that such information would assist patent offices which currently relied solely on foreign search and examination reports in their decisions to grant patents. However, the Delegation would not be in a position to support any proposal that sought to harmonize laws regarding the substantive examination of patents. In that regard, the Delegation stated that it would not be in a position to support the proposals of the Delegations of Spain and the United States of America as they sought to propose best practices and to set benchmarks to be accepted voluntarily by Member States.

56. The Delegation of Senegal, noting all the proposals on the issue of quality of patents, endorsed the statements made by the Delegation of Algeria on behalf of the African Group, which had clearly flagged the concerns of the African Group and its apprehension of the whole concept of quality of patents as well as its definition and content. The Delegation refuted any idea of harmonization of quality or the patentability criteria. Further, it stated that the concept of quality of patents would necessarily involve respecting development considerations in each Member State, and a quality patent would have to be assessed in terms of public policies being pursued by each Member State. In its view, it was necessary to incorporate aspects of disclosure in analyzing the concept of quality of patents. Further, the Delegation expressed its belief that when considering the issue of quality of patents, an appropriate role of technical assistance for capacity building should be ensured. In its opinion, enhancing the skills and competence of patent examiners in the offices in LDCs should be taken into consideration so that they achieve the same level of capacity as other countries, was imperative with regard to handling patent applications which was a common goal. The Delegation observed that all Member States wanted to improve the international patent system by making it more balanced.

57. The Delegation of the Republic of Korea complimented the Delegation of the United States of America for its proposal contained in document SCP/19/4. The Delegation stated that the Republic of Korea had implemented different bilateral and multilateral work-sharing programs, including the PPH, joint prior art searches and collaborative search and examinations, in order to avoid the duplication of examination work resulting from the proliferation of cross-national filings. It noted that the registration rate and the first action allowance rate for applications filed through the PPH programs were higher than those for ordinary patent applications. Both the first office action period and the completion period for patent examination had been reduced by nine

times of that for ordinary applications. The Delegation observed that the utilization of search and examination results through work-sharing programs, such as the PPH, led to reduced workload for patent offices and earlier securement of patent rights for applicants. Moreover, the Delegation noted that the Korean Intellectual Property Office (KIPO) had been participating in the collaborative search and examination pilot project on PCT applications with the USPTO and the EPO since 2010. During the second pilot project, which had run until the end of 2012, KIPO examined 60 patent applications as a first examiner and 88 additional cases as a peer examiner. According to the results of a survey carried out among the examiners participating in the projects at KIPO, on 92% of the applications with KIPO as a first examiner, feedback was received, for example, on additional citations, search strategies, interpretation of the claims on prior art or patentability from peer examiners. Ninety-six per cent of the participating examiners at KIPO conducted additional searches and provided feedback on the examination results from the first examiners. Against that backdrop, 90% of the KIPO examiners answered that such work-sharing programs contributed greatly to the increased accuracy of patent examination. Also, over 80% of the KIPO examiners responded that, when the results from such cooperative programs entered the national phase, international search and examination results could be relied upon for their accuracy. Accordingly, more time was only needed for administrative processing and supplementary searches were not necessary. Therefore, based on those results, the Delegation expressed its belief that such work-sharing programs enhanced the efficiency of the patent system and improved the accuracy of patent examination. It therefore supported the proposal of the Delegation of the United States of America, and stated that establishing and further utilizing work-sharing programs could improve the IP system. In that context, the Delegation expressed its hope that studies on work-sharing programs could contribute to enhancing any international cooperation programs.

58. The Delegation of Ireland, speaking on behalf of the European Union and its 27 Member States, endorsed the proposal made by the Delegation of the United States of America regarding the efficiencies of the patent system. The Delegation noted that the European Union and its 27 Member States were engaged in many work-sharing initiatives through national patent offices. It strongly supported exploring the issue of work-sharing in the SCP as a means to increase the efficiency and the effectiveness of national and international patent systems. In its view, work-sharing could help reduce backlogs of unexamined patent applications and improve the quality of granted patents. The Delegation therefore welcomed the opportunity to explore the benefits of work-sharing for national and regional patent offices.

59. The Delegation of Poland, speaking on behalf of CEBS, thanked the Delegation of the United States of America for submitting document SCP/19/4 regarding the efficiencies of the patent system. The Delegation stated that the CEBS Group was already involved in work-sharing programs, whether on a regional or bilateral basis, and noted the benefits of such activities, both for offices and for applicants. The Delegation strongly supported the proposal that Member States collaborate in the activities listed in paragraph 5 of document SCP/19/4. The Delegation highlighted the usefulness of discussing work-sharing issues in the SCP, and finding out how that initiative could be translated into practice among the Member States, as well as how such work-sharing activities contributed to improving the work of national offices.

60. The Delegation of India emphasized that quality of patents was important not only for the development of any patent system but also for technological development of the country. The Delegation stated that if patents were not commercially exploited due to lack of their quality disclosure, they failed to fulfill in securing the objective of the national legislations for their grant as to encourage the inventions, to contribute to the promotion of technological innovation and transfer and dissemination of technology. In respect of the proposals submitted by the Delegation of Denmark (document SCP/17/7), the Delegations of Canada and the United Kingdom (document SCP/17/6) and the United States of America (document SCP/17/10), the Delegation reiterated that the full disclosure of the invention, including the most relevant prior art and the best mode of performing the invention without any further experimentation or know-how, were most relevant for improving the quality of patents. In that regard, the Delegation was of the view that

Article 29 of the TRIPS Agreement clearly mandated such disclosure, including providing information concerning the applicant's corresponding foreign applications and grants. As regards the sharing of search and examination work, as contained in the proposal submitted by the Delegation of the United States of America (document SCP/19/4), the Delegation noted that work-sharing had been proposed in the second session of the PCT Working Group, during which several countries had expressed their reservation against the institutionalization of a work-sharing program. In that regard, the Delegation quoted the views expressed by the DAG during the third session of the PCT Working Group (document PCT/WG/3/13): "as a matter of principle, we do not favor the principle of automatic validity of international search and examination reports, nor do we consider that a national patent office is under any obligation to accept automatically any report by another national patent office". The Delegation considered that, since a patent was granted according to the applicable national law, an examiner remained bound by the national patent law, which mandated that he had to carry out search and examination and, despite the issue of duplication, he had to perform his statutory duties. However, in its view, a patent examiner was free to use search and examination reports of other offices, if so desired, as most of the countries made available their prosecution history including the search reports. Moreover, international search and examination reports prepared by the International Search Authorities and the International Preliminary Examining Authorities were also made available by WIPO and could be used by examiners. Therefore, the Delegation was of the opinion that such work-sharing could be initiated on a voluntary basis. With regard to the proposal submitted by the Delegation of Spain for the improvement of understanding the requirement of inventive step, the Delegation reiterated that inventive step was the final gatekeeper of the patent system. The question of inventive step was viewed from the perspective of a "person skilled in the art". An invention was said to be lacking inventive step if it was obvious to that person skilled in the art. The Delegation considered that the level of knowledge of such a hypothetical addressee played the most important role in the patent system in deciding the issue of obviousness. The Delegation pointed out that, since the TRIPS Agreement did not define inventive step or the person skilled in the art, sufficient flexibility was provided in the TRIPS Agreement to the members to define the level of a skilled person, depending upon the technical development of the country. In its opinion, accepting a lower level of the skill of such hypothetical person would render even a minor improvement non-obvious, and would thus increase the burden of frivolous patents and would be detrimental to the interest of the developing countries. Conversely, the Delegation was of the view that a higher level of the skill of such person would allow only those inventions which had a higher threshold of inventiveness and, therefore, led to technical and industrial development. Therefore, the Delegation observed that the proposed study might be useful for understanding the differences in terms of inventive step. However, the Delegation stated that it would be more useful to understand the different level of thresholds in the different national legislations for the sufficiency of disclosure in addressing the issue of quality of patents.

61. The Delegation of Argentina noted that the discussions in the SCP regarding the proposals on patent quality submitted by the Delegations of Canada, the United Kingdom, Denmark and the United States of America had highlighted the importance that each member country attached to having high quality patents. At the same time, the Delegation stated that it reaffirmed the work of the SCP with regard to reviewing the various interests upon which a balanced patent system could be built. Notwithstanding the efforts that had been made in order to clarify what was understood by quality, the Delegation observed that the Committee still had no common understanding regarding the term "patent quality". The Delegation agreed that patent offices could contribute greatly to making sure that a patent system operated properly by only granting patents for legitimate inventions. In that way, the Delegation considered that the patent system was complying with its social and economic role. However, the fact that the Committee still had not clearly defined the concept of patent quality, the Delegation stressed the importance of having a better definition and understanding the scope of patent quality before deepening the discussion on a detailed work plan. The Delegation stated that the adoption of high standards in examination of the patentability and full disclosure of the invention was of crucial importance in the balanced IP system, so as to avoid granting frivolous patents. In its view, the Committee had not only to preserve and guarantee the

use of TRIPS flexibilities, but also to define the criteria of patentability in compliance with national priorities as an important tool for developing countries to promote their inventions. The Delegation considered that the way in which the patentability criteria were applied was crucial for the public domain knowledge, which was decisive in various technological fields, such as pharmaceuticals having a direct impact on access to drugs. Since any attempt to harmonize the conditions of patentability in national laws would eliminate flexibilities provided for in Article 27.1 of the TRIPS Agreement, and bearing in mind that IP was not an end in itself but an instrument to further economic and social development, including the promotion of innovation, economic growth, public health, food safety and education amongst other objectives, the Delegation was of the opinion that the proposal had to be looked at within the framework of trade and development of each country. In its view, that was in line with the recommendations of the Development Agenda. Regarding the proposals submitted by the Delegations of the United States of America and Spain in documents SCP/19/4 and SCP/19/5, respectively, the Delegation noted that the documents were still under review and reserved the right to formally make comments in the future.

62. The Delegation of Germany endorsed the proposal made by the Delegation of the United States of America (document SCP/19/4), against the background that it clearly underlined that the sovereignty of the various offices would be maintained.

63. The Delegation of Canada expressed its support for the proposal of the Delegation of the United States of America regarding efficiencies of the patent system. As a party to the PPH agreements with Denmark, Finland, Germany, Israel, Japan, the Republic of Korea, Spain, the United Kingdom and the United States of America, the Delegation stated that Canada firmly believed in the value and efficiencies that could be derived from work-sharing agreements. The Delegation noted that the PPH provided, under certain conditions, a means of prioritizing examination of patent and accelerating the first examination action.

64. The Delegation of Egypt supported the statements made by the Delegations of Brazil on behalf of the DAG, and Algeria on behalf of the African Group, and thanked the Delegations of Canada, Denmark, Spain, the United Kingdom and the United States of America which had presented proposals. Noting that there was no uniform point of view as regards the quality of patents, and there were different understanding as far as the context in which the term was used, the Delegation pointed out that the SCP had to agree what work the International Bureau should carry out with respect to quality of patents. The Delegation urged that the concerns of the African Group should be addressed in the Committee. Further, the Delegation stated that the question of disclosure and quality of patents should be addressed, and that as provided by Article 29 of the TRIPS Agreement, necessary steps had to be taken by Member States in order to make available information concerning corresponding foreign applications or grants. In addition, the Delegation noted that, since patent applications were presented in many languages, the SCP should also address the question of language in that context.

65. The Delegation of Nigeria complimented the Delegations of Denmark, Spain and the United Kingdom on their proposals. It endorsed the statement made by the Delegation of Algeria on behalf of the African Group, rejecting any proposal that addressed the harmonization of patent laws. The Delegation expressed its belief that the issue of disclosure and technology transfer should be considered by the SCP, so as to ensure that patents were commercially exploited. The Delegation welcomed the proposal of the Delegation of the United States of America contained in document SCP/19/14 on work-sharing, as far as it enhanced the efficiency of the patent system and the sovereignty of offices would be maintained.

66. The Delegation of the United States of America clarified that the work-sharing programs described in its proposal preserved the national sovereignty of the participating countries by ensuring that patentability decisions were made by the national offices based on the applicable national laws. The Delegation explained that the work product that was shared between the participating offices was neither given full faith and credit nor was it adopted as their own by an

office. In its opinion, instead, the work product provided a better starting point from which the normal procedures in the national offices could be started. The Delegation expressed its belief that such a better starting point could result in improved patent quality and efficiency for the participating offices.

67. The Delegation of Spain reiterated its belief that its proposal was of interest to all countries, independent of their level of development, because that would make it possible to improve the examination procedure within patent offices and provide more adequate implementation of the concept of inventive step without the necessity of the harmonization of legislation. In its view, that aspect might be worth further consideration by delegations. The Delegation stated that, its proposal was linked to recommendation 45 of the Development Agenda, which stated that Member States should “approach intellectual property enforcement in the context of broader societal interests and especially development-oriented concerns”. In its view, the patent system could contribute to the objectives of the broader interest of society, technology innovation and transfer and diffusion of technology only where the protection was granted and maintained for such inventions. It supported the proposal made by the Delegation of the United States of America, as a way forward to streamline search and examination procedures, and at the same time, maintain the sovereignty of each country with the view of obtaining patent quality described in its own proposal.

68. The Delegation of India, while appreciating the clarification made by the Delegation of the United States of America, reiterated that, since the search and examination reports were already available on the web sites of national offices and on the Centralized Access to Search and Examination (CASE) portal developed by WIPO, those could be used on a voluntary basis.

69. The Delegation of Australia supported the work on quality of patents. It endorsed the proposal made by the Delegation of the United States of America regarding efficiencies of the patent system, and supported efforts to increase quality and reduce duplication of work in relation to the examination and grant of patents. In that context, the Delegation reiterated its support to the proposals of the Delegation of Denmark and the Delegations of Canada and the United Kingdom in relation to quality of patents. It thanked the Delegation of Spain for its proposal on improvement of the understanding of the requirement of inventive step. The Delegation expressed its belief that an exchange of information and experiences based on the above proposals on quality of patents would be useful when reviewing its own policies and practices. For example, in relation to inventive step, sharing experiences could increase transparency for applicants seeking the granting of patents overseas, increase quality of granted patents and, therefore, increase certainty and validity of granted patents.

70. The Representative of ALIFAR reiterated his comments made at the previous sessions on the proposals of the Delegations of Canada and the United Kingdom and the Delegation of Denmark contained in documents SCP/16/9 and SCP/18/12, respectively, and his comments available on the SCP electronic forum website related to the seventeenth session of the SCP. In his view, the quality of patents was of fundamental importance for ensuring that the patent system worked, and it had to comply with its political, social and economic objectives, providing for a proper balance between the various interests involved, such as those of innovators, competitors and consumers. He observed that the concept of patent quality was very difficult to define. In his view, in the current international patent system, the term "quality" had to make reference to those patents that were granted for inventions that complied with the requirements of patentability and the national priorities of each country, after a rigorous process of patent examination. However, the Representative was of the opinion that it should by no means be considered that patent quality meant to overly accelerate the process of granting patents without considering the interests of the various parties involved. He reiterated his concerns about the perspective the Committee was taking at patent quality, which could lead to greater harmonization of patent law, especially the criteria of patentability, exclusions from patentable subject matter, opposition systems and the various administrative systems for revocation and invalidation as well as exceptions and limitations. The Representative stated that such harmonization would undermine the flexibilities

provided for by the international treaties, which was important for developing countries in order to correctly, adequately and properly implement their own respective public policy objectives. He noted that a number of delegations had recognized that it was necessary to strengthen work-sharing with respect to search and examinations carried out by foreign offices in order to facilitate the work of a patent examiner. The Representative considered that such facilitation was somewhat risky, as in the case of national examination, which could mean a relaxing of the patentability criteria and lead to facilitation and importation of foreign patentability criteria that had been applied by a foreign patent office. He stressed the importance of the different levels of patentability criteria in relation to international cooperation and considered that, since it was known that technical administration offices were more permeable to changes than congressional bodies, a number of developed countries had begun promoting their own interests in developing countries and in LDCs through cooperation with technical bodies, without the necessity of legal reforms that required a far-reaching debate in congressional bodies and parliaments. In his opinion, it was a lot easier and more efficient to implement changes by technical assistance and capacity building programs than with legislative reform. In that context, he observed that the worst scenario for developing countries and for LDCs in the area of quality of patents was to advance towards a system that would accelerate the granting of patents, a fast-track approach, and relaxing the criteria and standards, which could give rise to greater restriction of market forces and greater difficulties for the development of homegrown industries of developing countries and LDCs. Therefore, he stated that the SCP should reiterate the need to continue examining that matter in depth before developing a work program that might run counter to the interests of some countries, especially developing countries. The Representative noted that the Delegation of South Africa had raised important questions and concerns during the eighteenth session of the SCP, referring to the actual purpose of the discussion and benefits that could be achieved not only for the promoters of the proposals but also for all Member States. The Representative supported the proposal made by the Delegation of India, underscoring the need to request inventors to fully disclose their inventions. In his opinion, the patent applicants should describe in detail the inventive elements of inventions and provide comprehensive information on corresponding patent applications that had been rejected by other patent offices. He stressed the importance of the proposal saying that all patent applications in the field of pharmaceuticals should include the International Non-proprietary Name (INN) in order to facilitate their identification by public entities and competitors. In his view, such identification was unclear at present, since patent applications only referred to the chemical structure of the product. With regard to the quality of chemical or pharmaceutical patents, the Representative stated that it was often hard to identify the invention. Further, the Representative stressed the importance of making available different legal instruments, such as those used in Brazil and Argentina. In the case of Argentina, he referred to the Guidelines for Patentability Examination of Patent Applications Relating to Chemical and Pharmaceutical Inventions, published on May 8, 2012. Those Guidelines outlined a rigorous analysis for the examination of the criteria of patentability for chemical and pharmaceutical inventions. In that way, he considered that the right to health could be secured without hampering investments and innovation. He further noted that the Guidelines were also intended to counter the evergreening principle, so as to avoid granting patents for inventions that did not actually involve inventive step, and to provide rules with respect to various categories of inventions in the pharmaceutical field, such as polymorphic structures, second medical use, dosage regimes, isomers, Markush claims, selection inventions and combinations of already known substances. With regard to Brazil, he referred to the principle of previous assessment of safety provided by the Law of 2001, which required that, with regard to patent applications for chemicals and pharmaceutical products, it had to be proven that those products were innocuous before a patent could be granted. In that way, he considered that the public policy could be changed in order to avoid that pharmaceutical patents affected the right to health, and supported the efforts made by the Brazilian authority to further improve that mechanism.

71. The Representative of AIPPI thanked the Secretariat for their efforts in the support of the work of the SCP. In his view, the SCP, as an open forum for discussing different aspects of the patent system with the aim of including all stakeholders and of creating a balanced patent system,

was very valuable for the world of patents which considered the different points of view of Member States. He welcomed the proposal of the Delegation of Spain, stating that inventive step was one of the key factors of a modern patent system, and that assessing information in that aspect from different jurisdictions was very valuable. Noting that AIPPI recently conducted comparative law studies among its member groups on the patentability criterion of inventive step, and agreed on common positions in that field, the Representative expressed his willingness to contribute to the discussions within the work of the SCP.

72. The Delegation of Ireland, speaking on behalf of the European Union and its 27 Member States, reaffirmed the important role of opposition procedures and similar administrative revocation and invalidation mechanisms for ensuring the proper functioning of patent systems. In particular, it emphasized their contribution to increasing the quality of patents by providing simple, rapid and inexpensive alternative to litigation. In that context, it reiterated that the freedom of all Member States in deciding whether or not to introduce such procedures or mechanisms into their national legislation should be respected. It was of the view that the Committee should continue its work on opposition systems, and considered the elaboration of a compilation of models of opposition systems and other administrative revocation and invalidation mechanisms in a non-exhaustive manner.

73. The Delegation of the Russian Federation confirmed its willingness to undertake further work on the issue of opposition systems and other administrative revocation and invalidation mechanisms, and supported the statements of delegations relating to exchanging experiences on issues such as oppositions, both before and after the grant of a patent, the submission of comments by third parties, the conduct of a re-examination as well as administrative revocation and invalidation of a patent. The Delegation noted that the Secretariat had already prepared documents SCP/17/9 and SCP/17/9 Add. related to opposition systems, which contained information regarding procedures for the filing of oppositions at the pre-grant stage and a list of requirements for such oppositions and procedures for challenging the validity of a patent. It stated that the procedure described in the documents for invalidating patents was similar to the administrative procedure for challenging the validity of patents in the Russian legislation, in particular, an opposition to the grant of a patent might be filed by any person prior to the expiration of the patent term. A person who had filed an opposition had the right to provide any form of proof confirming the well-established nature of the grounds for the opposition. A patent owner had the right to respond to the grounds for the objection and also to provide revised claims for an invention. A decision on the opposition was taken, taking also into account the arguments put forward in the patent owner's response, and could be challenged in the courts. Referring to the proposalsmade by the Delegations of Denmark and Switzerland at the previous session of the SCP, the Delegation considered that the information contained in document SCP/18/4 was worth of particular attention, taking into account the comments made by Member States, including the Russian Federation. In its opinion, mechanisms similar to the opposition system, such as judicial proceedings involving the parties, should also be examined. The Delegation explained that the Russian Federation had a specialized court dealing with IP rights, which administered justice by examining and resolving disputes linked to the provision and termination of legal protection of patents and utility models, cases on the infringement of patent rights and cases concerning the use of results of an intellectual activity (i.e., so-called "patent disputes"). As part of judicial proceedings, disputes relating to both the infringement of a patent and its validity were examined. In that regard, disputes would be referred to a specialized court, which consisted of citizens, such as patent or utility model owners. In order to deal with special issues arising when examining specific cases relating to the competence of the specialized court, its apparatus provided for the establishment of a group of advisers with qualifications corresponding to the court's specialization. A specialized court adviser prepared materials for judges in different sectors of science and technology, essential for analyzing technical issues related to the specific case. In addition, the specialized court had the opportunity to direct requests to other competent authorities in order to clarify and consult on the substance of the dispute. Therefore, in its view, the establishment of such a specialized court allowed, at the international level, to unify the IP enforcement practice and to bring it closer to the international

standards of legal proceedings for the protection of IP. In addition, the Delegation stated that the creation of the specialized court had positive effects, namely: (i) it increased the effectiveness of legal proceedings in the sphere of IP protection; (ii) it ensured the unity of law and enforcement practice and eliminated the difference in approaches to the interpretation of legal provisions, and increased the legal security; (iii) it enhanced the level and quality of protection of the rights of citizens and legal entities; (iv) it served as an incentive for enhancing creative, scientific and technical activities in the country; and (v) it facilitated the growth of a competitive economy. The Delegation considered that the specialized court in the Russian Federation was an essential step towards the establishment of a system capable of preserving and increasing national intellectual potential. In conclusion, the Delegation emphasized that opposition systems and administrative mechanisms for revocation and invalidation were extremely important for the proper functioning of the patent system and, in particular, for enhancing the quality of patents, therefore, in its opinion, that item should be further developed.

AGENDA ITEM 7: PATENTS AND HEALTH

74. Discussions were based on documents SCP/16/7, SCP/16/7 Corr., SCP/17/11, SCP/18/5, SCP/18/INF/3 and SCP/18/INF/3 Add.

75. The Delegation of Belgium, speaking on behalf of Group B, recognized the importance of the agenda item “patents and health” to developing countries and LDCs. However, it pointed out that delegations should acknowledge the mandate of the Committee and fully respect the efforts and activities that had been undertaken with respect to patents and health in other WIPO Committees and Geneva-based international organizations. In its view, the possibility of further discussions on that topic should be analyzed from three angles: (i) the respect for the core mandate of the SCP; (ii) the need to avoid duplication involving unnecessary financial obligations for WIPO and/or other international organizations; and (iii) the most recent developments in the area of patents and public health.

76. The Delegation of Ireland, speaking on behalf of the European Union and its 27 Member States, noted the concerns of developing countries and LDCs, as well as the challenges and constraints that they faced in handling public health problems. In that regard, the Delegation expressed its support in undertaking activities which might assist those countries. It was also aware of the efforts made by WIPO, the WHO and the WTO as presented in document SCP/17/4 and the recently published trilateral study entitled “Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade”. In its view, more in-depth analysis of the trilateral study was currently needed to determine further steps. The Delegation highlighted the work undertaken by WIPO in the area of patents and health in the context of the CDIP. It noted that, so far, documents CDIP/5/4 Rev. and CDIP/7/3, which dealt with patent-related flexibilities, the multilateral legal framework and their legislative implementation at the national and regional level, had been discussed. Against that background, the Delegation stated that any further work in the area of patents and health as well as the relevant forum for such work should be carefully considered in order to avoid unnecessary duplication of efforts, entailing additional financial obligations either for WIPO or other international organizations. The Delegation therefore considered that, before moving forward, the Committee should analyze existing projects and activities in the field of patents and health, as listed in document SCP/18/5, in order to identify patent-related issues which could be addressed in the SCP. The Delegation noted that, further work in that area should reflect a balanced approach, taking into account various interfaces and factors of relevance to patents and health, drawing for instance inspiration from the proposal of the Delegation of the United States of America. In its opinion, further deliberations on that issue should be considered after a period of proper evaluation of the WTO, WHO and WIPO study, for example, including an exploration of the issue of expired patents relating to health.

77. The Delegation of Poland, speaking on behalf of CEBS, acknowledged the importance of the agenda item of patents and health, while recognizing that that was a complex issue. Therefore, it supported adequate activities which might assist developing countries in addressing the concerns by adapting their national patent legislation. It welcomed the report on promoting access to medical technologies and innovation, elaborated by WIPO, the WHO and WTO. Through the evaluation of other activities, studies and information exchanges as well as general information on technical assistance projects implemented by other WIPO bodies, particularly the CDIP, or other international organizations, the analysis and evaluation by the SCP should aim at identifying patent-related issues. It noted that the forum for such work should be carefully considered in order to avoid unnecessary duplication of work, involving additional financial obligations for WIPO. It was of the view that any discussion on that issue should be balanced, and should take into account the crucial role of the patent system in the process of research and innovation of new methods.

78. The Delegation of Algeria, speaking on behalf of the African Group, emphasized the importance of the discussion focusing on the relationship between patents and health, including the contributions of each Member State. It noted that the importance of the topic had been recognized by the United Nations in its Millennium Development Goals (MDGs). In its opinion, as a UN Specialized Agency, WIPO had the statutory obligation to further discuss that matter. The Delegation expressed its appreciation that certain delegations recognized the importance of taking action and adopting activities in the SCP, which is under its mandate. It recalled that the proposal of the African Group, submitted jointly with the DAG, had been on the table for three years, and so far, Member States had not approved any of the elements or parts thereof. The Delegation reiterated that its proposal focused on three different aspects, namely: (i) conducting studies in order to analyze the impact of patents on public health; (ii) exchange of information on that matter; and (iii) technical assistance. Referring to the trilateral study that was published recently by the WTO, WIPO and WHO, the Delegation stated that the work of the SCP should not be limited thereby, since the study covered only one minor, though an important, element pertaining to the access to medical technologies. In the view of the Delegation, the SCP was an all-embracing platform that should be able to look at all the various aspects of that issue.

79. The Delegation of Brazil, speaking on behalf of the DAG, stated that providing access to essential medicines at affordable prices was a goal of all countries, and a necessary step for the achievement of the UN MDGs. It noted that the relationship between the patent system and health also offered a clear picture of the inherent trade-off in IP, i.e., governments offered incentives for innovation while controlling eventual negative effects on competition, ensuring an adequate balance between rights granted and access to the products. It further noted that the Doha Declaration on the TRIPS Agreement and Public Health conveyed the understanding that health technologies were different from other products and should not be treated as a commodity. The Delegation reiterated its position and urged the Committee to adopt the proposal contained in document SCP/16/7. In its view, the document contained a balanced work program which did not intend to “weaken” or “reduce” patent protection, but rather, to understand the effects of patent laws in order to strike a balance between rights and flexibilities according to national reality. The proposal could build on the information and data presented by the trilateral study published by the WHO, the WTO and WIPO.

80. The Delegation of the Russian Federation supported conducting research on patents and health on a long-term basis, taking into account a reasonable consensus and consideration of the interests of all Member States. During the process of discussing that particular subject, a number of delegations, including its Delegation, had supported the proposal by the Delegation of the United States of America relating to multi-faceted study of the accessibility of unpatented medicines, in order to obtain objective data on the influence of patents thereon. In its view, a positive solution to the problem of access to medicines depended on making progress on different factors, such as the harmonization of national standards and technical requirements for the safety of medicines, regulation of tariffs and other customs measures for such medicines, price regulation in the pharmaceutical sector and protection of IP. A similar task was currently being undertaken in the

Russian Federation. The Delegation noted that the legislation in force created a number of barriers to the release to the market of foreign innovative medicines and medicines for treating rare diseases. In the Russian Federation, there was an understanding that it was necessary to improve the procedure of clinical research and obtaining regulatory approval, to improve the procedure for obtaining authorization for importation related to samples of medicines for quality examination and the procedure for changing the registration, to introduce the possibility of appeal against the expert decision and to design medicines for treating rare diseases. The Delegation considered that those initiatives were required to incentivize circulation of medicines in the Russian market, both for domestic and foreign producers, which was particularly important in the context of Russia's accession to the WTO. As of August 22, 2012, a Federal Law had entered into force in the Russian Federation forbidding the use of clinical and pre-clinical trial test data of original medicines without the consent of the originator for a period of six years from the date of State registration of the original medicine, i.e., data exclusivity. It stated that on the one hand, the system protected the interests of producers of innovative medicines, who had invested substantially in the development of the medicine, and on the other hand, consumers gained access to a more expensive medicine during the data exclusivity period and could afterwards purchase cheaper generics. It considered that the legal provisions on data exclusivity aiming at ensuring the balance between the interests of the producers and consumers could be refined in the context of the TRIPS Agreement for the regulation of trade of medicines. In the view of the Delegation, research on those elements relating to the complex issue of access to medicines, in accordance with the proposal by the Delegation of the United States of America, could be of use for national practices. At the same time, the Delegation supported the proposal made by some delegations regarding a presentation by the Secretariats of the results of the trilateral study, conducted jointly by WIPO, the WHO and WTO. The Delegation expressed its understanding that the purpose of the study was to provide a comprehensive view of the full range of issues, including the consolidation of the efforts of the three international organizations in the area of technical assistance. In its view, it would be appropriate to organize a similar presentation at the beginning of the twentieth session of the SCP, as a good basis for discussion of the issue.

81. The Delegation of Egypt supported the statements of the DAG and the African Group on the topic under discussion. It reminded the Committee that the issue had been discussed since the seventeenth session but no progress had been noted. As a result, it became imperative for the Delegation to make a headway on that item and to reach a decision within the Committee. The Delegation stated that appropriate decisions on various proposals on the table and specific steps to be taken by the SCP had to be made. The Delegation also supported the comments made by some Member States, in particular, those made by the Delegation of Spain which had supported certain aspects of the proposed work program. Further, it supported the position of the DAG on undertaking a study and specific steps to analyze those elements within the work program.

82. The Representative of IIPI stated that pharmaceutical research often tracked diseases that mostly affect the researchers' countries, and as a result, some diseases became neglected. The Representative noted that, while in developed countries, government-sponsored university research had created many effective health solutions, there had also been some important successes in developing countries, such as in the Philippines, which demonstrated that such an approach was also viable for developing countries. The Representative explained that, in the case of the Philippines, the Department of Science and Technology had funded health research programs through the Council for Health Research and Development. Many of those programs had resulted in inventions that promised to improve the lives of Filipinos. Those programs had taken advantage of the unique knowledge that Filipinos had of their own health problems. For example, Dr. Raul Destura of the University of Philippines in Manila, who had received funding from the Council for Health Research, had invented the BiotechN, which was a test for detecting dengue fever. BiotechN was currently undergoing through trials in three hospitals in the Philippines. The preliminary results were very promising. The test was at least as accurate as other tests, but significantly faster and cheaper. Similarly, researchers at the University of the

Philippines, who had received funding from the Council for Health Research, had invented Life Link, a telemedicine system that transmitted patients' health data. That data was in the third stage of development. That innovation was ideal for assisting underserved populations who often lived in areas wherein wired infrastructure was prohibitively expensive. The Philippines Council for Health Research also funded research for new developments which targeted neglected diseases overlooked by research institutions in developing countries, but which greatly affected the people. The Representative expressed his belief that it was not a lack of creative and innovative citizens that prevented developing countries from taking full advantage of the international patent system, instead, it was simply the inability to effectively indentify and fully develop inventions. Therefore, the Representative noted that IIPI was working with the USPTO and the Intellectual Property Office of the Philippines to improve technology capture and commercialization at Philippine universities. In his opinion, by strengthening national capacity in that area developing countries would be in a position to produce health solutions for diseases that affect the populations the most.

83. The Chair invited WIPO, the WHO and WTO to introduce the trilateral study entitled "Promoting Access to Medical Technologies and Innovation – Intersections between Public Health, Intellectual Property and Trade" to the Committee.

84. The Secretariat stated that, in the course of the last years, the WHO, WIPO and WTO had established an informal, practical and well functioning trilateral cooperation at the working level on issues at the interface of public health, IP and trade. WIPO Member States had requested such practical level cooperation in the Development Agenda Recommendation 40 which asked the Secretariat to intensify cooperation on IP-related issues with UN agencies and the WTO. The Secretariat noted that it had reported about that cooperation and activities undertaken in the seventeenth and eighteenth session of the SCP. It recalled that such working relationship had matured from: (i) many years of working level contacts at various occasions; for example – for many years, speakers from the WHO, WIPO and WTO had participated in seminars and training courses organized by one or more of those organizations; and (ii) processes in each of the three organizations, such as the CIPIH and the process leading to the adoption of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI), work in the WTO Council for TRIPS undertaken in line with the Doha Declaration on the TRIPS Agreement and Public Health, and the WIPO Development Agenda. The trilateral cooperation was intended to contribute to enhancing the empirical and factual information basis for policy makers and supporting them in addressing IP issues in relation to public health. In the context of the trilateral cooperation, the following events had been organized: (i) a Joint Technical Symposium on Access to Medicines: Pricing and Procurement Practices, July 16, 2010; (ii) a Workshop on Patent Searches and Freedom to Operate, February 17, 2011; and (iii) a Joint Technical Symposium on Access to Medicines, Patent Information and Freedom to Operate, February 18, 2011. Those events had looked at very specific issues of immediate topical importance at the interface of public health, innovation and trade. The Secretariat underscored that the trilateral study went further. It contained an in-depth overview over the policy debate on health, IP and trade, and aimed at providing a comprehensive, neutral and balanced overview over the policy debate and provided an information basis for the discussion in the years to come. The study was a direct result and logical consequence of the ongoing trilateral cooperation. It was founded on the experience gained that there was a need for a comprehensive compendium of the issues at stake. In the first place, the study was intended to be used as resource and background material for capacity building activities undertaken by the WHO, WIPO and WTO either in cooperation or separately. It was meant to support the trilateral cooperation itself. The Secretariat noted that such comprehensive background resource had not existed, and that was the first joint publication of the WHO, WIPO and WTO. It allowed the Secretariats of the three organizations to jointly reach out to the health, IP and trade communities. The Secretariat emphasized that it was an important means to reach a broader audience with deeper and better information. It further underscored that the character of the study was to inform, not to evaluate. The Secretariat emphasized that it would be for the reader to make assessments and use the information to make informed choices and decisions. It was thus a strictly factual and neutral resource, and therefore did not promote any particular views,

did not attempt to evaluate, and did not provide any specific conclusions for follow-up nor any recommendations. The Secretariat stated that, very importantly, the study placed down a very clear marker and guide as to where the organizations were now on the institutional and legal framework to address IP, trade, and health issues. It described what had been done in the three organizations in the area and what the Secretariats had done within their mandates. The study was structured in four Chapters, which was meant to enable users to grasp the policy essentials, and then to look more deeply into areas of particular interest, specifically related to innovation and access: Chapter I presented the general background to health policy, set out the distinct roles and mandates of the three cooperating agencies, and outlined the global disease burden that defined the essential challenge for health policy. Chapter II outlined the essential elements of the international health, IP and trade policy frameworks. It summarized the key insights of economics for medical technology, and reviewed the policy issues associated with traditional medical knowledge. In respect of patent law, Chapter II provided an overview of the international frameworks and rules, explained the rationale of the patent system, outlined patent procedures, rights conferred by a patent, addressed exceptions and limitations and introduced the essentials of patent information. Chapter III provided a more detailed overview of the innovation dimension of medical technologies. It looked at the innovation challenge presented by neglected diseases and related alternative and complementary instruments to promote research and development. It outlined the role of IP rights in the innovation cycle. Regarding patent law, Chapter III considered selective aspects that were especially relevant to the innovation dimension of medical technologies, such as patenting material that exists in nature, first and second medical indications, incremental and adaptive innovation, patent filing strategies and a number of post grant issues, such as research exceptions, licensing and research and development (R&D) agreements, patent thickets, patent landscapes and freedom to operate. Chapter IV described the context for access to medical technologies and the current access framework for essential medicines. It then set out the key determinants of access related to health systems, IP and trade. It reviewed in particular pricing policies, taxes and mark-ups, procurement mechanisms, regulatory aspects, initiatives to transfer technology, local production, trade agreements, tariffs and competition policy. In respect of patent law, Chapter IV addressed a number of pre-grant issues, such as patent procedures and patent quality, looked at pre- and post-grant review procedures, considered post-grant determinants of access, such as certain exceptions and limitations to patent rights, including regulatory review exceptions, compulsory licenses and government use, and also exhaustion of rights, patent term extensions, enforcement of IP and patent information. That structure resulted from a very conscious choice to discuss selected issues from a specific innovation and access perspective. While the cross-cutting nature of some themes was considered in the first two chapters which sketched out the general policy framework, specific issues were later elaborated in the chapters on innovation and access which looked in more detail at how those elements had bearing on innovation and access, respectively. Extensive cross-references linked the elements of the separate Chapters and helped readers navigate the issues discussed in different parts of the study. The Secretariat noted that all reasonable precautions and care had been taken by the three organizations to verify the information contained in that publication. However, in case of any mistakes in the study, it invited the delegations to inform the Secretariat. It emphasized that the publication was very much a Secretariat product, by colleagues in the WHO, WIPO and the WTO, and therefore benefited from the joint expertise of the three organizations. That work had allowed engaging many colleagues in the three organizations beyond the core group of colleagues, which was directly responsible for research, authoring and review. It noted that the work had been extensively and repeatedly reviewed by colleagues in each of the three organizations. In that regard, the Secretariat indicated that the study was also a tool to enhance and strengthen the trilateral cooperation itself.

85. The Representative of the WHO expressed his appreciation for the opportunity to present the WHO's perspective with regard to a joint study by the WHO, WIPO and the WTO “Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, IP and Trade.” He emphasized that the study had been termed by the Director General of the WHO, Dr. Margaret Chan, as “…a big report with a noble mission” in her speech at the launch of the study

on February 5, 2013, along with the Director Generals of WIPO and the WTO. She had called it noble because the central core of that work was aimed at improving access to medicines and related technologies as part of health service provision, especially to those who continued to suffer and die for want of those public health goods. That joint study was a testament that WHO was not alone in pursuing that goal, and despite different mandates of WIPO and the WTO, the organizations were united as members of the UN system in that cause. Referring to the statement made by the Secretariat as to how those three organizations had come together, the Representative added that the organizations had been urged by their Members and led by their respective leadership, to forge a trilateral cooperation which was a unique example of inter-agency collaboration at the multilateral level for shared objectives of assisting governments and benefitting people in their quest for accessible health care through functional health systems as their fundamental human right. Member States of the WHO had provided a repeated mandate to its Director General to work on issues regarding to access to medicines in relation to IP protection. The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, which the WHO Member States had adopted in 2008, also guided the WHO to collaborate with other competent international organizations in providing technical assistance to Member States. The trilateral cooperation was partly a product of that guidance and mandate by its Member States. From a public health point of view, that study had first of all treated medical innovation as an important dimension of access. The phenomenon of globalization was affecting disease epidemiology and resulting in redistribution of burden of disease. To address those challenges, new medical technology tools needed to be developed, existing interventions needed to be re-tooled and their access needed to be ensured. Development of heat stable medicines and vaccines, reformulation of existing medicines in new fixed-dose combinations for better supply and compliance, including better pediatric formulations, medical devices for the aging populations across the world, and safer and effective medicines for neglected tropical diseases were examples where medical innovation was urgently needed, and once developed, those technologies needed to be delivered to those who needed them the most. He noted that the study hence brought together innovation and access as two sides of the same coin. The WHO had been involved in promoting access to medicines and health technologies by addressing its multifarious but traditional determinants that lay within the purview of health sector, i.e., selection of essential medicines and priority health technologies, affordable prices and adequate financing, procurement and supply systems. He stated that study however brought together a plethora of other policy determinants which were at the cross-roads of law and economics, i.e., IP and trade and cover areas, such as, competition policy, tariffs, IP protection law, pricing policies, traditional knowledge (TK) and its management, innovative financing mechanisms – and most importantly, it focused on the interplay of those policy arenas and what kind of opportunities and challenges those intersections could present to the policy makers. It illustrated those intersections with practical examples and with the help of empirical evidence which was much more available than when those discussions had started in 1996 at the World Health Assembly, the very next year of the creation of the WTO. The study presented the evolving burden of disease and health risks as a basis to set priorities for medical innovation and access. Globally, for example, non-communicable diseases were projected to account for over three quarters of all deaths by 2030 and uni-polar depressive disorders were going to be number one cause with highest percentage for disability adjusted life years. Those considerations, the study argued, should guide innovation and access efforts at the present time and for the future. Regulation of health technologies was another area which the study presented both, in the context of innovation, i.e., clinical trials, and access, i.e., assurance of quality, safety and efficacy of medicines and health technologies for their production through compliance to good manufacturing practices, for market authorization and for their supply through public and private channels. The importance of robust regulation through institutional development of reliable national regulatory authorities and the importance of regulatory harmonization were emphasized throughout the study. The challenges of regulatory pathways for biotechnology products and bio-similars were amply described. The study also presented, for the first time, tariff data on pharmaceutical products and highlighted an interesting fact, i.e., whereas most industrialized countries had removed tariffs on pharmaceuticals, not all developing countries had done the same. That was paradoxical to a parallel desire to improve access to medicines. In countries where majority of

medicines were imported and out-of-pocket expenditures to buy health care were high, i.e., up to 70%, subjecting essential medicines to tariffs and taxes resulted in prices high enough to be unaffordable to poor people. The study raised such policy issues also to draw the attention of policy makers. The Representative further highlighted one major issue that the WHO had been trying to grapple with for about a decade, i.e., when markets failed to provide incentives for development of medical technologies required in developing countries especially for neglected diseases, how to encourage such R&D. The study presented that work in the WHO by highlighting the need for development of alternative mechanisms for financing and incentivizing such essential R&D. That was where innovative financing and new ways of working for ensuring needed R&D were described. The Representative noted that a big part of the study dealt with IP protection issues and how different multilateral, plurilateral but also regional and bilateral trade agreements affected innovation and access. Challenges posed by difficulties in accessing relevant patent information, ever-greening trends in patent management, sometimes poor quality of patent applications accepted by national patent offices and cumulative effects of all those on public health in terms of inefficient procurement and delays in availability of generic medicines were also discussed. The Representative noted that, in a nutshell, there were two central messages of the study: first, in a complex policy world of the 21st century when universal health coverage was becoming a passionately pursued goal and people's expectations and demands were rising for high quality accessible health care, the supply side had to readjust itself in terms of innovation and delivery of health care, including health technologies, and, in order to make it possible, the policy makers had no choice but to be better informed, evidenced based and affirmative in action. He noted that in order to accomplish that task, they had to deal with many policy domains to strike coherent policy solutions to respond to challenging situations. Second, through technical cooperation among themselves, the WHO, WIPO and WTO could assist national policy makers by providing technical assistance for development of balanced and coherent policies for need-based medical innovation and reliable access. The study was a reflection of that commitment by the three organizations, and provided a backdrop for their future cooperation and provision of technical assistance in those areas.

86. The Representative of the WTO welcomed the possibility to present his perspective on the development and the use of the trilateral study to the SCP. He emphasized that the Secretariat and the Representative of the WHO had been very straightforward in comprehensively outlining the study and had touched on some of the key areas of the study both relating to patent law and the broader context of access and innovation. Therefore, he wanted to inform the SCP on a little further background from the point of view of the WTO. For the WTO, the trilateral study represented more of a consolidation of many years of technical cooperation relating to aspects of public health and the interplay with the international trading system and especially concerning the TRIPS Agreement and Public Health. Such work on technical cooperation had been catalyzed in particular by the 2001 Doha Declaration on the TRIPS Agreement and Public Health and the ensuing work in the WHO and in the Council for TRIPS. He highlighted that it was worth bearing in mind that the trilateral study was effectively a sequel to a joint publication with the WHO, a publication in 2002 which had covered, in general, the WTO Agreements relating to public health and had focused on those areas of policy that had been most dynamic and of most interest or demand when it had come to technical cooperation requested by its members, i.e., in the areas of innovation and access to medical technologies. That focus on access and innovation was mirrored in the Doha Declaration itself, which recognized that IP was important for the development of new medicines and also recognized the implications for prices. He reiterated that the Doha Declaration had noted the innovation and access dimensions of the IP system. During the last decade or so, he noted that WTO had seen a broadening focus in the policy debate in the demand for technical cooperation, for example, going beyond access to medicines as such, looking at a broader scope of access to medical technologies. He added that there was also a growing innovation debate, a debate about innovation models and mechanisms, and noted that innovation policy recently found its way onto the agenda also of the TRIPS Council. He reiterated that the Doha Declaration itself was a milestone in the WTO's cooperative work in that area. It was a recognition that the IP system was not an isolated specialist demand, nor, for that matter, a monolithic barrier to public

health. Instead, the Doha Declaration set IP system as one element of the complex set of policy tools required to solve global problems. He noted that the emphasis was increasingly laid on how different policy measures could work together coherently and for mutual benefit. That was stated in the very policy intersections that gave the present report its momentum and its very title. That had been sketched out transparently in the presentations, which attempted to illuminate how those different policy domains fitted together. He reassured that the Doha Declaration remained a blueprint for the work of the WTO towards greater coherence and an inclusive, cooperative approach that had culminated in the study. The Doha Declaration was also one step in a journey towards greater recognition of the understanding that access to medicines required the right mix of health policies, IP rules, and trade policy settings, all taken together and involved the judicious and informed use of a range of measures, including competition policy, effective procurement strategies, attention to tariffs, as the Representative of the WHO had just mentioned, and other trade-related drivers of cost as well as choices within the IP system. He emphasized that coherence between those different aspects of policy was one key to finding sustainable solutions, and the search for the tools to create such a coherent approach was the spirit behind the joint study. The Representative pointed out the two layers of policy coherence and intersections that the study explored. First, at the level of policy and legal principles, it discussed the points of interaction between the legal and policy principles in different domains so that law and policy instruments could be interpreted and applied in practice to promote public health. The Doha Declaration was an example of that. However, the study explored the interplay between trade policy, competition policy, IP policy, etc., looking for points of intersection and positive reinforcement between those policy elements. Further, he noted that the other aspect of intersection was at the level of empirical data. He clarified that one impetus behind the study was the increasing availability and inclusiveness of data in a range of intersecting areas. In particular, for policy makers, that would offer an opportunity to work from an improved, more integrated base of information that would combine data on public health, determinants of access to medical technologies, coverage of relevant IP rights and trade policy settings. For example, in considering the challenges of access to medicines, there were not only policy challenges involving attention to procurement policy, competition policy, as well as pricing, tariff and IP policy, but also the actual practice of access to medicines. The procurement of medicines could be guided by a richer base of information, considering existing and emerging disease burdens, pricing of medicines, IP coverage and other practical data coming from different fields, which might be used in a more integrated way. The Representative pointed out that from a practical point of view, that was one area that the study could be useful in connection with the technical cooperation toolkit of the WTO in its cooperation not only with WIPO and WTO but also with a wider range of technical cooperation partners who did form part of the WTO's ongoing work in the areas relating to public health and IP. Those included other members of the UN family, NGOs working in the public health field and representatives of various areas of industry. He stressed that the trilateral study was seen as the basis for an ongoing, more empirically informed, inclusive and broad-based approach to technical cooperation and capacity building. Therefore, policy makers had better information and a more systematic overview of the various policy tools and instruments available, and how they fitted together. In that sense, those policy makers could make the most effective decisions to promote national development and public health objectives. He commended for the opportunity to present the study and hoped to go forward with the ongoing cooperation, not merely with the two other trilateral partners, but with a wide range of partners in the room, working together towards a stronger information base and stronger policy making capacity in that very important field.

87. The Chair opened the floor for questions and comments from members and observers of the SCP for an in-depth discussion.

88. The Delegation of Belgium, speaking on behalf of Group B, thanked WIPO, the WTO and the WHO for presenting the trilateral study. In that regard, it noted the interesting and thorough quality of the study and expressed its belief that WIPO, the WTO and the WHO should continue to cooperate as they had done in the aforementioned study. In the view of the Delegation, the Committee should focus further on ways in which it could add value to the work already performed

in relation to patents, health and trade issues, without duplicating work that had been carried out either within or outside of WIPO, as highlighted in the study and in document SCP/18/5. Moreover, the Delegation stated that such an approach should be balanced and inspired by the different ideas and proposals already on the table.

89. The Delegation of Poland, speaking on behalf of CEBS, expressed its gratitude to the the WHO, the WTO and WIPO for the valuable and comprehensive presentation of the trilateral study. It stated that the study provided a broad scope of analytical and factual material on technical cooperation and a dialogue on the issues concerning public health, IP and trade. It noted that the presentation brought the SCP closer to cross-cutting issues and the factors that had impact on access to medicines. The Delegation emphasized that the study significantly contributed to the work of the SCP by enhancing its knowledge on challenges faced and policies applied, as well as on ongoing technical cooperation activities undertaken and programs developed by the three organizations. It constituted a rich basis to streamline further analysis and evaluation in the context of other activities, studies and general information on technical assistance projects implemented by other WIPO bodies or other international organizations.

90. The Delegation of Sri Lanka, speaking on behalf of the Asian Group, thanked WIPO, the WHO and the WTO for the comprehensive study, which was extremely useful. It wished to highlight that public health policy and related activities were of utmost importance to many countries in the Asian region, which often included provisions in national laws to provide free healthcare access to the population. It stated that effective and affordable generic medicines were key in that context. It noted that countries within the Asian region were constantly finding ways to improve access to medical products and maximizing efforts to improve public health. The Delegation indicated that, often, Asian countries did not have the complete capacity needed to achieve that goal, which was why capacity building and transfer of technology were fundamental in those discussions in order for developing countries and LDCs to realize effective health coverage. The Asian Group had recognized the joint projects contained in document SCP/18/5 which aimed at achieving those goals. However, it requested to reach a common understanding of the next steps, in particular, future projects planned to improve technology transfer and capacity building towards the development of, and access to, safe, effective and affordable generic medicines in developing countries and LDCs. The Delegation expressed its belief that it would be important to further understand and map out future improvements in global public health. It thanked the authors of the study for their hard work, and looked forward to further deliberations on that subject.

91. The Delegation of Algeria, speaking on behalf of the African Group, expressed its gratitude to the representatives of the three organizations, the experts and the entire team that had taken part in the preparation and compilation of such a comprehensive study. It noted that the study contained full information and explained what the UN, its specialized agencies and the WTO had done in the area of promoting access to medical technology innovation. The Delegation pointed out that by compiling information on the various existing legal standards, regulations and practices as well national experiences, the study was a compilation of what had been done at the national and international levels in order to facilitate access to medicines. The Delegation however stated that, even though there was a trilateral cooperation that seemed very effective between WIPO, the WHO and the WTO, African countries had difficulties in understanding the practical upshot on the field. Therefore, the Delegation stated the following comments: first, with regard to its format and form, it highlighted that the mandate of the study and the terms of reference thereof were not clear. It raised a question as to whether the ideas and viewpoints expressed in the study reflected the state of the discussions in each of those organizations. Nonetheless, it was pleased that the study made references to an all-embracing strategy, the WHO Plan of Action. With regard to innovation, the Delegation was concerned about a strategy that formally and exclusively recognized the fact that IP had a positive impact, and highlighted the negative impact with regard to access to medicine. Welcoming a clear reference to that effect in the study, it however regretted that there was no reference to what the WHO called “Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective”. The Delegation pointed out that those

guidelines were of crucial importance when talking about access to medicine and also with regard to facilitating access to medical technology, and raised the question as to why there was no reference to the WHO's examination guidelines. Secondly, the study indicated clearly the flexibilities, realities and limitations with regard to the current patent system, but did not look into the structural and technical constraints for developing countries with regard to using those flexibilities. While the study recognized the existence of flexibilities at the international level, in the view of the Delegation, it did not recognize that the majority of developing countries did not have the technical capacity to make use of those flexibilities, for example, compulsory licensing. It noted the difficulty of establishing such a license as it was difficult to know how the royalties should be set. It observed that there were many questions of a technical nature and, therefore, the countries were overwhelmed by the different formalities. It underscored that, for developing countries, it would be very important to have a study on what WIPO, the WTO and the WHO could do in order to help developing countries to make use of those potential flexibilities. It indicated that the establishment of such a study was contained in the proposal of the African Group. It reiterated the gratitude of the African Group for the study which, in its view, was a very good working basis when looking at what had been done on the trilateral basis. The Delegation, however, reiterated that that should in no way condition what WIPO did on its own.

92. The Delegation of Brazil, speaking on behalf of the DAG, thanked the WTO, WIPO and the WHO for the work on the trilateral study and for the presentations made. It highlighted that the study was an excellent example of what could be achieved by the cooperation between organizations dealing with the matter. It observed that the study aimed at filling the gap in understanding the relationship between IP, trade and access to public health. It noted that, because of the recent publication and the amount of detailed information contained in the study, Member States had still been processing it. The Delegation considered that the study expressed the complexity of the subject and the many challenges members faced in addressing their health needs. It observed that the issue was especially sensitive for developing countries given their lack of resources for research and development of medicines to address endemic, tropical and neglected diseases. It was pleased by the statement of the Representative of the WHO that health was a human right, and that the study was the first step for the cooperation not only between the trilateral partners but also with Member States and other organizations dealing with the matter. It underscored that the goal of striking a balance and providing neutral and factual information was another example which could be mainstreamed in the work developed elsewhere. The study moved away from simplified axiomatic truth that IP itself was a positive tool or an obstacle for enhancing access to medicine. Many factors affected it, some within the IP system, such as the availability of patents and their use by right holders, some outside the IP system such as pricing and government procurement policies. In its view, the study provided other relevant information that public health policies demanded government intervention in order to be effective and that competition policy was effective for enhancing access to medical technology and fostering innovation in the pharmaceutical sector. It indicated that those matters could be further explored by the joint proposal of the African Group and the DAG, without prejudice to other issues. It concluded that the study was an encouraging sign for the work of the SCP. In that context, it observed that the study as well as the report of the WHO Consultative Expert Working Group on Research and Development: Financing and Coordination, clearly showed that current financing mechanisms for pharmaceutical researchers were not aligned to the needs of developing countries and thus demanded creative action by policy makers and stakeholders. More than ten years after the Doha Declaration, the Delegation was of the view that it was high time for the SCP to further explore the issue in order to overcome the challenges many members still faced.

93. The Delegation of Senegal expressed its gratitude to the Secretariats of the WTO, the WHO and WIPO for having framed the trilateral study which addressed a number of questions and for their presentations. It proposed that the organizations continue to work along those lines in order to facilitate and promote access to medicines and to pharmaceutical and medical technology. The Delegation supported the statement made by the Delegation of Algeria on behalf of the African Group, and added that the study could be further deepened with regard to the practical and

legal framework and access to medicines and medical technology, looking at various issues of IP. However, the Delegation indicated that the mandate and the terms of reference of the study, which were designed to simply look at a factual analysis, limited the scope of the study. In its view, the study could have been more open-ended and forward looking in nature. Therefore, it noted that some Member States looked forward to examine the constraints of developing countries especially with the use of flexibilities, and to share the experiences from countries that had already used those flexibilities. It indicated that in order to enable the different countries to draw inspiration from those examples, the DAG and the African Group had proposed to work along those lines. With regard to the importance of importing drugs, the Delegation pointed out that countries such as Senegal did not export medicines and were not interested in suspending customs duties with regard to importing drugs. However, it noted that Senegal made use of subsidies with regard to facilitating access to medicines.

94. The Delegation of Chile thanked the Secretariats of WIPO, the WHO and the WTO for the presentation and the work contained in the trilateral study. It observed that that had required joint work of a number of organizations and multilateral bodies on one of the most important areas that the SCP could focus on. Noting that the study did not seek to arrive at conclusions but mainly embodied factual information in order to provide direction for the decision making in each country, the Delegation noted that it was assessing that information. The Delegation drew the attention of the Committee to page 189, Table 4.1 of the study pertaining to the two bilateral treaties signed by Chile. It stated that with respect to the last column of the table referring to the Doha Declaration on the TRIPS Agreement and Public Health, those bilateral treaties included the provisions reaffirming, in particular, the Doha Declaration and requested that the information be included in the study. With regard to future work of the SCP, the Delegation suggested that the information in the study be utilized within the framework of the SCP without duplicating the work of compiling such extensive information. It observed that there was space for the SCP to discuss and analyze the conclusions that could be drawn from the information, taking into account the proposals made by Member States.

95. The Representative of KEI stated his comments as follows: (i) cost-sharing approaches in implementing Article 39.3 of the TRIPS Agreement; and (ii) the human right dimension in dealing the R&D treaty. With respect to the obligations of the WTO members to implement Article 39.3 of the TRIPS Agreement, the study stated that "during the Uruguay Round negotiations, the option of making data exclusivity an explicit obligation under the TRIPS Agreement was discussed, but negotiators instead adopted the general wording of the current Article 39.3." He observed that the study made it clear that, although making an explicit reference to data exclusivity was mulled in the Uruguay Round negotiations, that position did not receive sufficient support and thus, adopting the more general wording of the current Article 39.3 TRIPS Agreement was the only acceptable option for the Uruguay Round negotiators. The Representative noted that the most interesting part of the study's treatment of test data protection was in its description of State practices in implementing Article 39.3 of the TRIPS Agreement. The trilateral study described the concept of cost-sharing as an alternative to data exclusivity which would permit the reliance on originator data, provided that the "generic supplier participates in the costs of generating the data". He observed that the study noted that the United States of America, for example, provided for both data exclusivity and a mandatory data compensation system in relation to data submitted in applications for regulatory approval of pesticides, but not pharmaceuticals. He informed the SCP that the European Free Trade Association (EFTA)-Korea FTA, in Article 3, Annex XIII, also included a compensation scheme as an alternative to data exclusivity. He suggested that countries currently involved in free-trade and plurilateral trade agreements further examine the cost-sharing approach. He further noted that Chapter II.A(1) of the study dealt with the human rights dimension in relation to trade rules and IP. The study presented the human rights framework as an "important mechanism to further the public health policy goals of ensuring and improving access to medicines for those who are most in need" in light of the double burden of infectious and non-communicable diseases faced by low and middle-income countries. Referring to the description in the study on human rights which stated: "in the context of neglected diseases where innovation in medical technologies

has not kept with the needs of developing countries, the right to health includes an obligation for states to promote R&D of new medical technologies," he pointed out that the human rights dimension should be at the forefront of the current international discussions to "secure an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries". In connection with the discussions at the WHO, the Representative referred to the description of the de-linkage concept in the study as follows: "One important concept that evolved from this discussion is the concept of delinking price of the final product from the costs of R&D. This concept is based on the fact that patents allow developers to recoup the costs and make profits by charging a price in excess of the costs of production. This way of financing R&D is viewed as constituting a barrier to access to medicines in countries where populations pay out of their own pockets for medicines and thus cannot afford to pay high prices. The principle of delinking was based on the premise that costs and risks associated with R&D should be rewarded, and incentives for R&D provided, other than through the price of the product." The Representative urged the SCP to further analyze and examine the "de-linkage" and R&D treaty concept in future discussions on patents and health.

96. The Representative of the Medicines Patent Pool (MPP) welcomed the recognition of its work by three key intergovernmental agencies in the trilateral study exploring different strategies for access to innovation and medical technologies in developing countries. The Representative observed that the study expressed that patents could be used "expressly to leverage public health outcomes" when licensed with the right terms and conditions. He further emphasized that the study also noted that the MPP, in particular, had "reinforced the trend towards voluntary licensing programs that increased access to medicines by enabling new formulations and enhancing provision of cheaper generic medicines for developing countries," adding that voluntary licensing of HIV medicines in general had been an increasing trend since the MPP's creation in 2010. He highlighted that patent pools were a key recommendation of an expert working group of the WHO on incentivizing research and development for the developing world. Patent pools, in particular, the Medicines Patent Pool, had been endorsed in the UNAIDS 2011 Political Declaration on HIV/AIDS to help reduce the price of medicine and encourage the development of needed new formulations. He informed the Committee that the MPP Executive Director also invited pharmaceutical companies holding key HIV medicine patents to work with the MPP to pool their patents and technology in order to broaden both access and innovation. He invited governments to take a more active role in both promoting patent pooling and encouraging industry by, for example, providing incentives to partner with the Medicines Patent Pool.

97. The Representative of AIPPI thanked the three organizations for their comprehensive study. He stated that AIPPI would evaluate the technical aspects of the study and would provide comments. He considered it helpful that the study had left the technical world of IP protection and was mainly governed by the needs of the global health system. In his view, that was crucial for fine-tuning the IP protection system in order to bring about the best medical care possible around the world.

98. The Chair invited the Secretariat and the Representatives of the WHO and the WTO to provide any further comments and replies to questions raised.

99. The Secretariat thanked delegations for their positive feedback as well as for the comments pointing out the elements which were missing in the study or were not appropriately addressed. It noted that the latter feedback was appreciated to improve the work. It emphasized that the study was a resource material but was intended neither to make any evaluation nor to solve any issues. That information resource should enable the public, delegations and any other interested person in participating in the debate to come up with better informed decisions.

100. The Representative of the WHO paid tribute to the delegations which had encouraged the organizations to carry out and continue the trilateral cooperation. He informed the Committee that the organizations had been constantly engaged at the Director General's level as well as at the

technical level for planning relevant activities of mutual interest which could benefit policy makers and its Member States. In response to the question raised by the Delegation of Algeria on behalf of the African Group relating to the guidelines for examination of patent applications, he noted that in developing countries, it was known that many national patent offices did not even have substantive examination facilities or expertise. Therefore, he observed that when a patent application was filed, in reality, it was accepted although there were questions as to the acceptability and quality of those applications. In that regard, he pointed out that on page 172, Section (b), the issues regarding patent examination and registration as well as available resources for such process was discussed. Specifically, Box 4.12 at the bottom of the page entitled "Guidelines for the examination of pharmaceutical patents: developing a public health perspective" mentioned a number of guidelines. He stressed in that context that the idea of the study was to make available all the relevant and important discussions on relevant issues as well as whatever resources were available by those three organizations and beyond. He noted that the study tried to put the resources together so that an interested policy maker, who wanted to understand and to make relevant policy in his or her own context, could make best use of it.

101. The Representative of the WTO was pleased and greatly encouraged by the positive reception that the study had been given and by the comments made by the delegations and observers. He highlighted that the study had deep roots in the technical cooperation work of three agencies, and, to some extent, was an exercise in transparency since a lot of the material would otherwise be scattered in PowerPoint slides and various programs on the three web sites. He pointed out that the study was an attempt to have a clearer framework for ongoing technical cooperation and had been a conscious effort to be as broad and inclusive as possible without going into technical detail. He emphasized that there had been a strong recognition that policy makers might have a sound technical expertise in one field but might not be inclined to engage or to translate those principles to other policy domains. He pointed out that the three organizations had obviously represented the three broad policy domains in terms of their mandate and expertise. He indicated therefore that the study had been an attempt to draw that material together in a non-technical way that enabled policy makers to navigate through that complex environment. Therefore, the study did describe the concepts and the various choices made by countries and WTO members. In that sense, it was descriptive rather than endorsing or advocating any particular approach. The emphasis in drafting the study was more on trying to describe the factual situation as accurately as possible with the purpose that the concepts and ideas that emerged in those cross-cutting policy debates were better understood rather than necessarily describing the correct approach for any country. With respect to the specific points highlighted by the Delegation of Chile concerning the relevant bilateral trade agreements entered by Chile, he noted that the trilateral study in itself was not intended to advance original research or new research in itself. He emphasized that it was meant to be an overview of available materials. Therefore, the relevant section pointed out by the Delegation of Chile referred, in fact, to a longer staff working paper that had looked into those issues in more detail. He ensured the Delegation of Chile to take its comment into account, if appropriate, in the study itself, but he invited the Delegation to also look at the underlying and separate research work that was part of the broader ecosystem of the trilateral study. He concluded by confirming that the study was seen as a platform for continued capacity building, as a source of information and data for capacity-building programs. He reaffirmed that the future work of the WTO would continue along the lines of the established program, i.e., continued technical cooperation, responding to the demand from its members, both for collective activities, such as the annual Workshop on Intellectual Property and Public Health organized by the WTO in collaboration with the WHO and WIPO, and national workshops which often had a public health component to them. In addition, he noted that an important part of the Trilateral Cooperation had been a series of policy symposia, meant to provide support for policy makers rather than to pre-empt the policy discussions, to provide a more informed basis to draw on the knowledge and understanding that was available from a wide range of experts in Geneva and beyond. In his view, those past symposia had been very important inputs to the trilateral study and such symposia could be a forum for continuing the dialogue.

102. The Delegation of the Russian Federation thanked the WHO, the WTO and WIPO for the empirical and factual information contained in the trilateral study which would give the SCP an opportunity to analyze that subject in greater depth. The Delegation noted that the accessibility of safe and effective medicines was a multifaceted problem, which touched on many areas of law, national policy, physical infrastructure, the social sphere and education, and also different economic factors. In the view of the Delegation, the priority approaches in relation to the provision of accessibility were the creation of conditions for stable step-by-step development of the pharmaceutical sector, provision of State guarantees for patients to obtain high-quality medicines, improvement of the quality of control of all stages of circulation of medicines, and the reduction of the burden of administrative barriers. The Delegation considered that work to adapt regulatory requirements to international standards was required to make the Russian pharmaceutical market part of the global medicines market. At the same time, the Delegation shared the concern of a number of States concerning the formation of a price policy by the monopoly producer of a patented medicine. The Delegation informed the Committee that in the Russian Federation, the State regulated prices exclusively for medicines, which were included in the list of the most important and essential medicines, produced both locally and abroad. The State approved the list of essential medicines authorized for purchases using budgetary funds, which provided support for the health of people suffering with non-fatal diseases who did not have sufficient funds to acquire expensive medicines. The Delegation noted that provision of that particular form of accessibility was directly reflected on the patient and had major social significance – it improved the practice of prescription of medicines by doctors. Further, the Delegation stated that, within the framework of the Russian legislation in force, questions of the use of patented medicines were resolved on an individual basis through voluntary or compulsory licensing. The Russian legislation allowed for the possibility of the parallel import of medicines. At the same time, there was an understanding of the need to enhance the procedure of clinical trials and to obtain permission to conduct such trials; enhancement of the procedure for obtaining authorization to import samples of medicines in order to examine their quality, and also procedures for introducing changes into the registration file, as well as introduction of the possibility to appeal the conclusions of expert organizations. The initiatives in question were required to provide more beneficial conditions for the circulation of medicines in the Russian market, both for domestic and foreign producers, which was especially topical in the context of Russia's accession to the WTO. The Delegation further noted that as of August 22, 2012, the rules contained in the Federal Law on Medicines had entered into force, forbidding the use of information on clinical and pre-clinical research on an original medicine without the consent of the developer for a period of six years from the date of State registration of the original medicine. The Delegation noted that on the one hand, that rule defended the interests of the producers of innovative medicines, who had invested a substantial number of resources in the development of the medicine, and on the other hand, consumers would gain access to a more expensive medicine, and while the exclusivity of data were valid, consumers lacked the opportunity to purchase cheaper generics. In order to ensure a balance between the interests of the producers and consumers, it was assumed that the rules contained in the above law on exclusivity of data would be refined in the context of the TRIPS Agreement. The Russian Federation supported the constructive proposals aimed at reducing high prices for patented medicines, in particular, by changing the mechanisms for financing scientific research. Further, the Delegation considered the study of the issues relating to the influence of the patent system on the accessibility of medicines as well as analysis of the factors limiting accessibility of patented and non-patented medicines to be extremely important.

103. The Delegation of India thanked the Chair for providing an opportunity to have the presentation on the trilateral study. The Delegation expressed its concern regarding the issue of public health and the needs of developing and least developed countries in terms of access to medicine for diseases commonly prevalent in those countries. The Delegation noted that, recognizing the importance of that issue, the Doha Declaration had affirmed that the TRIPS Agreement did not and should not prevent members from taking measures to protect public health. By considering the flexibilities in the TRIPS Agreement, India had amended its law by incorporating several provisions to address the issue of public health which included a provision on the grant of

compulsory licenses in the following cases: in case the patented products were not available to the public at reasonably affordable prices or that public needs were not satisfied; in case of emergency; for export of patented pharmaceutical products in certain exceptional circumstances to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address the public health problem; and use of invention for the purposes of government use. The national patent law also contained a "Bolar" provision and a provision allowing parallel import as an important tool enabling access to affordable medicine at lower prices. Further, the Delegation stated that patents were crucial for pharmaceutical innovations, and that without the patent system, there would be no financial incentive to fund the cost of discovery and development of the new medicines. However, the Delegation noted that the prices for medicine was often above the production costs in developing countries. Since developing countries accounted for a very small fraction of the global pharmaceutical market, in its view, income to be generated for further research and development was not dependent on the profits from those markets. Noting that the patent system had provided little incentive for research and development of medicines needed for treating diseases affecting developing countries, the Delegation highlighted the ineffectiveness of relying solely on the private sector to develop such medicines. It stated that, in many countries, due to the absence of health insurance systems, the payment of pharmaceuticals was "out of pocket". Therefore, in its opinion, escalating prices unrealistically played a central role in denying access to lifesaving medicines. The Delegation also considered that the competition policies were relevant in addressing the problem of access to medicines. In particular, the Delegation noted that the creation of sound and competitive market structure implementing the competition law and its enforcement would play an important role in enhancing access to medical technology and fostering innovation in the pharmaceutical sector. In addition, competition law had an important role to play in preventing restrictive conditions in licensing agreements relating to transfer of technology. Referring to Section 140 of the Indian Patent Act which listed cases where certain restrictive conditions in a license could be considered void, the Delegation requested the Secretariat to prepare a study on the practices being adopted by the companies in various countries concerning voluntary patent licensing and whether those practices were in line with the principle of competition to enable Member States to make suitable policy interventions at the national level to address that issue. Further, the Delegation reaffirmed its view that the effective utilization of flexibilities could also contribute to providing access to medicines at reasonably affordable prices to developing countries. In that context, the Delegation expressed its support to the proposal of the Delegation of South Africa on behalf of the African Group and the DAG on patents and health in order to find a balance between patent rights and public health. The Delegation considered that there was an urgent need to study flexibilities under international treaties, the effective implementation of compulsory licensing provisions under national patent laws, as well as the impact of the grant of compulsory licenses on the prices of patented drugs. In addition, the Delegation was of the view that the mandatory disclosure of International Nonproprietary Names in patent applications would play an important role in enabling the easier identification of generic names of medical products, which in turn would provide policy space for the utilization of patented inventions through legal means for earlier commercialization, addressing public health issues relating to diseases which were common in developing countries.

104. The Delegation of the United States of America reiterated its support for the Doha Declaration on the TRIPS Agreement and Public Health. As affirmed in the Doha Declaration, the United States of America respected Member States' right to protect public health, in particular, to promote access to medicines, and supported the vital role of the patent system in promoting the development and creation of new and innovative lifesaving medicines. Turning to the proposal of the African Group and the DAG, the Delegation expressed its disagreement with the premise of that proposal which implied that by removing obstacles related to patents and making full use of patent flexibilities available under international agreements, access to medicines in developing countries and least developed countries would be significantly improved. In the view of the Delegation, as it had expressed before in the Committee and in other international fora, patents did not prevent countries from taking measures to protect public health. The Delegation continued that, in fact, patents provided incentives to pharmaceutical industries around the world to develop

new treatments and new medicines to make them available in developing countries, and to carry out the transfer of technology that ultimately benefited those countries. In its view, without patent protection, there would likely to be fewer new drugs, treatments and diagnostic tools. The Delegation considered that there were multiple factors not related to patents that impacted the availability of medicines. It expressed its belief that focusing on patent protection as the obstacle to the availability of drugs would distort the complex and multifaceted picture and would not address the problem of access. In its opinion, that was confirmed by the trilateral study. The Delegation continued that the trilateral study had looked at the determinants of access to medical technologies and innovation, and concluded that the mere existence of intellectual property rights on a product was neither a barrier to, nor its absence of, a guarantee of access to that product. Chapters 3 and 4 of the study, in particular, highlighted that many other issues contributed to the availability of medicines, such as regulatory regimes, pricing policies, tariff policy, procurement mechanisms, sale and use of the substandard fake counterfeit medicines and complex supply chains. Turning to its proposal on patents and health, the Delegation stated that the proposed work program included three basic elements. First, inviting the WHO to make a presentation to the SCP on the availability of generic medicines in developing countries and least developed countries on non-patent barriers to availability of safe and effective medicines, and on the effect of falsified counterfeit medicines on the availability of proper medicines. Second, conducting a study on the positive impact of patent systems in providing lifesaving medicines to developing countries. In its opinion, such study would help restore balance to the discussion by evaluating the role of patent protection in providing incentives for research and development leading to innovative medicines and in fostering the technology transfer necessary to make both generic and patented medicines available. The third element of its proposal was to reflect the complexity of evaluating patents in public health, conducting a study to examine the availability of lifesaving medicines that were not protected by patents and the reasons for their lack of availability. In the view of the Delegation, such study was a necessary and responsible way to ensure that evaluation of the role of patents in affecting public health outcomes was properly informed and not obscured by other existing challenges. The Delegation took note of the preliminary comments to its proposal that had been made during the seventeenth session of the SCP and the comments that been compiled in documents SCP/18/INF/3 and SCP/18/INF/3 Add. The Delegation noted that the trilateral study contained a discussion on determinants of access and, to some extent, examined a variety of factors that determined availability of medicines. The Delegation expressed its willingness to pursue at least some elements of its proposal to provide a balanced analysis of the role of patent protection in availability of medicines. In particular, the Delegation was of the opinion that the proposed comprehensive study on the positive impact of patent systems in providing lifesaving medicines to developing countries as an important contribution to the discussion. In conclusion, the Delegation reiterated its position that any work, studies, conferences or technical assistance that came out of the SCP should be balanced and carried out within existing budgetary resources and not be duplicative. The Delegation emphasized that it could not support any work that would shift the balance towards flexibilities at the expense of rights and obligations, jeopardize the neutrality and objectivity of the Secretariat or sovereignty of Member States and place WIPO in a position of interpreting or criticizing other international agreements on the grounds that they constrained the use of the TRIPS flexibilities or would be duplicative.

105. The Delegation of Algeria, speaking on behalf of the African Group, made the following comments: firstly, relating to the status to be given to the trilateral study, the Delegation recalled that the SCP had not given any mandate to WIPO to undertake or to present any such study. Therefore, the Delegation was not in agreement to recognize the trilateral study as a working document of the SCP. In its opinion, the study should stay as an information document to help Member States discuss the issue. Secondly, the African Group, having done a comparison between the proposal of the African Group and the DAG and the trilateral study, observed that some elements in their proposal were missing in the trilateral study. Therefore, in the opinion of the Delegation, the argument that its proposal was duplicative of the work presented in the trilateral study was not a pertinent one. Referring to the first element of the African Group and the DAG's proposal relating to challenges and limitations faced by developing countries and LDCs in making

use of public health-related patent flexibilities, the Delegation stated that while the trilateral study provided an account of the various patent-related flexibilities that could be used by those countries to facilitate access to medicines and provided some examples on how some developing countries had used compulsory licenses, it did not explore the legal and structural impediments and capacity constraints that developing countries and LDCs had been facing in making full use of those flexibilities. It noted that the proposal of the African Group and the DAG called for empirical data and details to be made available on the experience of countries' use of compulsory and government use licenses on medicines which were not analyzed in the trilateral study. Further, noting that their proposal called for an analysis of the admissibility of Markush claims which, in its view, were broad and theoretical claims used as a common practice for filing evergreening patent applications, the Delegation stated that the trilateral study did not address that issue. It also did not exhaust the need for sharing information and experiences among countries on the use of patent-related flexibilities for promoting access to medicines. Therefore, the Delegation was of the view that while the trilateral study provided useful information, the SCP still had space to discuss their proposal. Referring to the proposal of the United States of America on patents and health, the Delegation stated that that proposal did not address the substantial arguments in the African Group and DAG's proposal, and sought to guide the discussions in the SCP on issues that were not related to patents and, hence, were irrelevant to the SCP and outside the WIPO's mandate. The Delegation stated that, for example, while the availability of generic medicines in developing countries and LDCs was a serious issue and patents had a significant impact therein, the proposal of the United States of America failed to acknowledge that patents could constitute a barrier to access to generic medicines in those countries unless they were balanced with public health-related flexibilities that were provided under the TRIPS Agreement.

106. The Delegation of Brazil, speaking on behalf of the DAG, expressed its support for the statement made by the Delegation of Algeria on behalf of the African Group. The Delegation stated that the proposal of the African Group and the DAG was not against patent protection. While the Delegation recognized the important role of patents in providing innovative medicines, it nevertheless noted that patents, as had been reported by the EU's Pharmaceutical Inquiry Report of 2008, might be used as obstacles to access to medicine. Referring to the trilateral study, the Delegation stated that the study provided for a good basis for the SCP to focus and build on. As an example of mechanisms outside the IP system which could be used by countries to increase access to medicine, the Delegation referred to a price control mechanism which was employed in its country. In its opinion, that was a very relevant aspect of public health policies. Referring to the compulsory license mechanism which was a factor within the IP system, the Delegation stated that through use of that mechanism, Brazil could reach 75 per cent reduction of price on medicines related to HIV/AIDS. Regarding the proposal made by the Delegation of the United States of America on that subject, the DAG was of the opinion that some elements of that proposal could bring significant challenges for the acceptance by the Committee. In particular, the Delegation referred to discussions on sanitary aspects and substandard medicines under the subtopic of enforcement which, in its view, were unrelated to the patent system. For DAG, WIPO's mandate and the objectives of the SCP did not pertain to those debates, since they had been already discussed in the WHO. The Delegation stated that the DAG and Brazil were fully against the production and commercialization of substandard or counterfeit medicines. However, such debate in the SCP would overlap with discussions in other fora, constituting unnecessary duplication. In addition, in the opinion of the Delegation, alternative mechanisms as suggested by the Delegation of the United States of America, such as tiered pricing and voluntary licensing, were adequate for specific cases and should not be seen as the generic solution for access to medicine. The Delegation pointed out that WHO's Commission on Intellectual Property Rights, Innovation and Public Health had reported the obstacles and the strategies for the use of such alternative mechanisms and the extent to which those policies depended upon the voluntary cooperation of right holders.

107. The Delegation of the United States of America, referring to the statements made by the Delegations of Algeria and Brazil, stated that since the trilateral study had addressed some of the

non-patent related elements contained in its proposal, it had no intention to pursue them. However, the Delegation was interested in pursuing some of the elements of its proposal, namely, the comprehensive study on the positive impact of patent system in providing lifesaving medicines to developing countries, which was, in its view, within the mandate of the SCP.

108. The Delegation of Argentina expressed its appreciation for the presentation made on the trilateral study. It considered that the study was an important contribution to further the discussions of the Committee on the topic. In its opinion, the question of patents and public health was of the utmost importance, and it stressed the importance of ensuring that there was no negative impact on the access to medicines. In some cases, the compulsory licensing mechanism had been used to guarantee the population access to medicine. The Delegation noted that according to the TRIPS Agreement, members of the WTO had flexibilities to define what an invention was and set definitions on the conditions for patentability, such as novelty and inventive step. The Delegation also referred to the Doha Declaration on the TRIPS Agreement and Public Health which reaffirmed the right of WTO members to make full use of the safeguard provisions of the TRIPS Agreement in order to protect public health and enhance access to medicines for poor countries. Further, the Delegation informed the Committee that different guidelines regarding chemical and pharmaceutical inventions were approved in Argentina in May 2012 with an objective of protecting public health. The Delegation expressed its belief that the proposal made by the African Group and the DAG was useful and balanced way forward. In its view, it was important that the SCP undertook the study on flexibilities provided for in the TRIPS Agreement and the implementation thereof. The Delegation reiterated its commitment to continue working in an active and constructive way on that topic. Finally, referring to the proposal made by the Delegation of the United States of America, the Delegation stated, as a preliminary comment, that the proposal had a scope different from the proposal presented by the DAG and the African Group. Furthermore, the Delegation was concerned about the conclusion made in that proposal, in particular, where it was stated that “measures that weaken patent protection systems through greater use of flexibilities are not useful in securing better availability of medicines”. In that regard, the Delegation pointed out that the WHO had recognized that patents could have an influence on access to medicines and had recommended widening the use of flexibilities within the framework of the TRIPS Agreement. In addition, the Delegation referred to numerous publications which suggested that the use of flexibilities would make it possible for governments to mitigate the negative impact of IP rights on the right to health. That debate was confirmed by the Doha Declaration on Public Health and the TRIPS Agreement, showing that legal systems must be in keeping with the interests of public health. Referring to the alternative approaches to the use of flexibilities, such as voluntary licenses and the tiered pricing contained in the proposal of the United States of America, the Delegation noted that those alternatives would depend upon the goodwill of right holders and therefore, they were questionable from the standpoint of sustainability. In relation to other topics, such as falsified drugs, and drugs of inferior quality, the Delegation was of the view that those topics went beyond the mandate of the Committee, as they were related to the laws on the commercialization of drugs. Thus, in its view, the proper forum for dealing with the issues of quality, safety and efficacy of medicines was the WHO rather than WIPO.

AGENDA ITEM 8: CONFIDENTIALITY OF COMMUNICATION BETWEEN CLIENTS AND THEIR PATENT ADVISORS: CROSS-BORDER ISSUES

109. Discussions were based on document SCP/18/6.

110. The Delegation of Belgium, speaking on behalf of Group B, emphasized that document SCP/18/6 provided a comprehensive explanation of approaches and remedies in the area of confidentiality of communications between clients and patent advisors at the national, bilateral and international level. The Delegation reiterated the importance of that topic, and strongly supported further work on it. In its opinion, the development of guidelines or any other soft law approach based upon non-binding minimum standards should be further analyzed. It was considered that

further work in that area was beneficial to all countries irrespective of their level of development, since it would enhance the credibility, reliability and stability of the international IP system. The Delegation reiterated that a non-binding approach did not result in a need for legislative changes in Member States.

111. The Delegation of Poland, speaking on behalf of CEBS, reiterated its interest in continuing the discussions on the issue of confidentiality of communications between clients and patent advisors and cross-border cases. It recalled that the Delegation had supported the statements made by the Delegations of the Russian Federation and Switzerland during the eighteenth session. In its view, a way forward for further work of the Committee was to elaborate non-mandatory minimum standards, which should provide guidelines to Member States on how to best address the topic and define national standards. The Delegation noted that such guidelines could contain possible options as well as minimum standards to be used as templates for national legislations or as tools for the mutual recognition of cross-border confidentiality of communications. In its view, permitting clients to benefit from confidentiality might enhance reliability and stability of the IP system, both in developed and developing countries, which would benefit from the achievement of a common solution among the different Member States. The Delegation was convinced that discussing that topic and developing non-binding principles or minimum standards to be applied on a voluntary basis would not interfere with national legislation. It was of the view that minimum standards were necessary to reflect and support the global nature of trade and IP, where patents for the same inventions were often sought simultaneously in a number of jurisdictions. Therefore, it strongly supported the continuation of the work on the topic within the SCP.

112. The Delegation of Ireland, speaking on behalf of the European Union and its 27 Member States, remained convinced that the convergence of the existing diverse systems in the area of confidentiality of communications between clients and patent advisors among Member States would be beneficial for users of the patent system, irrespective of the level of development of each country. It stated that the time was ripe to consider concrete mechanisms to address the recognition of foreign patent advisors' privilege. To avoid the need to amend national legislation or to change national judicial systems, a soft law approach should be considered, whereby Member States adopted non-binding principles that could be applied at the national level. The Delegation attached great importance to continue the work on the issue in the Committee. The Delegation recalled that, at the eighteenth session of SCP, work on that issue had been substantially backed up by a large number of users and organizations that considered the topic of vital importance. The Delegation sought clarification with respect to the resistance shown by some Member States against taking a non-binding soft law approach on that topic, and at the same time, addressing problems experienced by many Member States.

113. The Delegation of Switzerland stated that the Committee had a role to play on the issue of confidentiality of communication between clients and patent advisors in cross-border cases. Due to the fact that only a few countries provided clear legislation in that field, the Delegation supported the idea of minimum standards which should not be mandatory, but should give Member States guidelines on how to best address that topic and define national standards. Therefore, it supported continuing the work on cross-border aspects of confidentiality of communications between clients and patent advisors by the SCP. It suggested that the Secretariat, taking into account the views expressed and contributions made in the framework of the discussions in the SCP on that issue and based on the document SCP/18/6, prepare a guide with possible options as well as minimum standards, which could be used as templates for national legislation or as tools for the future recognition of cross-border confidentiality of communications. It noted that the progress of that work should be presented by the Secretariat at the next session of the SCP.

114. The Delegation of the Russian Federation recalled that, during a number of sessions of the SCP, it had expressed its willingness to continue the work on that issue. Thus, at the eighteenth session of the SCP, it had supported the idea of a further study of minimum international standards in that area, as reflected in paragraph 142 of document SCP/18/12 Prov.2. In its view, that might

contribute to firmly establishing the recognition of the right to professional secrecy of foreign patent attorneys and protection from compulsory discovery, on a mutual basis. The Delegation noted that, in the Russian Federation, national standards of professional secrecy of confidential communications of patent attorney with its client lagged significantly behind the standards of some other States. Therefore, proposals were made to introduce a fully-fledged institute of patent-attorney privilege into national legislation. As regards the protection of secrecy in cross-border cases, the Delegation stated that obviously, confidential information protected by the right to secrecy did not *de jure* lose such protection. Recognizing that the privilege had evidential significance in relation to the documentation exchanged between a client and a patent attorney, the Delegation observed that cross-border issues were of interest for the Russian community of patent attorneys, in connection with the international protection of commercial and professional secrecy existing in WIPO Member States. It noted that concrete examples from judicial practice, especially on how confidential materials obtained by patent attorneys from a client in one country might be used in judicial proceedings in another country, and the issue of discovery of documents in court proceedings were of importance. In its opinion, such information and its further analysis would allow Member States to reduce existing legal uncertainty in that particular area and to build a basis for regulation of that issue. To date, Russian legislation obliged a patent attorney during the performance of his/her duties not to transmit or disclose any information contained in the documents received from a client without the written consent of the person whose interests he represented. The Delegation explained that there was an exception for cases in which legislation provided that the patent attorney had no privilege if court proceedings required the disclosure of such confidential information. The Delegation of the Russian Federation supported further work of the SCP on that issue and the proposal made by the Delegation of Switzerland on the adoption of minimum standards or general non-binding principles, which might be applied at the national level. The Delegation was of the opinion that such standards and principles might provide the possibility to make a more informed evaluation of the need for legislative changes in the Russian Federation on whether to develop an instrument of mutual recognition of confidentiality on a cross-border level.

115. The Delegation of Brazil, speaking on behalf of the DAG, emphasized that document SCP/18/6 provided a good overview of the discussions in the Committee. The debates on the agenda item had provided for different approaches to the issue. Some countries were in favor of a basis for international standards, others were of the view that bilateral arrangements would best suit their needs. Further, some Members showed sensibility due to the characteristics of their legal system, and questioned the desirability of a solution which would affect civil law aspects. Taking those diverse opinions into account and the many differences between national legal systems, the Delegation expressed its belief that the best approach would be to leave flexibility for each country to define their own standards. The documents produced by the Committee so far, such as documents SCP/14/4, SCP/17/5 and SCP/18/6, could be used by countries interested in revising their national legislations. Lastly, the Delegation was of the opinon that the definition of minimal standards was not regarded as essential for the moment.

116. The Delegation of China stated that the issue of confidentiality was very valuable in guaranteeing legal services, but stressed that different situations for different countries had to be recognized. Therefore, it considered that while an investigation and survey on that issue could be useful, the Committee should not come to the conclusion that it was necessary to conduct any immediate activities.

117. The Delegation of Algeria, speaking on behalf of the African Group, recalled that the African Group had always demonstrated a favorable position to that item since the fourteenth session. However, in its view, the Committee had carried out all possible activities with respect to the topic under discussion. It noted that even if that matter was being dealt with by all Member States, it was not being dealt with in the same manner: some countries looked at the patent advisors as legal counsels, as barristers or as solicitors and some others in a different light. Therefore, it considered that, for the time being, there was no basis upon which the Committee could determine

a law in that regard, be it soft law or be it something more binding. Hence, the African Group expressed its concerns about exercising any voluntary standards, which was considered as going beyond the scope of the SCP. The Delegation expressed its view that all countries dealt with that issue by civil law, and not by patent law, based on the law of evidence in civil procedural law or civil law. Hence, it questioned whether the SCP had to deal with that matter, which seemed to fall outside its mandate.

118. The Delegation of India reiterated its view that the national laws of many countries, including India, did not have such provisions. Therefore, in its opinion, any attempt in establishing minimum standards in that regard would clearly undermine the national legislations of member countries, particularly of those which did not have such provisions. Consequently, the Delegation did not support to establish any minimum standards on that issue. The Delegation also aligned itself with the statement made by the African Group.

119. The Delegation of Senegal supported the statement made by the Delegation of Algeria on behalf of the African Group on the issue of the protection of confidentiality of communications between clients and their patent advisors. Noting that those matters were dealt with either by common law, or by disciplinary regulations under civil law, the Delegation stated that it would be very difficult to deal with them in a standard-setting manner that seemed to be proposed by some delegations. In its view, the role of IP was not to deal with issues relating to the relationship between professionals and their clients.

120. The Representative of FICPI stated that his organization had always been in favor of establishing an international system for a privilege of information between patent advisors and clients. He announced that, FICPI was conducting, together with AIPLA and AIPPI, a colloquium on protection of confidentiality inn IP advice from June 26 to 28, 2013. He informed the Committee that some NGOs and governments would receive an invitation to that colloquium.

121. The Representative of JPAA stated attorney-client privilege between clients and attorneys was basically prescribed under procedural law. He noted that there were several cases that had claimed that the privilege of Japanese patent attorneys was recognized before the courts of the United States of America. However, in his view, since Japan did not have a discovery system under its procedural law, the attorney-client privilege for Japanese patent attorneys was not correctly understood by the courts in the United States of America. The Representative explained that JPAA was therefore preparing a suggestion on a revised provision in the law on Japanese Patent Attorneys. With a view to the importance of the issue for patent holders, he strongly supported the continuation of discussions in the SCP. He further supported a soft law approach, consisting minimum standards as proposed by the Delegation of Poland on behalf of CEBS.

AGENDA ITEM 9: TRANSFER OF TECHNOLOGY

122. Discussions were based on documents SCP/18/7 and 8.

123. The Delegation of Belgium, speaking on behalf of Group B, thanked the Secretariat for its preparation of documents SCP/18/7 and 8, which provided interesting insights into the interaction between the patent system and many other elements implicated in technology transfer. In its view, the documents had clearly demonstrated that technology transfer was affected by a wide variety of elements, which included factors such as the quality of patents, a well-functioning PCT system and other elements on which the CDIP had worked arduously. The Delegation considered that the Committee should focus on the core mandate of the SCP with an evidence-based policy, based on the latest information available. The Delegation therefore suggested that the Committee should re-evaluate further work on the agenda item, once a full picture of further developments within the CDIP would be available.

124. The Delegation of Ireland, speaking on behalf of the European Union and its 27 Member States, thanked the Secretariat for preparing document SCP/18/8, expanding the study on patent-related incentives and impediments to the transfer of technology through practical examples and experience. Further, the Delegation noted with satisfaction the systematic approach and objectivity shown in document SCP/18/7, listing various activities on transfer of technology undertaken by WIPO. In its view, in general, that document showed that all efforts to improve the patent system had a positive impact to technology transfer, either directly through recommendations and projects established under the Development Agenda, or indirectly through a number of patent-related activities, including the development of legal and institutional frameworks, technological infrastructure and tools, capacity-building or raising awareness. In that respect, a 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 mentioned as examples of essential elements for the patent system to fulfill its objectives in terms of innovation and transfer of technology. As regards the Development Agenda and CDIP projects concerning technology transfer, the Delegation noted that there were five pending projects listed in document SCP/18/8, aiming at the issue of transfer of technology. In particular, it recalled that extensive work was to be undertaken under the project on "IP and Technology Transfer: Common Challenges – Building Solutions", implementing recommendations 19, 25, 26 and 28 under the Development Agenda. The Delegation therefore reiterated that until the completion of those projects and its follow-up analysis, it was not in favor of launching new initiatives on the transfer of technology within the SCP.

125. The Delegation of Poland, speaking on behalf of CEBS, thanked the Secretariat for updating document SCP/14/4 Rev.2 and for preparing documents SCP/18/7 and 8. It stated that those documents provided valuable insight into the complexity and interplay between the patent system and many other factors implicated in technology transfer. It observed that the documents also proved that while patent protection played a significant role in technology transfer, it was only one among many factors influencing such transfer. The Delegation also noted that there were still a number of technology transfer projects under way in the CDIP, for example, as referred to in documents CDIP/6/4 Rev. and CDIP/8/7. Therefore, in order to avoid the duplication of work between the SCP and the CDIP, the Delegation suggested that the SCP wait for the results of the work described in document CDIP/8/7 in order to take more informed decision on how to proceed.

126. The Delegation of Algeria, speaking on behalf of the African Group, stated that issues relating to transfer of technology were of paramount importance to the African Group. It thanked the Secretariat for documents SCP/18/7 and 8 submitted at the last session. It reiterated its comments made at the previous session, indicating that the study had not explored the extent to which patents could be an obstacle to transfer of technology and had focused only on the positive contribution made by patents to transfer of technology. The Delegation considered that, within the mandate of the SCP, all of those other aspects could be studied. With respect to the questions as to whether the work in the CDIP was overlapping with the work of the SCP, the Delegation was of the view that the discussion in the CDIP did not cover the issue of transfer of technology with a particular reference to patents. The Delegation observed that, in terms of the organization of the work of the CDIP, it consisted of five regional meetings, through which each region was supposed to identify its own challenges in terms of transfer of technology. As a participant to one of those regional level conferences, the delegation noted that the said conference had provided a holistic discussion on IP and copyright issues, but no discussion had been held whether or not the patent system was positive or negative in terms of its contribution to transfer of technology. The Delegation therefore stated that work done under the auspices of the CDIP on transfer of technology did not overlap with work that could be undertaken by the SCP.

127. The Delegation of Brazil, speaking on behalf of the DAG, thanked the Secretariat for preparing document SCP/18/8 on examples and experiences on patents and transfer of technology. In its view, it was commendable that success cases were studied, which brought encouraging results for developing countries with regard to the patenting system. Nevertheless,

the Delegation reiterated its view that failure cases were as important as success cases for that analysis, as they had the potential of providing feedback to Member States and therefore, would assist the improvement of public policies. While recognizing the importance of aspects pointed out by some delegations, such as quality of patents and the work under the PCT, the Delegation stated that transfer of technology also included other matters. In its opinion, technology transfer was a complex subject with many factors affecting an effective transfer of technology. The Delegation emphasized that the issue of absorptive capacity of national industries was directly related to the discussion of transfer of technology. Thus, it considered that the mere existence of a patent system did not automatically imply that a successful transfer of technology was carried out. Therefore, the Delegation stated that exploring such other factors was relevant for many Member States, in particular, developing countries. Additionally, the Delegation was of the view that anti-competitive practices which might be found in licensing contracts had to be effectively countered by governments, as provided for in Article 40 of the TRIPS Agreement, taking into account its potentially detrimental effect for society. Recalling a long history of the discussion on transfer of technology and patents, the Delegation noted that, in 1961, Brazil had made a proposal to the General Assembly of the UN, requesting the Secretariat to elaborate a report on "the role of patents in the transfer of technology to under-developed countries". Recently, those debates had been on the agenda of the UN Framework Convention on Climate Change (UNFCC). The Delegation observed that it was also part not only of the Development Agenda, through recommendations 22, 23, 25, 28, 29, 31 and 45, but also in Article 8 of the TRIPS Agreement which underscored the relevance of the issue thereby continuing the work on that issue in the SCP would be of benefit to all members.

128. The Delegation of Ireland, speaking on behalf of the European Union and its 27 Member States, expressed its preference that, for the time being, further work on transfer of technology should be discontinued in the SCP, pending analysis of the results of the CDIP projects. However, it noted that the European Union and its 27 Member States might consider expanding document SCP/18/8 by including further practical examples and experiences, provided that those remained objective, evidence-based and did not duplicate other work.

129. The Delegation of India reminded the Committee that patents were granted under national laws to ensure that protection and enforcement of patent rights contributed to the promotion of transfer and dissemination of technology to the mutual advantage of the producers and users of technical knowledge in a manner conducive to the social and economic welfare, as stated in the TRIPS Agreement. In its opinion, document SCP/18/7 did not reflect various obstacles faced with respect to transfer of technology and measures as to how to promote technology transfer, in particular, to developing countries. The Delegation noted that sophisticated technologies were owned and protected by persons from developed countries who did not seem to be inclined to transfer the technology, unless the recipient developing countries provided for strong patent protection, the so-called "TRIPS plus" provisions. Recalling its intervention during the eighteenth session that there had been a need to study the various impediments in licensing agreements relating to transfer of technology to developing countries and LDCs, the Delegation stated that such impediments needed to be examined in greater detail for the benefit of, not only the members of the SCP, but also for those who were interested in developing their businesses and investments in those countries. Accordingly, the Delegation urged that the study should be made more comprehensive by incorporating more examples on the issues.

130. The Delegation of the United States of America thanked the Secretariat for the extensive work on transfer of technology, as carried out in preparation for the current and the previous sessions of the Committee which resulted in documents SCP/14/4 and its several revisions, SCP/18/7 and 8. The Delegation stated that voluntary transfer of technology was an important component of economic development. In view of the extensive work already carried out, it considered that the topic had been thoroughly explored in the SCP with a study of the link between patent-related technology transfer examples, national experiences and listing of WIPO activities in the area of technology transfer. In its opinion, one of the most important benefits of the patent

system, in addition to stimulating innovation and investment, was the dissemination of technological information which provided a powerful tool for voluntary technology transfer. The Delegation observed that the patent system delivered to society a wealth of knowledge in every patent application upon its publication, which promoted the development and improvement of technology and prevented unnecessary duplication of research. In addition, the patent system provided a wealth of knowledge that was in the public domain, in the form of disclosures from patents that had expired because of the payment of maintenance fees or other reasons that made the patents no longer valid and enforceable. The Delegation stated that document SCP/14/4 Rev.2 highlighted the complexity of the issue of transfer of technology, and had increased the understanding of that complexity. Importantly, the study identified that, though a patent protection played a significant role in technology transfer, it was only one among many factors influencing such transfer. The Delegation considered that the study provided valuable insights into the complexity and the interplay between the patent system and many of the other factors implicated in technology transfer. The Delegation observed that the document led to the conclusion that technology transfer could not be increased by simply addressing the patent system, but also by other factors, such as, the absorptive capacity of the receiving party, which also had to be addressed before effective technology transfer could take place. In its opinion, many of those other related factors seemed to fall outside the scope of the SCP. Specifically, document SCP/18/7 on WIPO's activities on transfer of technology described the various activities carried out by WIPO. In its view, that document showed that many programs were already under way at WIPO with respect to technology transfer, such as the innovation and technology transfer support structures for national institutions, access and support to specialized database, developing tools for access to patent information, and the project “IP and Technology Transfer: Common Challenges – Building Solutions”. In view of the many programs already undertaken by WIPO on the topic in various phases of completion, primarily in the CDIP, the Delegation expressed its belief that the scarce resources of WIPO should not be used at that point for expanded or additional studies on technology transfer in the SCP. Rather, it considered that the ongoing studies and projects in the CDIP should first be completed and evaluated and their results should be analyzed. The Delegation concluded that a new work program related to technology transfer in the SCP would be premature and duplicative if undertaken without the benefit of the results of those programs.

131. The Representative of IIPI stated that the international IP system, particularly the patent system, benefited developed countries more than developing countries. In his opinion, one main reason for that imbalance was the abandonment of innovation in developing countries. He noted that although many developing countries found it difficult to capitalize on patents because of the inventors' inabilities to access and search patent information and license publicly-funded inventions, some countries, for example, the Philippines, had been proactive in attempting to overcome those difficulties. The Representative explained that the Philippines Technology Transfer Act of 2009 transformed technology capture and commercialization in the country. The Act, modeled on the United States of America’s Bayh-Dole Act of 1980, had made research and development institutions the default owners of IP rights arising from government-funded research. Prior to the Act, individuals and institutions in research and development had negotiated *ad hoc* agreements assigning percentage of ownership of those rights. The Representative observed that concluding those agreements had been time-consuming and had prevented researchers from commercializing their inventions. In addition to legal effects, the Act had directed Philippine institutions' attentions towards universities as potential IP negotiators. In the same year that the Act had come into force, the IPO of the Philippines had released its vision according to which the Office had dedicated to the implementation of a demystified and development-oriented patent system. Soon afterward, the IPO had announced its intention to establish, with the assistance of WIPO, a network of Innovation and Technology Support Offices (ITSOs), which served as libraries for patent information, primarily in universities. The Representative noted that the program had been successful thus far, resulting in the establishment of over 60 ITSOs throughout the country. The Representative stated that for three years, IIPI had worked with the IPO and the USPTO to capitalize on that momentum through its innovation opportunities program, which continued to help

a number of ITSOs to more effectively manage and commercialize their IP. He explained that those capacity building efforts aimed to ensure that innovation had the widest possible impact, both domestic and abroad. In his opinion, the case of the Philippines demonstrated that so-called "smart legislation", combined with international partnerships, could correct many of the imbalances in the international patent system.

132. The Delegation of the Russian Federation stated that the effects of the global crisis between 2008 and 2010 had led to even greater attention being paid to innovation by business, the State and society, and had facilitated the re-orientation of developed economies towards the innovation sector. It observed that, in many countries, renewal plans had been adopted, providing incentives for using modern technologies and a variety of innovations. At the end of 2011, the Government of the Russian Federation approved the Strategy for Innovation Development for the period up to 2020, which was aimed at the transition of the country's economic development to the innovation stage and the creation of the infrastructure of a post-industrial society, together with the use of natural resources, the internal market, science and high-quality human capital, the creation of competition and formation of real demand for innovation and stimulation of the conversion of the innovation-based economy. The Delegation noted that the most direct means to create and subsequently enhance the innovation economy was linked to the optimization of the effectiveness of legal regulations in the IP sphere. In objective terms, as a result of the accession to the WTO by the Russian Federation, strategic development was becoming an essential factor in national innovation policy in the context of the global market, and gave rise to: (i) enhancement of State regulations in the area of IP and mechanisms to protect IP; (ii) incentives to promote progress of scientific and technical activities through tax benefits and other preferential treatments; (iii) the creation of new forms of legal organizations, such as economic partnerships, investment associations etc.; and (iv) conducting of a balanced policy, taking into account competition issues, in the area of new products and technologies. The Delegation emphasized that the current strategic development was aimed at establishing constant links between scientific research and commercialization of the results of such activity. It noted that since incentives for the creation of new technologies, for their development and for their broad industrial use depended largely on a systematic approach when structuring the strategy for national innovation systems that combined fundamental scientific research and involvement of business and commercialization of their results, the legal mechanisms of IP rights had to be also considered. Therefore, the Delegation expressed its interest in continuing the discussion in the SCP of the issue of "transfer of technology". In its view, studying such issue and its connection to the patent system, strategies, mechanisms and forms of technology transfer, the relationship between patents and trade, investments and licensing as well as the identification of existing problems at the national and international levels, in particular, the misuse of exclusive rights based on patents, and the need to ensure a balance of rights between patent owners and technology users might facilitate a more successful implementation of the provisions of a strategy for innovation. The Delegation emphasized that the Strategy for Innovation and Development in the Russian Federation was the main strategy for the development of invention-related and patent-based activities, which was a precondition for the high-level technological development of the State.

AGENDA ITEM 10: CONTRIBUTION OF THE SCP TO THE IMPLEMENTATION OF THE RESPECTIVE DEVELOPMENT AGENDA RECOMMENDATIONS

133. The Chair suggested that delegations who wished to make statements on the contribution of the SCP to the implementation of the respective Development Agenda Recommendations submit them in writing to the Secretariat, and those statements would be transmitted to the WIPO General Assembly in line with the decision taken by the 2010 WIPO General Assembly relating to the Development Agenda Coordination Mechanism.

134. The SCP endorsed the above suggestion by the Chair.

135. On behalf of the European Union and its 27 Member States, the Delegation of Ireland submitted the following statement:

"On behalf of the European Union and its Member States, we would like to recall that the SCP, according to document SCP/1/2, paragraph 3 on page 2, was established to serve as a forum to discuss issues, facilitate coordination and provide guidance concerning the progressive international development of patent law including patent law harmonization. In fulfilling its mandate, this Committee can serve the well functioning of the patent system and the promotion of innovation and technology transfer, and also contribute to the implementation of a number of Recommendations of the Development Agenda.

"Since we have made relatively little progress on the different items on the agenda of this Committee, due to divergent views on how to move forward, it might be difficult to give a full picture at this stage of the implementation of the relevant Development Agenda Recommendations.

"From a procedural perspective, we would like to underline that in reporting to the General Assembly on its contribution on the implementation of the respective Recommendations of the Development Agenda, the SCP should stick to the modalities already agreed in the form of reporting. Also, according to established WIPO practice, we believe that this item in our agenda should not be a permanent one.

"We also would like to point out that when implementing a balanced work program of the SCP, we should avoid the duplication of work with other WIPO Committees and other international organizations."

136. On behalf of the DAG, the Delegation of Brazil submitted the following statement:

"DAG attaches great importance to the Coordination Mechanism of the Development Agenda, approved in 2010. According to the decision, the SCP is one of the relevant bodies to report to the General Assembly, and proceeded accordingly in 2011 and 2012. We therefore understand that this item in the agenda should be made permanent, thus correctly implementing the decision by the General-Assembly.

"The SCP has diversified its work program since the Development Agenda was approved. The agendas of the sessions are not one-sided and aim at involving subjects of interest to all Members. This balance is necessary to ensure that the Committee does not pursue, in a single-minded way, the interests of ever higher level of protection of patent rights and harmonization, what would leave aside development needs with an unwelcome " one-size-fits-all" approach.

"In this sense, the adoption by the Committee of the work program put forward by Brazil in document SCP/14/7 regarding exceptions and limitations to patent rights would be in line with Recommendation 17, which states that WIPO's activities should take into account the flexibilities in intellectual property rights' agreements. The discussions on quality of patents might relate to Recommendations 8 and 10, if it brings to light the need for providing access to patent databases and assistance to Members for improvement of national intellectual property institutional capacity through further development of their infrastructure, thus stimulating an efficiency which in turn plays an important role in the quality of patents.

"Nevertheless, much is to be done in other areas. Cluster C, on transfer of technology, still demands further work, since the obstacles and initiatives necessary to promote the transfer and dissemination of technology continue to be unclear for some Member States. Furthermore, the above-mentioned Recommendation 17 does not appear to be implemented in the subject of Patents and Health, which has, as one of its goals, to explore the flexibilities

which are useful to improve the policies with regard to health. Adopting the proposal by the African Group and the Development Agenda Group is an important step towards the implementation of this Recommendation.

"DAG expects to see the continuation of the works of this Committee with a balanced agenda that takes into account the needs of all Member States while supporting the goals of the Development Agenda."

AGENDA ITEM 11: FUTURE WORK

137. The non-exhaustive list of issues will remain open for further elaboration and discussion at the next session of the SCP.

138 Without prejudice to the mandate of the SCP, the Committee agreed that its work for the next session be confined to fact-finding and not lead to harmonization at this stage, and would be carried out as follows:

(a) Exceptions and Limitations to Patent Rights

(i) The Secretariat will prepare a document, based on input received from Member States, on how the following five exceptions and limitations are implemented in Member States, without evaluating the effectiveness of those exceptions and limitations: private and/or non-commercial use; experimental use and/or scientific research; preparation of medicines; prior use; use of articles on foreign vessels, aircrafts and land vehicles. 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/20 on the above five exceptions or limitations.

(iii) The Secretariat will prepare, for SCP/21, a document, based on input received from Member States, on how the remaining exceptions and limitations contained in document SCP/18/3 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; exceptions and limitations relating to farmers' and/or breeders' use of patented inventions. A 1/2 day seminar as proposed in document SCP/19/6 will be organized during SCP/21 on the remaining exceptions and limitations as referred to above.

(b) Quality of Patents, including Opposition Systems

Compilation, based on information received from Member States, of work-sharing programs among patent offices and use of external information for search and examination

(c) Patents and Health

Organize during SCP/20 a sharing session on countries' use of health-related patent flexibilities.

(d) Confidentiality of communications between clients and their patent advisors

(i) The Secretariat will prepare, for the next session of the SCP, a document compiling laws and practices on, and summarizing information on experiences relating to, the issue of confidentiality of communications between clients and their patent advisors received from Member States.

(ii) The Secretariat will, at the next session of the SCP, make a presentation, followed by discussion, on the issue of confidentiality of communications between clients and their patent advisors.

(e) Transfer of Technology

The Secretariat will revise document SCP/18/8 by adding further practical examples and experiences on patent-related incentives and impediments to transfer of technology on the basis of inputs received from members and observers of the SCP, taking into account the dimension of absorptive capacity in technology transfer.

AGENDA ITEM 12: SUMMARY BY THE CHAIR

139 The Chair introduced the draft Summary by the Chair (document SCP/19/7 Prov.).

140 Some delegations noted that their preference with respect to the dates of the twentieth session of the SCP was the week of December 9, 2013.

141 The Secretariat informed the SCP that its twentieth session was tentatively scheduled to be held during the week of December 9, 2013, in Geneva.

142 The Summary by the Chair (document SCP/19/7) was noted.

143 The SCP further noted that the official record of the session would be contained in the report of the session. The report would reflect all the interventions made during the meeting, and would be adopted in accordance with the procedure agreed by the SCP at its fourth session (see document SCP/4/6, paragraph 11), which provided for the members of the SCP to comment on the draft report made available on the SCP Electronic Forum. The Committee would then be invited to adopt the draft report, including the comments received, at its following session.

AGENDA ITEM 13: CLOSING OF THE SESSION

144 The Chair closed the session.

145 *The SCP unanimously adopted the report during its twentieth session on January 27, 2014.*

[Annex follows]

LISTE DES PARTICIPANTS/LIST OF PARTICIPANTS

I. ÉTATS MEMBRES/MEMBER STATES

AFRIQUE DU SUD/SOUTH AFRICA

Adurthy PRAGASHIE (Ms.), First Secretary, Permanent Mission, Geneva

ALGÉRIE/ALGERIA

Mohamed Amine HADJOUTI, directeur des brevets, Direction des brevets, Institut national algérien de propriété industrielle (INAPI), Alger
<brevets@inapi.dz>

Ahlem Sara CHARIKHI (Mme), attaché, Mission permanente, Genève

ALLEMAGNE/GERMANY

Uta BRAMBSOCH (Ms.), Deputy Head, International Industrial Property Design, Federal Ministry of Justice, German Patent and Trademark Office, Munich

ARGENTINE/ARGENTINA

Eduardo Ricardo ARIAS, Comisario de Patentes, Instituto Nacional de la Propiedad Industrial, Buenos Aires

AUSTRALIA

Tanya DUTHIE (Ms.), Assistant Director, Business Development and Strategy, International Policy and Cooperation, IP Australia, Canberra

BANGLADESH

Nazrul ISLAM, Minister, Permanent Mission, Geneva

BÉLARUS/BELARUS

Evgeny FEDOROV, Deputy Director General, Administration, National Center of Intellectual Property, Minsk
<a.chenado@belgospatent.by>

Aleksandr PYTALEV, Third Secretary, Permanent Mission, Geneva

BELGIQUE/BELGIUM

Leen DE CORT (Mme), attachée, Service public fédéral de l'économie, Petites et moyennes entreprises, Classes moyennes et énergie, Office belge de la propriété intellectuelle (ORPI), Bruxelles
<leen.decort@economie.gov.be>

Mathias KENDE, secrétaire, Mission permanente, Genève

BÉNIN/BENIN

Etienne KPOSSOU, chef du Service juridique, Centre national de la propriété industrielle (CENAPI), Ministère de l'industrie et du commerce, Cotonou
<cenapi02@yahoo.fr>

Charlemagne DEDEWANOU, Attaché, Permanent Mission, Geneva

BOTSWANA

Mmanyabela TSHEKEGA (Mrs.), Attaché, Permanent Mission, Geneva

BRÉSIL/BRAZIL

Caue FANHA, Secretary, Intellectual Property Division, Ministry of External Relations, Brasilia

BURKINA FASO

Mireille SOUGOURI KABORE (Mrs.), Attaché, Permanent Mission, Geneva

BURUNDI

Esperance UWIMANA (Mme), deuxième conseiller, Mission permanente, Genève

CANADA

Patrick BLANAR, Policy Analyst, Patent Policy Directorate, Industry Canada, Ottawa

CHILI/CHILE

Rogelio Fernando CAMPUSANO SÁEZ, Abogado, Subdirección de Patentes, Instituto Nacional de Propiedad Industrial (INAPI), Santiago
<rcampusano@inapi.cl>

Andres GUGGIANA, Consejero, Misión Permanente, Ginebra

CHINE/CHINA

WANG Weiwei, Official, Legal Affairs Department, State Intellectual Property Office (SIPO), Beijing
<wangweiwei_2@sipo.gov.cn>

ZHONG Yan, Project Administrator, International Cooperation Department, State Intellectual Property Office (SIPO), Beijing
<zhongyan@sipo.gov.cn>

COLOMBIE/COLOMBIA

Jose Luis SALAZAR LOPEZ, Director de Patentes, Superintendencia de Industria y Comercio, Bogota
<jlsalazar@sic.gov.co>

Maria Catalina GAVIRIA BRAVO (Sra.), Consejera, Misión Permanente, Ginebra

Juan Camilo SARETZKI, Primer Secretario, Misión Permanente, Ginebra
<juan.saretzki@misioncolombia.ch>

CONGO

Celestin TCHIBINDA, secrétaire, Mission permanente, Genève

COSTA RICA

Cristian MENA CHINCHILLA, Sub Director, Registro Propiedad Industrial, Registro Nacional, Ministerio de Justicia y Paz, San Jose
<cmena@rnp.go.cr>

CÔTE D'IVOIRE

Kumou MANKONGA, premier secrétaire, Mission permanente, Genève

DANEMARK/DENMARK

Anne REJNHOLD JØRGENSEN (Mrs.), Director, Policy and Legal Affairs Department, Danish Patent and Trademark Office, Ministry of Business and Growth, Taastrup

Flemming KØNIG MEJL, Chief Technical Adviser, Danish Patent and Trademark Office, Ministry of Business and Growth, Taastrup
<fsp@dkpto.dk>

EGYPTE/EGYPT

Walaa Zahy Abdo ABDELWAHED (Mrs.), Legal Examiner, Patent Office, Academy of Scientific Research and Technology, Ministry of Scientific Research, Cairo

EL SALVADOR

Rodrigo RIVAS MELHADO, Ministero Consejero, Misión Permanente, Ginebra

ESPAGNE/SPAIN

Leopoldo BELDA SORIANO, Jefe de Área de Patentes e Información Tecnológica, Departamento de Patentes e Información Tecnológica, Oficina Española de Patentes y Marcas, Ministerio de Industria, Energía y Turismo, Madrid

ESTONIE/ESTONIA

Raul KARTUS, Counsellor, Legal Department, Estonian Patent Office, Tallinn
<raul.kartus@epa.ee>

ÉTATS-UNIS D'AMÉRIQUE/UNITED STATES OF AMERICA

Paolo TREVESIN, Patent Attorney, Office of External Affairs, United States Patent and Trademark Office (USPTO), Department of Commerce, Alexandria, Virginia

Marina LAMM (Ms.), Patent Attorney, Office of Policy and External Affairs, United States Patent and Trademark Office (USPTO), Department of Commerce, Alexandria, Virginia

Karin FERRITER (Ms.), Intellectual Property Attaché, Permanent Mission, Geneva

J. Todd REVES, Intellectual Property Attaché, Economic Section, Permanent Mission, Geneva

ÉTHIOPIE/ETHIOPIA

Kassaye AYEHU, Minister Counsellor, Permanent Mission, Geneva

EX-RÉPUBLIQUE YOUGOSLAVE DE MACÉDOINE/THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA

Osmani ZUFER, Patent Examiner, Patent Department, State Office of Industrial Property of Macedonia, Skopje
<zufer.osmani@ippo.gov.mk>

FÉDÉRATION DE RUSSIE/RUSSIAN FEDERATION

Oleg DOBRYNIN, Director, Legal Department, International Cooperation Department, Federal Service for Intellectual Property (ROSPATENT), Moscow
<odobrynin @rupto.ru>

Natalia POPOVA (Ms.), Principal Specialist, International Cooperation Department, Federal Service for Intellectual Property (ROSPATENT), Moscow
<popovans@rupto.ru>

Elena SOROKINA (Mrs.), Head of Division, Federal Institute of Industrial Property, Federal Service for Intellectual Property (ROSPATENT), Moscow
<popovans@rupto.ru>

Arsen BOGATYREV, Attaché, Permanent Mission, Geneva

FINLANDE/FINLAND

Riitta LARJA (Ms.), Deputy Head of Division, National Board of Patents and Registration of Finland, Helsinki
<riitta.larja@prh.fi >

Liisa HUHTALA (Ms.), Counsellor, Ministry of Employment and the Economy, Helsinki

FRANCE

Daphné DE BECO (Mme), conseillère juridique, Service des affaires européennes et internationales, Institut national de la propriété industrielle (INPI), Courbevoie

Emilie GALLOIS (Mme), ingénieur examinateur, Direction des brevets, Service des affaires européennes et internationales, Institut national de la propriété industrielle (INPI), Courbevoie

GHANA

Sarah Norkor ANKU (Mrs.), Assistant Registrar-General/Assistant State Attorney, Registrar-General's Department, Ministry of Justice, Accra
<sarahnorkor.anku@gmail.com>

GRÈCE/GREECE

Myrto LAMBROU MAURER (Mrs.), Head, International Affairs, Department of International Affairs, Industrial Property Organization (OBI), Athens
<mlab@obi.gr>

HONDURAS

Fidel Antonio MEDINA CASTRO, Jefe del Departamento Legal, Dirección General de Propiedad Intelectual, Tegucigalpa
<fidelantonio_medina@yahoo.com>

HONGRIE/HUNGARY

Virag HGLAND DANI (Mrs.), Counsellor, Permanent Mission, Geneva

INDE/INDIA

K.S. KARDAM, Deputy Controller, Patents and Designs, Indian Patent Office, Ministry of Commerce and Industry, New Delhi

Alpana DUBEY (Mrs.), First Secretary, Permanent Mission, Geneva

INDONÉSIE/INDONESIA

Arif SYAMSUDIN, Deputy Director for Patent Examination, Directorate of Patent, Directorate General of Intellectual Property Rights, Ministry of Law and Human Rights, Jakarta

IRAN (RÉPUBLIQUE ISLAMIQUE D')/IRAN (ISLAMIC REPUBLIC OF)

Mehrdad ELYASI, Head, Patent Office, Industrial Property Office, Tehran

IRLANDE/IRELAND

Michael LYDON, Head of Patent Examination, Patents Office, Jobs, Enterprise and Innovation, Kilkenny
<michael.lydon@patentsoffice.ie>

Dolores CASSIDY (Ms.), Senior Examiner, Patents Office, Jobs, Enterprise and Innovation, Kilkenny
<dolores.cassidy@patentsoffice.ie>

ITALIE/ITALY

Vittorio RAGONESI, Legal Adviser, Ministry of Foreign Affairs, Rome

Tiberio SCHMIDLIN, First Secretary, Permanent Mission, Geneva

JAPON/JAPAN

Hiroki KITAMURA, Director, Multilateral Policy Office, International Affairs Division, General Affairs Department, Japan Patent Office, Tokyo
<pa0800@jpo.go.jp>

Tomohiro NAKANE, Assistant Director, Multilateral Policy Office, International Affairs Division, General Affairs Department, Japan Patent Office, Tokyo
<pa0800@jpo.go.jp>

Kunihiko FUSHIMI, First Secretary, Permanent Mission, Geneva

JORDANIE/JORDAN

Khaled ARABEYYAT, Director, Industrial Property Protection Directorate, Ministry of Industry and Trade, Amman

Zain AL AWAMLEH (Mrs.), Deputy Director, Industrial Property Protection Directorate, Ministry of Industry and Trade, Amman
<zain.a@mit.gov.jo>

LIBYE/LIBYA

Naema AL MERASH (Mrs.), Intellectual Property Division, National Organisation for Scientific Research, Tripoli

LITUANIE/LITHUANIA

Zilvinas DANYS, Deputy Director, State Patent Bureau of the Republic of Lithuania, Vilnius
<zilvinas.danys@vpb.gov.lt>

LUXEMBOURG

Christiane DALEIDEN DISTEFANO (Mrs.), Deputy Permanent Representative, Permanent Mission, Geneva

MADAGASCAR

Haja RASOANAIVO, Counsellor, Permanent Mission, Geneva

MALAISIE/MALAYSIA

Nurhana IKMAL, First Secretary, Permanent Mission, Geneva

MALI

Cheick Oumar COULIBALY, Counsellor, Permanent Mission, Geneva
<cheickoumar7@gmail.com>

MAROC/MOROCCO

Karima FARAH (Mme), directeur, Pôle brevet innovation technologique, Office marocain de la propriété industrielle et commerciale (OMPIC), Casablanca

Salah Eddine TAOUIS, conseiller, Mission permanente, Genève

MEXIQUE/MEXICO

Nahanny CANAL REYES (Sra.), Directora Divisional de Patentes, Instituto Mexicano de la Propiedad Industrial (IMPI), Mexico, DF.

Rosa Maria DOMINGUEZ MARTINEZ (Sra.), Coordinadora Departamental de Calidad y Opiniones Tecnicas, Direccion Divisional de Patentes, Instituto Mexicano de la Propiedad Industrial (IMPI), Mexico, DF.

Ricardo GALLEGOS MATHEY, Especialista en Propiedad Industrial, Instituto Mexicano de la Propiedad Industrial (IMPI), México, DF.

MONTÉNÉGRO /MONTENEGRO

Dušanka PEROVIĆ (Mrs.), Deputy Director, Intellectual Property Office of Montenegro, Podgorica

MYANMAR

Aye Mon WIN (Ms.), Deputy Director, Department of Technical and Vocational Education, Ministry of Science and Technology, Nay Pyi Taw

NAMIBIE/NAMIBIA

Peter NAPTHALI, Economist, Department of Trade and Commerce, Ministry of Trade and Industry, Windhoek

NÉPAL/NEPAL

Bal Sagar GIRI, Under Secretary (Legal), Ministry of Industry, Kathmandu

NIGÉRIA/NIGERIA

Eno-Obong Young USEN (Mrs.), Senior Assistant Registrar, Trademarks, Patents and Designs Registry, Federal Ministry of Trade and Investment, Abuja
<iponigeria@yahoo.co.uk>

NORVÈGE/NORWAY

Ingrid MAURITZEN (Mrs.), Head of Section, Norwegian Industrial Property Office (NIPO), Oslo
<inm@patentstyret.no>

Karine L. AIGNER (Ms.), Legal Adviser, Legal and International Affairs, Norwegian Industrial Propery Office (NIPO), Oslo
<kai@patentstyret.no>

OUGANDA/UGANDA

Eunice KIGENYI (Mrs.), Counsellor, Permanent Mission, Geneva

PAKISTAN

Ahsan NABEEL, Second Secretary, Permanent Mission, Geneva

PANAMA

Zoraida RODRIGUEZ (Mrs.), Deputy Permanent Representative, Permanent Mission, Geneva

PAYS-BAS/NETHERLANDS

Dominik FLIKWEERT (Mrs.), Intern, Permanent Mission, Geneva

PHILIPPINES

Epifanio EVASCO, Director, Bureau of Patents, Intellectual Property Office of the Philippines, Taguig City
<epifanio.evasco@ipophil.gov.ph>

Josephine REYNANTE (Mrs.), Minister, Permanent Mission, Geneva

Maria Asuncion INVENTOR (Mrs.), Attaché, Permanent Mission, GVA

POLOGNE/POLAND

Grażyna LACHOWICZ (Ms.), Adviser to the President, Cabinet of the President, Patent Office of the Republic of Poland, Warsaw
<glachowicz@uprp.pl>

Małgorzata POŁOMSKA (Ms.), Counsellor, Permanent Mission, Geneva

PORTUGAL

Ana BANDEIRA (Mrs.), Head, Patents and Utility Models Department, Portuguese Institute of Industrial Property, Lisbon

RÉPUBLIQUE DE CORÉE/REPUBLIC OF KOREA

Jeong-Hwan AHN, Deputy Director, Korean Intellectual Property Office (KIPO), Daejeon

Chung-Ho LEE, Deputy Director, Korean Intellectual Property Office (KIPO), Daejeon

Kwangnam KIM, Judge, Daegu District Court, Daegu

Shi-Hyeong KIM, IP Attaché, Permanent Mission, Geneva

RÉPUBLIQUE DE MOLDOVA/REPUBLIC OF MOLDOVA

Andrei MOISEI, Director, Legal Department, State Agency on Intellectual Property of the Republic of Moldova, Chisinau

RÉPUBLIQUE DOMINICAINE/DOMINICAN REPUBLIC

Luisa CASTILLO BAUTISTA (Sra.), Directora de Departamento, Departamento de Invenciones, Oficina Nacional de la Propiedad Industrial (ONAPI), Santo Domingo
<l.castillo@onapi.gob.do>

Ysset ROMAN (Sra.), Ministro Consejero, Misión Permanente, Ginebra

RÉPUBLIQUE TCHÈQUE/CZECH REPUBLIC

Svetlana KOPECKA (Mrs.), Director, International Department, Industrial Property Office, Prague
<skopecka@upv.cz>

ROUMANIE/ROMANIA

Petre OHAN, Director, Division for Appeals, Strategy, State Office for Inventions and Trademarks, Bucharest
<petre.ohan@osim.ro>

Gratiela COSTACHE (Mrs.), Legal Adviser, Division for Legal Affairs and International Cooperation, State Office for Inventions and Trademarks, Bucharest
<gratiela.duduta@osim.ro>

ROYAUME-UNI/UNITED KINGDOM

Hayley GOWEN (Ms.), Policy Advisor, International Policy Directorate, Intellectual Property Office, London
<hayley.gowen@ipo.gov.uk>

Philip MOUNTJOY, Policy Advisor, Patents Policy Global, Intellectual Property Office, Newport
<philip.mountjoy@ipo.gov.uk>

SÉNÉGAL/SENEGAL

Abdourahmane Fady DIALLO, directeur technique, Agence sénégalaise pour la propriété industrielle et l'innovation technologique (ASPIT), Ministère du commerce, de l'industrie et de l'artisanat, Dakar

Ndèye Fatou LO (Mme), première conseillère, Mission permanente, Genève

SERBIE/SERBIA

Aleksandra MIHAILOVIC (Mrs.), Head, Department for Legal Issues of Patents, Patent Sector, Intellectual Property Office, Belgrade
<amihailovic@zis.gov.rs>

SINGAPOUR/SINGAPORE

Simon SEOW, Director and Legal Counsel, Registry of Patents, Intellectual Property Office, Singapore

SLOVÉNIE/SLOVENIA

Helena ZALAZNIK (Mrs.), Head, Patent Department, Ministry of Economic Development and Technology, Slovenian Intellectual Property Office, Ljubljana
<helena.zalaznik@uil-sipo.si>

SRI LANKA

Natasha GOONERATNE (Mrs.), Second Secretary, Permanent Mission, Geneva

SUÈDE/SWEDEN

Marie ERIKSSON (Ms.), Head, Legal Affairs, Patent Department, Swedish Patent and Registration Office (SPRO), Stockholm

Patrik RYDMAN, Senior Patent Examiner, Patent Department, Swedish Patent and Registration Office (SPRO), Stockholm

SUISSE/SWITZERLAND

Alexandra GRAZIOLI (Mme), conseillère propriété intellectuelle, Mission permanente, Genève

Marie KRAUS (Mme), conseillère juridique, Division droit et affaires internationales, Institut Fédéral de la Propriété Intellectuelle, Berne

TADJIKISTAN/TAJIKISTAN

Farrukh NADZHMIZODA, Head of Division, State Examination of Inventions and Industrial Designs, National Center for Patents and Information (NCPI), Ministry of Economic Development and Trade, Dushanbe
<farroukh@mail.ru>

TRINITÉ-ET-TOBAGO/TRINIDAD AND TOBAGO

Mario WHITEMAN, Technical Examiner, Intellectual Property Office, Ministry of Legal Affairs, Port of Spain
<mario.whiteman@ipo.gov.tt>

Justin SOBION, First Secretary, Permanent Mission, Geneva

TUNISIE/TUNISIA

Nafaa BOUTITI, Head, Innovation Division, National Institute for Standardization and Industrial Property (INNORPI), Tunis

TURQUIE/TURKEY

Serkan ÖZKAN, Patent Examiner, Turkish Patent Institute, Ankara
<serkan.ozkan@tpe.gov.tr>

UKRAINE

Dmytro PAVLOV, Deputy Head, Division of Rights to Results of Scientific and Technical Activity, State Enterprise Ukrainian Industrial Property Institute, Kyiv
<dmitry_pavlov@uipv.org>

Inna SHATOVA (Ms.), Deputy Head, Industrial Property Division, State Intellectual Property Service of Ukraine, Kyiv
<inna_shatova@sips.gov.ua>

Denys YEHOROV, First Secretary, Permanent Mission, Geneva

VENEZUELA (RÉPUBLIQUE BOLIVARIENNE DU)/VENEZUELA (BOLIVARIAN REPUBLIC OF)

Oswaldo REQUES OLIVERO, First Secretary, Permanent Mission, Geneva

VIET NAM

Phi Anh PHAM, Deputy Director General, National Office of Intellectual Property of Viet Nam, Hanoi
<phamphianh@noip.gov.vn>

Van Son MAI, Counsellor, Permanent Mission, Geneva

ZAMBIE/ZAMBIA

Lillin BWALYA, First Secretary, Permanent Mission, Geneva

ZIMBABWE

Rhoda Tafadzwa NGARANDE, Counsellor, Permanent Mission, Geneva

II. ORGANISATIONS INTERGOUVERNEMENTALES/ INTERGOVERNMENTAL ORGANIZATIONS

CENTRE SUD (CS)/SOUTH CENTRE (SC)

Nirmalya SYAM, Program Officer, Geneva

ORGANISATION AFRICAINE DE LA PROPRIÉTÉ INTELLECTUELLE (OAPI)/AFRICAN INTELLECTUAL PROPERTY ORGANIZATION (OAPI)

Issoufou KABORE, chef de Service des brevets et autres créations à caractère technique, Yaoundé

ORGANISATION EURASIENNE DES BREVETS (OEAB)/EURASIAN PATENT ORGANIZATION (EAPO)

Aurelia CEBAN (Ms.), Director, Division of Appeals and Quality Control, Examination Department, Moscow

Ekaterina CHEKUN (Ms.), Principal Specialist, International Relations Department, Moscow

ORGANISATION EUROPÉENNE DES BREVETS (OEB)/EUROPEAN PATENT ORGANISATION (EPO)

Sylvie STROBEL (Ms.), Lawyer, International Legal Affairs Directorate, Munich

ORGANISATION MONDIALE DE LA SANTÉ (OMS)/WORLD HEALTH ORGANIZATION (WHO)

Zafar MIRZA, Coordinator, Department of Public Health, Innovation and Intellectual Property, Geneva

Peter BEYER, Senior Advisor, Department of Public Health, Innovation and Intellectual Property, Geneva
<beyerp@who.int>

ORGANISATION MONDIALE DU COMMERCE (OMC)/WORLD TRADE ORGANIZATION (WTO)

Jayashree WATAL (Ms.), Counsellor, Intellectual Property Division, Geneva

Xiaoping WU (Ms.), Counsellor, Intellectual Property Division, Geneva

UNION AFRICAINE (UA)/AFRICAN UNION (AU)

Georges Remi NAMEKONG, Minister Counselor, Geneva

UNION EUROPÉENNE (UE)/EUROPEAN UNION (EU)

Delphine LIDA (Ms.), Counsellor, EU Delegation, EEAS, Geneva
<delphine.lida@eeas.europa.eu>

Michael PRIOR, Policy Officer, DG Markt, European Commission, Brussels
<michael.prior@ec.europa.eu>

III. ORGANISATIONS NON GOUVERNEMENTALES/
NON-GOVERNMENTAL ORGANIZATIONS

Association américaine du droit de la propriété intellectuelle (AIPLA)/American Intellectual Property Law Association (AIPLA)
Thomas T. MOGA, Attorney, Washington, DC

Association asiatique d'experts juridiques en brevets (APAA)/Asian Patent Attorneys Association (APAA)
Kay KONISHI (Ms.), Co-Chairperson, Patents Committee, Osaka <konishi@p-nic.com>
Catherine LEE (Ms.), Member, Patents Committee, Seoul <ekl@bkl.co.kr>

Association européenne des étudiants en droit (ELSA International)/European Law Students' Association (ELSA International)
Linda LUBYOVA (Ms.), ELSA Slovakia, Banská Brystica
Ayca KARASIPAHI (Ms.), ELSA Austria, Vienna
Gabrielle PIERRE (Ms.), ELSA France, Paris
Zeyneb SARAOGLU, ELSA Turkey, Ankara

Association internationale pour la protection de la propriété intellectuelle (AIPPI)/International Association for the Protection of Intellectual Property (AIPPI)
Stephan FREISCHEM, Secretary General, Zurich
Michel SOFIA, Chair, Patent Committee, Zurich

Association latino-américaine des industries pharmaceutiques (ALIFAR)/Latin American Association of Pharmaceutical Industries (ALIFAR)
Rubén ABETE, Secretario General, Buenos Aires

Cámara Industrial de Laboratorios Farmacéuticos Argentinos (CILFA)
Luis Mariano GENOVESI, Gerente de Asuntos Jurídicos y de la Propiedad Intelectual, Buenos Aires <mgenovesi@cilfa.org.ar>

Centre international pour le commerce et le développement durable (ICTSD)/International Center for Trade and Sustainable Development (ICTSD)
Alessandro MARONGIU, Research Assistant, Geneva <amarongiu@ictsd.ch>

Chambre de commerce internationale (CCI)/International Chamber of Commerce (ICC)
Jennifer BRANT (Ms.), Consultant, General Electric, Geneva
Ivan HJERTMAN, European Patent Attorney, Stockholm

CropLife International
Tatjana SACHSE (Ms.), Legal Adviser, Geneva

Fédération internationale de l'industrie du médicament (FIIM)/International Federation of Pharmaceutical Manufacturers Associations (IFPMA)
Guilherme CINTRA, Manager, Geneva
Ernest KAWKA, Policy Analyst, Geneva

Fédération internationale des conseils en propriété intellectuelle (FICPI)/International Federation of Intellectual Property Attorneys (FICPI)
Arild TOFTING, CET Reporter General, Oslo <arild.tofting@ficpi.org>
Jerome COLLIN, Partner, Patent Section, Regimbeau, Paris <collin@regimbeau.eu>

International Intellectual Property Institute (IIPI)
Jorge AMIGO, Vice Chairman, Mexico City <jorgehamigo@gmail.com>
Andrew JAYNES, Executive Director and General Counsel, Washington

Japan Patent Attorneys Association (JPAA)
Takaaki KIMURA, International Activities Center, Tokyo <gyoumukokusai@jpaa.or.jp>

Knowledge Ecology International, Inc. (KEI)
Thiru BALASUBRAMANIAM, Geneva Representative, Geneva

Max Planck Institute for Intellectual Property and Competition Law (MPI)
Roberto ROMANDINI, Researcher, Munich

Medicines Patent Pool Foundation (MPP)
Erika DUENAS (Ms.), Advocacy Officer, Geneva

Médecins Sans Frontières (MSF)
Hafiz AZIZ UR REHMAN, Legal and Policy Advisor, Geneva

IV. BUREAU/OFFICERS

Président/Chair : Vittorio RAGONESI (Italie/Italy)

Vice-président/Vice-Chair : Sarah Norkor ANKU (Mme/Mrs.) (Ghana)

Secrétaire/Secretary : Philippe BAECHTOLD (OMPI/WIPO)

V. BUREAU INTERNATIONAL DE L'ORGANISATION MONDIALE DE LA PROPRIÉTÉ INTELLECTUELLE (OMPI)/INTERNATIONAL BUREAU OF THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO)

Francis GURRY, directeur général/Director General

James POOLEY, vice-directeur général, Secteur de l'innovation et de la technologie/
Deputy Director General, Innovation and Technology Sector

Division du droit des brevets/Patent Law Division:

Philippe BAECHTOLD, directeur/Director

Tomoko MIYAMOTO (Mme/Ms.), chef de la Section du droit des brevets /Head, Patent Law Section

Aida DOLOTBAEVA (Mlle/Ms.), juriste, Section du droit des brevets/Legal Officer, Patent Law Section

Thomas HENNINGER, administrateur adjoint, Section du droit des brevets/Associate Officer, Patent Law Section

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