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Standing Committee on the Law of Patents

Eighteenth Session
Geneva, May 21 to 25, 2012

DRAFT REPORT

prepared by the Secretariat

INTRODUCTION

1. The Standing Committee on the Law of Patents ("the Committee" or "the SCP") held its eighteenth session in Geneva from May 21 to 25, 2012.

2. The following States members of WIPO and/or the Paris Union were represented: Algeria, Angola, Argentina, Armenia, Australia, Austria, Barbados, Belgium, Bosnia and Herzegovina, Botswana, Brazil, Brunei Darussalam, Burkina Faso, Burundi, Cameroon, Canada, Chad, China, Colombia, Côte d'Ivoire, Congo, Costa Rica, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Djibouti, Dominican Republic, Egypt, El Salvador, Estonia, Finland, France, Georgia, Germany, Ghana, Hungary, India, Indonesia, Iraq, Ireland, Islamic Republic of Iran, Italy, Japan, Kazakhstan, Kuwait, Lebanon, Libya, Lithuania, Malaysia, Mexico, Morocco, Nepal, Netherlands, New Zealand, Norway, Panama, Paraguay, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Saudi Arabia, Senegal, Serbia, Singapore, Slovenia, South Africa, Spain, Sweden, Switzerland, Thailand, The former Yugoslav Republic of Macedonia, Togo, Trinidad and Tobago, Tunisia, Turkey, Ukraine, United Kingdom, United Republic of Tanzania, United States of America, Uruguay, Venezuela (Bolivarian Republic of) (Bolivarian Republic of), Viet Nam and Zambia (90).

3. Representatives of the African Intellectual Property Organization (OAPI), 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), *Association française des spécialistes en propriété industrielle de l'industrie (ASPI),* Chamber of Commerce and Industry of the Russian Federation (CCIRF), Civil Society Coalition (CSC), Fridtjof Nansen Institute (FNI), Fundaçao Getulio Vargas (FGV), German Association for Industrial Property and Copyright (GRUR), Institute of Professional Representatives before the European Patent Office (EPI), Intellectual Property Institute of Canada (IPIC), 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 Intellectual Property Attorneys (FICPI), International Federation of Pharmaceutical Manufacturers Association (IFPMA), Japan Patent Attorneys Association (JPAA), Knowledge Ecology International, Inc. (KEI), Latin American Association of Pharmaceutical Industries (ALIFAR), *Médecins sans frontières* (MSF) and Third World Network (TWN) (20).

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: "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 Members and Observers of the Standing Committee on the Law of Patents (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/17/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.), "Report on the International Patent System: Revised Annex II of document SCP/12/3 Rev.2" (SCP/18/2), "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), "Patents and Transfer of Technology: Examples and Experiences" (SCP/18/8), "Questionnaire on Quality of Patents: Proposal by the Delegations of Canada and the United Kingdom" (SCP/18/9), and "Accreditation of Observers" (SCP/18/10).

7. The following related documents were also considered by the Committee: "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), "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), "Report on the International Patent System" (SCP/12/3 Rev.2) and "Addendum to the Report on the International Patent System" (SCP/12/3 Rev.2 Add.).

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

AGENDA ITEM 1: OPENING OF THE SESSION

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

AGENDA ITEM 2: ELECTION OF A CHAIR AND TWO VICE-CHAIRS

10. The SCP unanimously elected, for one year, Mr. Vittorio Ragonesi (Italy) as Chair and Mrs. Sarah Norkor Anku (Ghana) and Mr. Simon Seow (Singapore) as Vice-Chairs.

AGENDA ITEM 3: ADOPTION OF THE AGENDA

11. The Delegation of Algeria, 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. It noted that the SCP, which dealt with the relationship between patents and innovation, could contribute to the discussions at the Committee on Development and Intellectual Property (CDIP) and the General Assembly regarding the implementation of the Development Agenda.

12. The Delegation of Egypt, speaking on behalf of the African Group, supported the proposal made by the Delegation of Algeria on behalf of the DAG.

13. The Secretariat recalled that, when confronted with that issue at the sixteenth session of the SCP, the Committee had decided to add an agenda item "Contribution of the SCP to the implementation of the respective Development Agenda recommendations", which had been considered not to be a standing agenda item.

14. The Delegation of the United States of America, speaking on behalf of Group B, stated that it could support the proposal made by the Delegation of Algeria on behalf of the DAG, with the understanding that the new item would not be a standing agenda item.

15. The Delegation of Venezuela (Bolivarian Republic of) supported the proposal made by the Delegation of Algeria on behalf of the DAG.

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

17. The SCP adopted the revised draft agenda (SCP/18/1 Prov.2) with the addition of a new item 12: Contribution of the SCP to the implementation of the respective Development Agenda recommendations (see document SCP/18/1).

AGENDA ITEM 4: ADOPTION OF THE DRAFT REPORT OF THE SEVENTEENTH SESSION

18. The Committee adopted the draft report of its seventeenth session (document SCP/17/13 Prov.2) as proposed.

AGENDA ITEM 5: ACCREDITATION OF OBSERVERS

19. The SCP approved the accreditation of the Drugs for Neglected Diseases *initiative* (DND*i*) as *ad hoc* observer (document SCP/18/10).

GENERAL DECLARATIONS

20. The Delegation of the United States of America, speaking on behalf of Group B, stated that Group B entered the eighteenth session of the SCP with the willingness to engage in a positive dialogue on the issues that were comprised in the balanced work plan, namely, exceptions and limitations to patent rights, quality of patents including opposition systems, patents and health, confidentiality of communications between clients and patent advisors and transfer of technology. The Delegation remained optimistic, and noted that the work on those topics would lead to a more thorough understanding of the specific issues impacting the international patent system. The Delegation reiterated that technical exchange of information on patent law, practice and policies should be the benchmark in measuring progress in the SCP and feed into the broader considerations of public policy issues at WIPO. The Delegation expressed its hope that those topics and an understanding of the varying viewpoints would lead to a more efficient, effective and accessible international patent system and would eventually lead to substantive patent law harmonization. The Delegation considered that discussions during the eighteenth session should be undertaken in a manner which improved the quality of the patent system as a tool to deliver economic and social policy objectives.

21. The Delegation of Paraguay, speaking on behalf of the Group of Countries of Latin America and the Caribbean (GRULAC) reaffirmed its desire to continue to support the activities of the SCP on the understanding that it would fulfill its mandate of encouraging substantive discussions among Member States regarding the progressive development of patent law. As regards the Report on the International Patent System, the Delegation suggested that it remain open to future revisions so that any legal modifications which might occur in Member States could be incorporated. As to exceptions and limitations, the Delegation noted the relatively large number of responses to the questionnaire received. Stressing the importance of that agenda item for GRULAC, while the Delegation expressed its regret that document SCP/18/3 had not been translated far enough ahead of time, the Delegation expressed its willingness to analyze the document and to move forward on that issue. On the issue of quality of patents, including opposition systems, the Delegation considered that the contents of document SCP/18/9 was a good way of moving the agenda forward on that particular issue without prejudging what was understood by each Member State by “quality of patents”. The Delegation stressed the importance of having access to databases for examining the compliance with patentability requirements. The Delegation stated that document SCP/18/4 placed in context various aspects of opposition procedures. While they could have positive effects, the Delegation noted that the necessary safeguards should be established in order to avoid abuse of the opposition systems with the sole objective of prolonging the patenting procedure. While supporting the discussion of item 9 of the agenda that dealt with patents and health, the Delegation noted that it was an extremely complex issue. With respect to confidentiality of communications between clients and their patent advisors, the Delegation was of the view that the discussion on that topic was nearly complete. According to its initial analysis, the best alternative would be dealing with the issue under national legislation, since practical solutions described in document SCP/18/6 had suggested practical difficulties for standardizing national practices in countries with different legal systems.

22. The Delegation of Algeria, speaking on behalf of the DAG, noted that discussions of the Committee were particularly important for the members of DAG. It noted that patent rights had considerable direct impact on social and economic development, and that the fundamental balance between the interests of those who held rights and the interests of the general public

had to be developed. The Delegation therefore considered that the activities of the SCP needed to facilitate the distribution and sharing of technologies so that the patent system helped to promote progressive innovation. In its opinion, the studies on the issues of exceptions and limitations, patents and health and quality of patents highlighted the challenges developing countries were faced with in terms of development. In that regard, the Delegation observed that facilitating a better understanding of the patent system also allowed developing countries to better adapt and adjust the system to respond to national development needs. Since it was vital to turn intellectual property to a service that supported economic development and growth, the Delegation considered that it was essential to implement the goals of the CDIP in a permanent manner, based on the coordination mechanisms and follow-up measures that were set out by the CDIP. The Delegation attached considerable importance to exceptions and limitations, which gave developing countries a space for maneuver in terms of intellectual property. It considered that developing a global intellectual property concept that also involved developing countries had a direct impact on development. It noted that developing countries were aware of the need to adapt their national patent legislations to their economic conditions, ensuring that exceptions and limitations were in place. Therefore, the Delegation stated that the SCP should make progress on the basis of the Brazilian proposal. The Delegation expressed its hope that the questionnaire on exceptions and limitations as well as the contributions of other Member States would allow the Committee to draw some conclusions on the types of exceptions and limitations in order to respond to its concerns. In its opinion, the SCP should move in the direction suggested by the Brazilian proposal, which was to set out non-exhaustively a list of exceptions and limitations which would provide a reference tool for Member States. Regarding quality of patents, the DAG reiterated its concern based on the lack of a precise definition of high-quality patents. The Delegation stated that the proposals submitted by some delegations could not be fully taken into account if the Committee did not have a collectively-agreed definition of high-quality patents. In its view, since high quality of patents needed to take into account the development objectives of each country, it was impossible to improve the quality of patents only by adopting the practices that were used by one or two national offices and were not adopted or shared by all Member States. The Delegation considered that such an initiative would not allow the DAG members to attain their goals. In its opinion, harmonization of patent laws could damage the room for maneuver within national legislation in each country. Regarding the issue of patents and health, being aware of the work that had been done by WIPO on that topic, the Delegation expressed its opinion that WIPO needed to bolster its engagement in that area by looking at its existing and future activities to achieve international objectives. Referring to the joint proposal by the African Group and the DAG, it stated that the proposed work program would help Member States, especially developing countries and least developed countries (LDCs), adapt their patent systems so as to take full advantage of the flexibilities within the international patent system and thereby to promote their public health policies. The Delegation was of the opinion that it was essential to resolve that problem and to remove the obstacles which developing countries were facing when they wished to apply flexibilities that were in place for public health. In its view, WIPO, as a specialized agency of the United Nations (UN) concerning intellectual property, was the agency that was suited to pursue that role, and the SCP was the best setting for discussing the issues. Noting the position of the Delegation of the United States of America on patents and health, the Delegation expressed its hope that the DAG would not be distracted from its main goal, namely, to permit developing countries and LDCs to take full advantage of the flexibilities that had been in place to support public health. With respect to transfer of technology, the Delegation expressed its hope that the documents provided by the Secretariat concerning transfer of technology would allow the SCP to take concrete steps on that issue. Finally, the Delegation hoped that, at its eighteenth session, the SCP would reach an agreement on that issue in order to implement an international patent system that was more balanced. The Delegation stated that the progress of the eighteenth session would depend on how much delegations would understand each other and were flexible to reach an agreement. The Delegation expressed its willingness to explore all elements that could help the Committee to move forward.

23. The Delegation of Denmark, speaking on behalf of the European Union and its 27 Member States, noted that the eighteenth session of the SCP would continue discussions on significant issues such as quality of patents, including opposition systems, exceptions and limitations to patent rights, patents and health, confidentiality of communications between clients and their patent advisors and transfer of technology, addressing important and complex questions of the international patent system. In its understanding, all of those discussions aimed at getting a more efficient and accessible patent system as a whole. In particular, the Delegation attached considerable importance to advancing work on the quality of patents along the lines proposed by the Delegations of Canada and the United Kingdom, Denmark and the United States of America. The Delegation renewed its commitment to continue working on the issues of opposition systems and confidentiality of communications between clients and their patent advisors, which were of benefit to users of the patent system. Further, the Delegation expressed its readiness to continue discussions on exceptions and limitations to patent rights and on possible future steps regarding that topic. In that context, the Delegation emphasized that the utmost importance of striking an appropriate balance between work on exceptions and limitations to patent rights and on legal standards for determining the patentability of inventions, as those two issues were closely interlinked. Given the importance of the issue of patents and health for tackling public health problems in developing countries and LDCs, the Delegation stated that it fully understood the interest of those countries to include that topic in the future work of the SCP. Taking into account the great number of ongoing projects, work programs and other activities within, in particular, WIPO, the World Health Organization (WHO) and the World Trade Organization (WTO), the Delegation was of the view that any possible initiative of the Committee in that area should be carefully considered in order to avoid duplication of efforts either within WIPO or among international organizations. Similarly, the Delegation stated that possible future activities of the SCP in relation to transfer of technology should be considered only after the completion of extensive work which was being undertaken under the project on intellectual property and technology transfer within the CDIP and its follow-up analysis. The European Union and its 27 Member States expressed the hope that a balanced work program of the Committee enabling fruitful discussions on technical issues concerning patent law would be promptly established. They further stated that that would lead to working towards the international harmonization of substantive patent law to which they were strongly committed.

24. The Delegation of Egypt, speaking on behalf of the African Group, stated that the SCP had advanced a balanced work program during the past few sessions, discussing issues equally important to Member States. The Delegation noted that it was particularly interested in the following substantive agenda items: patents and health, quality of patents, technology transfer, exceptions and limitations to patent rights and future work, in addition to the contribution of the SCP to the implementation of the Development Agenda recommendations. In its view, the mainstreaming of the Development Agenda in WIPO bodies was an imperative, and as such, the African Group considered that discussions and work of the Committee should be guided by the relevant Development Agenda recommendations. The Delegation recalled that the African Group had requested the SCP, at its fifteenth session, to include in its future work the topic “patents and health” which had already been included in the non-exhaustive list of issues. It was one of the key priorities of Africa. The Delegation observed that empirical evidence indicated that nowhere a global health challenge was more acute than in Africa, and therefore, access and affordability to medicines and diagnostic tools for the poor was a fundamental challenge to Africa. In its view, an integrated solution was required to alleviate the plight of African countries in reducing the cost of healthcare delivery, especially in accessing affordable medical products, including medicines, vaccines and diagnostic kits. The Delegation expressed its belief that WIPO could play a pivotal and vital role in that regard by promoting the understanding on the relation between patent costs and procurement practices related to access to medical products. Furthermore, it noted that WIPO could facilitate the understanding on the challenges countries encountered when using patented products for their research and development of new medicines or for improving access to those medicines. Most importantly, the Delegation observed that WIPO could ensure that the patent system, especially regarding

its built-in flexibilities, was being used optimally by all developing countries. Against that backdrop, the African Group expressed its hope for a constructive discussion and an approval of the proposal by the African Group and the DAG on patent and public health. The Delegation further stated that transfer of technology was an important issue, as in recent years, transfer of technology had become a topical issue in many international fora. The Delegation therefore considered that WIPO, by virtue of being the main organization responsible for intellectual property within the UN system, should actively lead the discussions on the interface between patents and technology transfer. The Delegation expressed its belief that more work still needed to be done in that area. Similarly, the Delegation stated that sufficient consideration must be given to the question as to how patent law flexibilities could be exploited to promote transfer of technology, which was an important question to developing countries. The Delegation recalled that the Development Agenda recommendations included substantive elements on the issue of transfer of technology which had to be mainstreamed across the activities of WIPO. In respect to future work, the African Group was of the view that the SCP should focus on issues of common interest to the membership, particularly for developing countries and LDCs. In that regard, the Delegation considered that the non-exhaustive list of issues should remain open for further elaboration and discussion and that any addition to the list should be agreed by consensus.

25. The Delegation of Iran (Islamic Republic of), speaking on behalf of the Asian Group, stated that the SCP should address the important questions relating to the current international patent system and come up with tangible solutions to the existing challenges. Expressing its satisfaction on the advancement of the balanced work program, it reiterated its commitment to continue discussions and engage constructively in all of the issues on the agenda. The Delegation expressed its hope that the Committee, through such discussions, would be able to contribute to the advancement of a more balanced, efficient and accessible international patent system. As regards the exceptions and limitations to patent rights, acknowledging the importance of the issue, the Delegation considered that it was crucial for Member States to determine the exceptions and limitations that were in line with their own circumstances to allow the highest levels of economic development to be achieved, while respecting their treaty obligations. It noted that the questionnaire as well as the overview of the responses to the questionnaire contained useful information, and expressed its hope for further advancement of that topic. Regarding the quality of patents, since it was one of the important issues in the patent system, the Asian Group welcomed any initiative which could help the enhancement of patent quality, while respecting differences in national patent laws. The Delegation expressed its belief that the definition of “quality of patents” should be broad and open for further views and comments. Noting that the work program proposed for the topic of quality of patents had three main components, i.e., technical infrastructure development, information access and exchange on quality of patents and process improvements, the Delegation expressed its support for further work under those components. The Delegation reiterated that training programs needed to be given due consideration and should be developed as the fourth component or as an underlying element between each component. The Delegation considered that discussion on that topic could lead to a more effective and balanced patent system which would take into account the interests of all members of society and promote innovation and development in the countries. The Delegation also expressed its Group’s keen interest in continuing discussions on the subject of technology transfer. Noting that that subject had been under discussions for a long period of time in the SCP, the Delegation welcomed document SCP/18/7 concerning WIPO's activities on transfer of technology, and observed that the Committee should focus on the patent perspective of technology transfer. The Delegation expressed its willingness to have a balanced discussion on the analysis of the incentives and impediments of the patent system in respect of transfer of technology. In addition, it noted that sufficient consideration should be given to patent law flexibilities and their possible role in the promotion of transfer of technology. The issue of patents and health and having access to essential medicines for an affordable price was also an important issue for Asian Group. The Delegation stated that the Committee should explore practical ways to respond to existing challenges, including the use of flexibilities

in international agreements. The Delegation welcomed document SCP/18/5 which listed projects and activities, including the status or outcome on patents and health in WIPO, the WHO and WTO. It considered that the information contained in that document was useful in developing a focused work plan on patents and health in the SCP. Regarding the issue of confidentiality of communications between clients and their patent advisors, The Delegation stated that the Asian Group welcomed further discussion in order to enable Member States to better understand the impact of different national laws on cross-border issues. Further, the Delegation expressed its belief that the SCP should continue keeping the non-exhaustive list of issues open in order to allow for a comprehensive and balanced work plan for the future.

26. The Delegation of Hungary, speaking on behalf of the Regional Group of Central European and Baltic States (CEBS), observed that, during the last three years, the members of the SCP had been discussing highly complex and pertinent issues, such as quality of patents, opposition systems, the confidentiality of communications between clients and their patent advisors, exceptions and limitations to patent rights, patents and health and technology transfer. The Delegation expressed its belief that the outcome of those discussions should serve as a substantial contribution to the Committee's main goal of strengthening and improving the functioning of the international patent system. The Delegation welcomed all of the valuable proposals submitted by Member States concerning the different topics on the agenda of the Committee. The Delegation attached particular importance to the work on quality of patents, and expressed its commitment to continuing discussions on the basis of the proposals put forward by the Delegations of Canada and the United Kingdom, Denmark and the United States of America. As a number of Offices in its region participated actively in the international cooperation in the field of patents, the Delegation considered that, as a first step, launching a questionnaire in order to gather more knowledge and evaluate different approaches implemented by Member States was highly appropriate. For those reasons, the Delegation expressed its hope that, during its eighteenth session, the SCP would finally be in a position to launch the questionnaire proposed by the Delegation of Canada and the United Kingdom in document SCP/18/9. Being a strong proponent of the issue of confidentiality of communications between clients and patent advisors, the Delegation stated that that topic needed further examination. In its view, finding remedies with respect to the identified problems would be a benefit to users of the patent system in every WIPO Member State. The Delegation was of the opinion that, as a first step, the adoption of non-binding principles could be a way forward. In addition, the Delegation stressed its readiness to have discussions on exceptions and limitations to patent rights, patents and health and transfer of technology. While the Delegation attached importance to those discussions, it emphasized that discussions on all topics should take place in a balanced manner, and that the Committee should not lose sight of the core principles of its mandate. Furthermore, the Delegation stated that, in order to be as efficient as possible, the SCP should avoid duplication of efforts, and constantly be attentive to the ongoing projects and activities carried out or undertaken in other WIPO bodies, in particular, the CDIP, or by other relevant international organizations, such as the WTO and the WHO. As a general principle, the Delegation stressed the importance of maintaining a balanced work program for the SCP, and hoped that members would all work for that common goal. The Delegation reiterated that discussions on technical issues on patent law would bring an outcome beneficial for all Member States of WIPO, and reaffirmed its commitment to working towards the international harmonization of patent law which might be in response to the needs of the users in the patent system.

27. The Delegation of India reaffirmed its views which had been expressed during the previous session of the SCP, in particular, on the issues related to transfer of technology, opposition systems, client-patent advisor privilege, quality of patents, the international patent system and patents and health. The Delegation emphasized that ever-greening practices and incremental innovations without substantial improvement would have adverse impact on delivery of health care services. It noted that, according to the Indian Patents Act, unless the invention showed enhancement of the known efficacy by way of significant differences in the

properties, apart from meeting independently the requirement of patentability, such invention could not be patented. Furthermore, the Delegation considered that the flexibility allowed under the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) could also greatly contribute to providing access to medicines at reasonably affordable prices to the poor of the world. In that context, the Delegation noted its satisfaction to the organization by WIPO of an upcoming seminar on compulsory licensing, price control and access to patented products by WIPO. The Delegation, however, was of the view that a study should be conducted by WIPO, documenting the compulsory license practices in its Member States and focusing on the manner in which Articles 31 and 40.2 of the TRIPS Agreement had been implemented by the Member States. Regarding the topic of quality of patents, the Delegation expressed its firm belief that patent offices across the world alone would not be able to maintain the quality of patents without maintaining the standards of examination and search. In its view, most of the patent offices in developing countries were in transition phases and needed to upgrade their systems, in particular the systems related to prior art search and human resource development. Therefore, the Delegation considered that the Patent Prosecution Highway (PPH) might not be the remedy for improving the quality of patents. Rather, in its opinion, it could weaken the examination processes in developing countries. The Delegation was of the view that steps should be taken to build capacity of intellectual property offices of developing countries in order to enable them to carry out their quasi-judicial functions in the best manner possible. Furthermore, the Delegation stated that there should be much more onus on applicants to disclose more prior art, in particular, they should also be expected to disclose search reports and findings related to the patentability of an invention contained in the corresponding foreign applications as well as their outcome to patent offices if such applications were rejected by other patent offices. It noted that Article 29 of the TRIPS Agreement clearly mandated such disclosure, including the provision of information concerning the applicant's corresponding foreign applications and grants. The Delegation explained that a provision in the Indian Patents Act required applicants to submit such information, and failure to do so was the ground for opposition as well as revocation of patents. Regarding document SCP/18/6 on the confidentiality of communication between clients and patent advisors, the Delegation expressed its concern about the proposal made by the ICC which obliged a country to recognize the privileges of other countries. The Delegation reaffirmed its view that such a move imposed extra-jurisdictional powers which was a violation of the sovereignty of a government. It noted that there was no provision for client-attorney privilege in the Indian Patents Act, and that Indian citizens who were science graduates and qualified the patent agent examination could practice as patent agents even without a law degree. In conclusion, the Delegation expressed its satisfaction on the progress made by the SCP in bringing out reasonable studies giving a clear picture on the existing situation across countries on the subjects under consideration. It stated that greater emphasis was required to ensure that developing countries and LDCs would benefit from the patent system. In that context, the Delegation suggested that the Secretariat prepare a study on the practices being adopted with respect to voluntary licensing of patents and whether they were in line with the principle of competition. In its view, the study would enlist the body of literature on the licensing practices adopted by companies across Member States which would have suitable policy interventions at the national level to address the issue.

AGENDA ITEM 6: REPORT ON THE INTERNATIONAL PATENT SYSTEM

28. The discussions were based on documents SCP/12/3 Rev.2, SCP/12/3 Rev.2 Add. and SCP/18/2.

29. The Secretariat noted that, with respect to the Annex of document SCP/18/3, it had received a communication from the Republic of Korea, indicating that its grace period had been extended from six months to one year. It explained that, while that information was not included in the document due to the late submission of the communication, it would be included in a future updated document.

30. The Delegation of Argentina made observations on document SCP/12/3 Rev.2. It requested that its comment, which would be submitted in writing, be added in Annex III of the above document. While the Delegation appreciated the attempt to reflect all points of view in the Report of the International Patent System, especially on the public policy issues, it considered that there were areas which deserved more in-depth consideration, particularly the implications of patents for development. Regarding paragraph 46 in Chapter II (the economic rationale for patents and different interests and needs in the international patent system), the Delegation stated that while some research had indicated that patent law, which was extremely complex, affected foreign direct investment, in its view, the characteristics of intellectual property rights was one of those elements that might determine the attractiveness of foreign direct investment, which was also influenced by the cost factors, the size of the market, commercialization costs and other local issues. The Delegation observed that those countries which had reinforced their intellectual property rights were not the only countries that saw a change in investments. Referring to paragraph 45 on the positive impact of stronger patent laws in developing countries on bilateral trade, the Delegation noted that some economic analysis indicated that, at the level of bilateral trade, the effects were ambiguous, and that there were difficulties in relating dynamic issues with a policy of increased IP protection. The Delegation observed that, in the Chapter related to economic rationales, there was the assumption of an increase of the international technology market. However, in its view, only few countries participated in that market, and most of the studies had been undertaken in developed countries. The Delegation stated that a better patent system would be required in developing countries in order to support innovation and development. As to the effectiveness of patents as an incentive to innovation (pages 83 to 88 in the Spanish version), development related concerns, the Delegation considered that there were other weaknesses in the patent system which would deserve objective study, for example, the extent of litigation and measures restricting competitions because of poor quality of patents. The Delegation urged the Secretariat that, in the future, the report should address the implications of the patent system from a public policy perspective, particularly on issues such as health, biodiversity, transfer of technology, among others. In its view, intensifying research in that area would improve the various aspects of the patent system and contribute to a better understanding of the role of the patent system in developing countries.

31. The Delegation of India noted the following points relating to the Indian Patents Act with respect to document SCP/18/2: (i) there was no suit of infringement during the period between the date of the lapsing of the patent due to lack of renewal and the date of the publication of reinstatement; (ii) the Government had the power to revoke patents in the cases where the protection of the security of the country was concerned under Section 157A of the Act; (iii) the Government had the power to revoke a patent in public interest, for example, where patents were misused and generally prejudicial to the country; (iv) in order to avoid providing misleading information, the entire provision of Section 3(d) should be referred to in connection with the exclusions from patentability; and (v) as far as the sufficiency of disclosure was concerned, the entire provisions of Section 10(4) of the Act referring to sufficiency of disclosure, which related to a deposit of biological material, needed to be incorporated. The Delegation explained that in order to ensure the completeness of applications, applicants should provide the characteristics of the biological material in the specification including the name and address of the deposit authority and the date and the number of the deposit, and disclose the source and origin of the material in the specification if such material was used in the invention. The Delegation noted that it would submit its comments in writing.

32. The SCP agreed that this agenda item would remain on the agenda of the next session of the SCP. The above documents would be updated based on the comments received from Member States.

AGENDA ITEM 7: EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

33. The discussions were based on documents SCP/14/7 and SCP/18/3.

34. The Delegation of Brazil expressed its satisfaction with the recent discussions held in the SCP. It noted that important aspects of the patent system had been discussed, providing useful input for governments when examining and improving their standards with regard to patents. Furthermore, it stated that the Development Agenda also appeared to be taken into account by delegations, as could be seen in some of the proposals under the agenda of the eighteenth session, thus underlining the relevance of the SCP to the Development Agenda recommendations. In its view, 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. The Delegation expressed its belief that a flexible policy space was necessary in order to allow a Member State, whether a developed or developing country, to develop and adapt the set of exceptions and limitations more adequately for their realities. The Delegation recalled that it had proposed, at the fourteenth session, that the Committee adopt a work program on that topic. Considering the time elapsed and the amount of information provided through the discussions and the questionnaire, the Delegation was of the opinion that time was ripe for the formal adoption of its proposal by the SCP. The Delegation noted that document SCP/18/3 contained interesting information displayed in a panoramic view, allowing an overview of responses to the questionnaire. The Delegation, however, considered that the simple existence of an exception or limitation 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 its proposal, which aimed at investigating which exceptions and 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 also proposed that, at a later stage, the Committee consider the elaboration of an exceptions and limitations manual, in a non-exhaustive manner, to serve as reference for WIPO Member States.

35. The Delegation of the Russian Federation recalled that, at previous sessions of the SCP, it had submitted to the Secretariat information on the presence in the legislation of the Russian Federation of rules establishing specific limitations and exceptions to patent rights (paragraph 80 of document SCP/15/6), and had assisted the preparation of documents relating to the questionnaire (documents SCP/17/3 and SCP/17/3 Add.), having included therein particular features which were not part of any section of the questionnaire, i.e., provisions of the Russian legislation relating to the right of subsequent use and obtaining a patent for an invention created during the performance of work based on a State or municipal contract. The Delegation further recalled that, at the seventeenth session, among other delegations, it had put forward a proposal to conduct further analysis of the responses to the questionnaire and to devise essential recommendations (or guidelines) on the subject. In its view, its proposal corresponded to the program of work proposed by the Delegation of Brazil that consisted of three stages: (i) to exchange information on provisions of national and regional legislation concerning limitations and exceptions to patent rights and experience of implementing such provisions; (ii) a study on the effectiveness of limitations and exceptions existing in national legislation for solving problems of development and the conditions of their implementation; and (iii) to review the possibility of producing a manual (or guidelines) on limitations and exceptions to patent rights. The Delegation considered that the SCP should move from the first stage to the second stage of the program of work in question. As regards the analysis of the questionnaire, the Delegation expressed the view that, aiming at systematizing the forms of exceptions and limitations to patent rights and evaluating the legal basis and consequences of introducing appropriate exceptions and limitations, the proposals made by a number of delegations at the previous session was worthy of attention. In its opinion, the results of such

analysis could be a good basis for continuing with subsequent stages, including a preparation of a manual (or guidelines). In addition, the Delegation considered that the results of the analysis could bring practical benefit when devising recommendations on the rational application of different forms of exceptions and limitations, along the lines of Member States which had created positive momentum in resolving such issues at the level of national legislation. Furthermore, the Delegation reiterated its proposal that a draft questionnaire on exclusions from patentable subject matter be prepared by the Secretariat.

36. The Delegation of South Africa reiterated its support to the proposal by Brazil, and stated that the first phase of the Brazilian proposal had been achieved by the questionnaire and document SCP/18/3. Therefore, it expressed its belief that the SCP should proceed to the second phase of the Brazilian proposal, analyzing how the various exceptions and limitations described in document SCP/18/3 were utilized by different countries in addressing various public policy objectives, particularly public health and security, among others. In addition, the Delegation supported the suggestion by the Delegation of the Russian Federation with respect to broadening the scope by also looking at case studies before moving to the third phase of the Brazilian proposal.

37. The Delegation of Chile stated that the question of exceptions and limitations to patent rights was a matter of the gravest concern in its country. It expressed its belief that exceptions and limitations were critical for the maintenance of an intellectual property and patent system which was balanced and which would achieve the goal of promoting innovation. Noting the relatively large number of countries responding to the questionnaire, 72 countries, the Delegation noted that document SCP/18/3 provided complete and sufficient information and was a good basis for further work. The Delegation expressed its appreciation for the proposal by Brazil, which was sufficiently broad in scope and would allow the Committee to continue analyzing those matters in future sessions. As to the manner in which the SCP should pursue the analysis of the issue of exceptions and limitations, the Delegation expressed the opinion that the second phase of the work program contained in the proposal by Brazil was a practical manner of pursuing the analysis and a viable solution.

38. The Delegation of Algeria, speaking on behalf of the DAG, reaffirmed its position regarding the critical importance of exceptions and limitations in the countries of the DAG. In its view, through such exceptions and limitations, intellectual property was fully integrated in development strategies of developing countries. The Delegation noted that the questionnaire, which corresponded to Phase 1 of the work program proposed by the Delegation of Brazil had been replied by many delegations, which had set forth the experience in each country and how exceptions and limitations had been used in each country. The Delegation expressed the opinion that, at the current session, the SCP should adopt Phase 2 of the work program in the Brazilian proposal: undertaking a study on the exceptions and limitations which had an effective impact on patent rights and how they were implemented and how the country had recourse to the exceptions and limitations.

39. The Delegation of Argentina reiterated its support to the work program proposed by Brazil and stressed the importance of officially adopting the work program and initiating Phase 2 of that work program. Furthermore, the Delegation expressed its support to the interventions made by the Delegations of South Africa, Chile and Algeria on behalf of the DAG. The Delegation expressed its satisfaction with document SCP/18/3 that set forth the responses to the questionnaire, including the statistical analysis and giving a much clearer picture of those responses. The Delegation highlighted that exceptions and limitations to patent rights allowed Member States to achieve a balanced patent system which recognized innovation and protected existing rights. In its view, they allowed countries to have the necessary room for maneuver within which national legislation could be adapted to align it to their development strategies. The Delegation considered that further analysis of exceptions and limitations would allow Member States to consider the way they could adapt their legislation and the best way to derive

benefits from the national IP system.

40. The Delegation of Denmark, speaking on behalf of the European Union and its 27 Member States, noted that the information gathered on the basis of the 73 replies to the questionnaire, 20 of which were from the Member States of the European Union, increased the knowledge of the SCP about the national or regional legal frameworks regarding exceptions and limitations to patent rights. While the Delegation recognized the importance attached to those issues, regarding future work on that topic, it stated that an appropriate balance between right holders and the interest of the general public should be maintained. It therefore considered that neither exclusions from patentable subject matter nor exceptions and limitations to patent rights should be discussed without due consideration of the corresponding legal standards that were applied to determine whether an invention was patentable, such as novelty, inventive step and industrial applicability. The Delegation expressed its commitment to participating actively and constructively in the debate in order to contribute to the final fulfillment of the Committee's objectives.

41. The Delegation of the United States of America stated that document SCP/18/3 provided a good foundation for continued discussion on patent rights. Supporting WIPO's efforts in the Development Agenda recommendation 14, the Delegation recalled that the Development Agenda recommendation 14 required not only an emphasis on the understanding and use of flexibilities under the TRIPS Agreement but also the rights and obligations. Thus, in its view, any work on that matter had to be balanced and one interpretation to the detriment of another should not be emphasized, given the fact that the SCP was not intended to focus on trade. The Delegation reiterated its position that it did not support the notion that all flexibilities existing in international agreements must be interpreted and implemented in the same manner, because such notion reflected a limited and incomplete understanding of those agreements. In its opinion, the word “flexibility” did indeed refer to a flexibility which was not a one-size-fits-all understanding of international agreements and the options they provided for intellectual property regimes. A one-size-fits-all interpretation would be an inflexible interpretation of the diverse ways in which countries could choose to protect intellectual property in the manner that best suited their national interests. Furthermore, the Delegation pointed out that the resulting argument that all IP protections should be pulled to the lowest common denominator had been clearly rejected by many WIPO Member States.

42. The Delegation of India recorded its full support to the Brazilian proposal, especially with its second phase where an analysis would be carried out on the exceptions and limitations as to their effectiveness in addressing development concerns, which was an essential part of the entire proposal. In its view, the Committee could carry forward the overview presented in document SCP/18/3, and would then explore how the exceptions and limitations could be implemented at the practical level. The Delegation noted that, with respect to Section 1 of the document, traditional knowledge was missing from the list of exclusions from patentable subject matter. It stated that traditional knowledge, which was explicitly excluded from patentability in India, was a very important item from the viewpoint of the Delegation.

43. The Delegation of China noted that the responses to the questionnaire from Member States provided the Committee with very rich and representative information. In its view, the responses comprehensively reflected the legislations in various countries on exceptions and limitations. The Delegation considered that exceptions and limitations were an important element in legislations. Based on the progress the Committee had made in the project, the Delegation considered that the SCP could carry on with a comprehensive analysis of the information gathered so far, including the studies prepared by external experts and information from Member States. It noted that the Committee should also consider its target audience and feasibility and effects of the activities in order to be fully prepared for the completion of the project.

44. The Delegation of Spain supported the statement made by the Delegation of Denmark on behalf of the European Union and its 27 Member States. The Delegation welcomed the fact that the questionnaire had been answered by a large number of Member States. Similarly, it expressed its appreciation for the provision of the Spanish translation of the Annexes to document SCP/15/3 after its requests that had been made during the previous three sessions. The Delegation expressed its hope that, in the future, when a translation into Spanish of a voluminous document was requested, such a translation would be made available more promptly so that interested countries might be able to participate in the relevant discussions.

45. The Representative of AIPPI noted that, in relation to the intervention by the Delegation of India on traditional knowledge, the AIPPI had put the issue of traditional knowledge and how it related to intellectual property rights on the agenda of its meeting in October 2012 in Seoul. The Representative indicated that, after that conference, he would inform the Secretariat of the debates and any resolutions that might be adopted.

46. The Representative of KEI asked whether the original responses to the questionnaire submitted by Member States were made available.

47. The Secretariat noted that they were available on the SCP electronic forum in a table format so that the information could be retrieved country by country and per exceptions and limitations.

48. The Representative of KEI welcomed the fact that more than 70 countries had responded to the questionnaire and provided detailed information. However, looking at the answers submitted by the United States of America in which he lived, the Representative was of the view that they were unduly modest about some of their activities, for example, in the compulsory licensing area. Not mentioned in the response by the United States of America was the fact that, since 2006, the Supreme Court had required that in every proceeding for an injunction to enforce a patent, the judge considered the possibility of a compulsory license as an alternative to the enforcement of the injunction. The Representative explained that, as a consequence, the United States of America had issued probably the largest number of compulsory licenses that any country had had since the Second World War, in particular on medical inventions but also other inventions as well. He noted that the United States of America had issued a compulsory licensing for Toyota on transmission, twice for Microsoft on software patents, for Johnson & Johnson and Abbott on medical devices (for Johnson & Johnson on contact lenses) and for Medtronics on a heart disease valve. He noted that the United States of America had adopted a compulsory licensing provision in the new Healthcare Reform Act in relation to the introduction of generic biologic drugs in cases where the incumbent biologic company refused to provide adequate disclosure of patent rights to the generic competitor. With respect to the answer submitted by Italy, the Representative noted that it did not mention the fact that the Italian competition authorities had issued compulsory licensing on pharmaceutical patents or supplementary protection certificates (SPC) in cases where the Italian active pharmaceutical ingredient companies or chemical companies had wanted to export patented pharmaceutical drugs into other countries in Europe, including drugs such as generic versions of Proscar for cancer and for male pattern baldness as well as antibiotics and pain medicine. The Representative was of the view that responses to the questionnaire would be even more helpful if they could be supplemented with the practical cases where those statutes had actually been used. He considered that it might be useful if, at some point, there was an opportunity for people to supplement the country submissions with independent information about the actual use of certain flexibilities.

49. The Delegation of Hungary, speaking on behalf of the CEBS, stated that document SCP/18/3 was user-friendly and had the potential to feed into the discussions by the Committee members. The Delegation considered that, before any further work was done, the SCP would further benefit from responses to the questionnaire in order to have a full picture, and therefore,

suggested that the document be updated regularly. It was also of the view that the Group needed additional clarification as to the concrete proposal on the next phase by the Delegations of Brazil and of the Russian Federation. The Delegation stated that the terms of reference of any further study should be carefully elaborated, balanced and the scope of the work should include all WIPO Member States.

50. The Delegation of the United Republic of Tanzania stated that while rich information had been gathered from Member States, major work was ahead in terms of analyzing how those comments could contribute to the work of the Committee. It noted that failure of reaching balanced approach would impact the work of the Committee, because the SCP should not leave aside any concern that had been raised, unless it had been analyzed and given due consideration. In its view, a number of similarities, differences, divergences and convergences in the concerns that had been expressed had to, all in all, address development issues. The Delegation noted that all issues that had been addressed on exceptions and limitations on the one side, and patent rights on the other side had to be measured in an acceptable manner. The Delegation considered that there was no one-size-fits-all, and that Member States should still be given the opportunity to provide more comments on those complex issues of exceptions and limitations to patent rights.

51. The Representative of KEI observed that a number of interventions relating to exceptions and limitations had focused on the impact of patents on access to medicine. In his view, however, an area that needed serious consideration was the extent to which the smart phone and tablet computer industries were being in turmoil over the problem of patents, and the degree to which limitations and exceptions on patents were necessary in order for third parties to make, manufacture and build smart phones and tablet computers in an area where thousands of patents had to be cleared. He noted that such warfare in the patent space had been played out in the United States of America, Germany, Australia and other countries. The Representative suggested that, at some point, such issues be brought up to the Committee, as that was considered to be a real embarrassment with the patent system.

52. The Chair summarized the discussions by stating that several delegations had said that they were in favor of carrying out a more in depth analysis of the responses to the questionnaire. Other delegations had underscored the need to find a balance between the various issues that had been addressed by the Committee, which would require the Committee to reach a general agreement on all of the various topics. Other delegations had referred to the need to take into account traditional knowledge with respect to the exclusions from patentable subject matter. Yet others had highlighted the importance of carrying out specific studies on specific concrete cases with concrete applications with patents. Yet another delegation had suggested that the questionnaire be left open to include further responses that might still be sent in by some countries. Noting that no conclusion could be reached at this stage, the Chair asked whether, in the case of a general agreement on carrying out a more in-depth analysis of some of the issues highlighted by the questionnaire, delegations had considered whether some exceptions and limitations should be examined as a priority by the Secretariat, since 11 different types of exceptions and limitations were covered by the questionnaire.

53. The Delegation of Egypt, speaking on behalf of the African Group, stated that as it fully supported the phases that had been proposed by Brazil, it was premature to start prioritizing and choosing the type of exceptions and limitations at that point.

54. The Delegation of Denmark, speaking on behalf of the European Union and its 27 Member States, stated that it needed time to consult amongst its members in order to reflect on the question posed by the Chair.

55. The Delegation of Algeria, speaking on behalf of the DAG, stated that although the DAG was ready to look into any option that would enable the Committee to progress in its work, the

question raised by the Chair could distance the Delegation from its main objective, which was a non-exhaustive manual on existing exceptions and limitations. The Delegation clarified that it could not opt for prioritization at this stage, and preferred a holistic exercise.

56. The Delegation of South Africa, supporting the intervention made by the Delegation of Algeria on behalf of the DAG, stated that the questionnaire laid the foundation for the Committee to go forward. Therefore, in its view, there was no need to prioritize any of the exceptions and limitations outlined. It was of the opinion that all that was listed in the questionnaire was relevant. The Delegation stated that the Committee should start delving into the analysis of how to implement those exceptions and limitations. In its opinion, the Committee should look at the modalities taking into account what the Delegation of the Russian Federation had proposed, for example, inviting Member States to provide additional information on the implementation or conducting case studies.

57. The Chair clarified that setting priorities did not necessarily mean that some topics would be excluded and that an in-depth analysis on all topics could be conducted in various stages rather than simultaneously.

AGENDA ITEM 8: QUALITY OF PATENTS, INCLUDING OPPOSITION SYSTEMS

58. The discussions were based on documents SCP/18/INF/2, SCP/18/INF/2 Add., SCP/18/4, SCP/18/9 and SCP/17/7, 8, and 10.

59. The Delegation of the United Kingdom introduced its proposal prepared jointly with the Delegation of Canada. The Delegation reminded the SCP of the history of the agenda item of quality of patents: following the introduction of the revised proposal contained in document SCP/17/8, the Delegation observed that a large number of delegations had taken the floor to ask questions, seek clarification and make proposals for work programs falling under that agenda Item. The Delegation observed that the greatest number of questions raised had surrounded the definition of quality. Some Member States had suggested that they had been unable to support further work until such time as the definition was clarified. The Delegation expressed its belief that developing a common definition acceptable to all would be difficult if not impossible. It explained that quality had different meanings for different Member States, and it might change in the process of development. However, in its view, through exploring the criteria that Member States used to define “quality of patents” within their national systems, greater understanding would be promoted within the Committee. To that end, following the seventeenth session of the SCP, the Delegation, together with the Delegation of Canada, had prepared a questionnaire, contained in document SCP/18/9, drawing on suggestions made in writing to the electronic forum, such as those from Denmark, Germany, and the United States of America, amongst others, and questions raised orally during the sixteenth and seventeenth sessions of the SCP. The Delegation noted that the questionnaire was short and easy to complete, and yet allowed for more open-ended responses where appropriate. The Delegation expressed its appreciation for the interest the questionnaire had generated, as several delegations had responded to the questionnaire. In particular, the Delegation expressed its gratitude to the Delegations of Brazil, France, Portugal, the Republic of Korea, the Russian Federation and Spain, which had provided detailed and helpful responses to the questionnaire, and to the Delegation of Costa Rica for its supportive comments. The Delegation was of the view that the responses received to the questionnaire, even though not officially endorsed by the SCP, demonstrated a widespread support across the membership of the Committee for at least preliminary work on quality of patents to begin. The Delegation therefore requested the Committee’s full support by mandating the Secretariat to officially distribute the questionnaire, collate responses and prepare a preliminary study on quality of patents, including the various definitions and criteria that Member States used, for consideration at the next session of the Committee. The Delegation stated that the Secretariat’s preliminary study could clarify: (i) the various definitions of “quality” that

Member States used and the criteria they applied; (ii) the technical infrastructure, for example training or IT systems, which Member States used to ensure quality of patents within their national systems; and (iii) details of process improvements Member States sought to make to ensure quality of patents.

60. The Delegation of Canada expressed its appreciation to the Delegation of the United Kingdom for its collaboration on that important agenda Item. It expressed its gratitude to the Delegations of Brazil, France, Portugal, the Republic of Korea, the Russian Federation and Spain for providing detailed and constructive comments on their proposal and the questionnaire. Taking note of the comments received from Member States, both in writing and during the last session, on the prospect of furthering the Committee's work on quality of patents, the Delegation observed that while all Member States had appeared to recognize the importance of the work to the global patent system, some had raised concerns regarding the lack of a clear definition. The Delegation stated that it interpreted that concern as a desire to ensure that the agenda item moved forward in the right direction. The Delegation remained of the view that the specifics of defining quality must ultimately be guided by Members' objectives for the patent system and must therefore allow flexibilities. In its opinion, that however did not mean that the proposed work should not move forward. Establishing guideposts, even without a well-defined road, could still allow people to get where they wished to go. The Delegation expressed its continued belief that the proposed work based on the three main components identified in the proposal by the Delegations of Canada and the United Kingdom (document SCP/17/8), i.e., technical infrastructure development, information access and exchange on quality of patents and process improvement, would be an important tool that would assist all members, and that the questionnaire contained in document SCP/18/9 would clarify the path forward. As a result, the Delegation echoed the request by the Delegation of the United Kingdom for the Committee's full support in mandating the Secretariat to officially distribute the questionnaire, collate responses and prepare a preliminary study on the definition of the term "quality of patents" for consideration at the next session of the Committee.

61. The Delegation of Denmark introduced its proposal contained in document SCP/17/7. The Delegation explained that its proposal was about exploring the idea of improving the quality of search and examination of patents in national patent work by using results of search and examination performed by foreign patent offices. It clarified that the intention of the proposal was not to explore the use of foreign work in search and examination as a means for reducing backlogs or to suggest a common practice or common standards. The Delegation noted that the Danish Patent and Trademark Office had a long-standing tradition of using foreign search in examination work in its own national search and examination procedure. In its Office, the foreign search and examination work was used to the widest extent possible. The Delegation noted that such use of foreign search and examination results did not entail any acceptance or transfer of the decisions made by other patent offices or of foreign patent laws, but it was up to the examiner's discretion to determine the extent to which he or she could use the foreign work. In its view, an important objective of using the foreign search in examination was to improve the quality of national patent offices' own search and examination work, and that in turn led to more robust patents of high quality. The Delegation observed that one of the most important preconditions for granting robust patents was to ensure that the prior art relevant to the patentability of the invention had been revealed. In its opinion, only then were the patentability criteria to be assessed properly. The Delegation considered that having foreign search work at hand would ensure that the prior art which might otherwise not had been found due to, for instance, language barriers or lack of access to specific documentation was revealed. Furthermore, the Delegation was of the view that it guaranteed that the search result for a national patent application was at least as good as the one produced by the foreign office. To conclude, the Delegation stated that improvement of the quality of search and examination of national patent applications through the use of foreign search and examination work was an issue of interest to all Member States at all levels of development, as well as to users and society in general. Therefore, the Delegation proposed that the SCP consider the following

questions: (i) how did national patent offices use foreign search and examination work? (ii) what were the benefits of using foreign search and examination work? (iii) what were the challenges in using foreign search and examination work? and (iv) how could potential obstacles for using foreign search and examination work be overcome?

62. The Delegation of the United States of America welcomed the opportunity to continue studying and discussing the important topic of quality of patents. Noting that granting high quality patents was fundamental to have a well-functioning patent system that promoted innovation, economic growth, employment and the general welfare, the Delegation introduced its proposal contained in document SCP/17/10, in which the offices of Member States were invited to reflect upon and share the high level goals that they considered crucial to a patent system that produced high quality patents. The Delegation explained that those high level goals represented the offices' specific targets against which the quality of national patents and patent examinations were measured. The second part of the work program involved analysis of how foreign offices assessed the grant of patents and the work of the examiners and determine how well the goals set by the offices and its specific targets were met. The Delegation explained that that aspect of the proposal was directed to the operations and procedures that were employed in the various national offices to ensure the quality of patents. The Delegation considered that its proposal was complementary to the proposal made by the Delegations of Canada and the United Kingdom. Accordingly, in its opinion, the goals set forth in its proposal of SCP/17/10 could be met most efficiently by incorporating those questions into the questionnaire proposed by the Delegations of Canada and the United Kingdom in document SCP/18/9. The Delegation stated that effective quality assurance systems in the patent granting process were important in evaluating the work of the offices and were also fundamental to increased collaboration between the offices, because they increased the re-usability of the work product of one office by another office. In its view, much of the work of the USPTO was duplicated with the work done elsewhere, since innovators were increasingly seeking patent protection in multiple countries. Since 2008, more than 50 percent of the patent applications had come from non-U.S. inventors. The Delegation observed that it was well established that countries provide national patent laws that reflected the priorities of those countries and national agencies decided themselves a system that suited the overall national interest based on economic objectives, educational systems, capital availability and employment goals among other factors. The Delegation, however, considered that those differences should not prevent the offices from collaborating with the goal of operating more economically and reducing transaction costs for the users of the global IP system. It noted that the USPTO's quality assurance system was described in detail in the attachments to its response to the quality questionnaire proposed by Canada and the United Kingdom in document SCP/18/9. The results of each annual quality review were posted on the USPTO website in an effort to provide full transparency. As one of the goals of the present quality assurance system of the USPTO was to improve the predictability of its quality measures, the Delegation expressed its hope that describing its quality system would provide information that national offices could study and possibly consider in evaluating their own quality systems, even though it was fully aware that the quality systems for a large office would not be directly applicable to smaller offices. Furthermore, it stated that potential pay-off of having a better quality system used by the offices of the various Member States could be an increase in sharing of the work and experiences in patent search and examination, which would provide benefits to the offices as well as to the users of the national patent systems.

63. The Delegation of the United Republic of Tanzania wondered what was referred to by "quality of patents", since granted patents were supposed to meet the patentability criteria. The Delegation asked other delegations whether the quality of patents referred to the number of examiners and the infrastructure of the patent system or something else. In its view, unless the Committee had a consensus on the definition of quality of patents, since that term was understood differently by different delegations, each delegation would express its view on the basis of a different understanding. The Delegation expressed its belief that discussions on the

issue of quality of patents should be guided by the patentability criteria regardless of the country in which patents were granted.

64. The Delegation of Egypt, speaking on behalf of the African Group, expressed its appreciation for the introduction of the proposals. However, it stated that the Committee was yet to find definition of quality of patents. The Delegation reiterated its opposition to a one-size-fits-all approach and to issue international patents, i.e., harmonization. From the previous discussions and introductions of the proposals, the Delegation understood that quality of patents meant effective implementation of the national patent law and regulations at the national level by a national IP office. In its view, since there was nothing that prevented the collaboration between offices, an international search and examination authority status, for example, was granted to certain offices so that countries which did not have the capacity could receive quality examination results, ensuring that granted patents deserved patent protection. The Delegation noted that, for a developing country, ensuring quality of patents meant ensuring that the office adhered to all the exceptions and limitations to patent law in order to be geared to the development needs and national priorities, making sure that there was no frivolous or evergreening of patents and granted patents that served the purpose of development. The Delegation noted that such a perspective might be different from another country's perspective when it applied its own patent law. The Delegation therefore, expressed its difficulty in understanding the definition of the term “quality” in terms of implementation and practicability.

65. The Delegation of Japan expressed its appreciation to the Delegations of Canada, Denmark, the United Kingdom and the United States of America for their proposals. The Delegation stressed the importance of considering various elements in the patent granting procedures, including patent examination and opposition procedures, which were related to determining quality of patents from a practical perspective. The Delegation considered the three pillars proposed by the Delegations of Canada and the United Kingdom, i.e., technical infrastructure development, information exchange and process improvements, as important factors to achieve high quality patents. The Delegation therefore expressed its support to the fundamental idea behind the proposal by Canada and the United Kingdom. With respect to the concerns raised by some delegations on the definition of quality, the Delegation was of the opinion that what was significant was not to talk about the definition of quality itself, but to consider the way to improve it from various points of view. In its view, patent quality included various elements concerning the entire patent system, such as the quality of granted patent itself or the quality of patent examination. Nevertheless, the Delegation considered that it was significant for any countries to discuss how to improve sufficient quality of various elements in terms of building a better intellectual property system. The Delegation explained that it supported the proposed questionnaire, because it was designed to collect various information related to patent quality from each Member State and to share it among them, which, in its view, was effective to advance the discussions on the subject. Furthermore, the Delegation was of the view that, in the process of sharing information, the definition of patent quality would be clarified and Member States could share common recognition about it. It also considered that sharing information by using that questionnaire was consistent with the proposal made by the Delegation of the United States of America.

66. The Delegation of Brazil stated that since high quality patents were paramount to achieving the goals of the patent system, the Committee should engage in a discussion of that important issue looking at the contributions to the improvement of the patent system, including search and examination and evaluation of the workflow. The Delegation expressed its belief that patents of high quality were key to reach the objectives of patent protection as in Article 7 of the TRIPS Agreement, and noted that the work carried out in the field of quality management systems by the National Institute of Industrial Property of Brazil, as discussed in document SCP/18/INF/2 Add., had been making consistent efforts to upgrade the technological infrastructure with the increase in the number of patent examiners. That was evidenced by an increase in processing capacity and the reduction of the backlog. With regard to the proposals

submitted, the Delegation stated that the discussion of the national goals of a patent system as proposed by the Delegation of the United States of America was indeed an interesting one and reflected the debates undertaken in WIPO since the Development Agenda had been approved. The Delegation expressed its understanding that the underlying consideration was that one-size-fits-all approaches were not sufficient for the patent system because those goals vary from country to country, and were affected by many factors, including the national policy and the capacity of Member States to absorb technology. In its opinion, that also implied that a common definition of substantive patenting criteria would negatively affect the capacity of Member States to adapt the patent system according to the changes in the countries' reality. The Delegation observed that Development Agenda recommendation 17 regarding the flexibility in international intellectual property agreements and recommendation 11 which urged WIPO to assist Member States to strengthen national capacity for the protection of domestic creations, innovations and to support the development of national scientific technological infrastructure, among others, seemed to pertain to the discussion. As a contribution to the discussion, Brazil was of the view that a first step could be the exchange of information between IP offices regarding access to patent database in light of the shared objective of continuously rising patent quality. Some patent offices including the National Institute of Industrial Property of Brazil made search documents available on their websites. In its view, it was helpful to patent examiners to compare their examination results as long as the flexibility of use of the database was maintained. Since some countries, however, faced obstacles in accessing those databases, the Delegation suggested exploring the reasons behind such difficulties. Finally, the Delegation stated that work-sharing initiatives should remain strictly voluntary, and be undertaken by national offices in line with their developmental and public policy objectives.

67. The Delegation of Venezuela (Bolivarian Republic of) expressed its gratitude to the Delegations of Canada, Denmark, the United Kingdom and the United States of America. It however noted that using an unclear adjective was rarely a productive approach in international organizations. The Delegation considered that, since quality of patents was related to national development strategies and priorities of each Member State, trying to harmonize it would require flexibility on behalf of all. It stated that the flexibilities in national legislation were needed.

68. The Delegation of the Russian Federation recalled that, at the seventeenth session of the SCP, it had supported the proposal by the Delegation of Denmark, had provided the Secretariat with materials, as reflected in the report (paragraph 72 of document SCP/17/13 Prov.2), relating to the use by the Russian Patent Office (ROSPATENT) of the results of searches carried out in foreign patent offices on corresponding applications, which were used when examining convention applications filed with the ROSPATENT and in the process of examining applications under the Patent Prosecution Highway (PPH) procedure and PCT international applications that had entered into the national phase. The Delegation considered that, in order to further enhance the quality of patents by using the results of search and examination by foreign offices, it was necessary to continue work on the collection of the requisite information relating to the use by national patent offices of search and examination results. As regards the analysis of such information, taking into account the existence of differences in national regulations concerning the conduct of a search and the compilation of its results, the Delegation suggested that the Secretariat deal with the issue of producing uniform requirements regarding the search procedure, the compilation of search results and the publication of search reports. The Delegation also emphasized that a vital aspect of the situation under consideration was the treatment of issues concerning the creation of national search report databases and the provision of the possibility of access to such bases to other offices. Furthermore, the Delegation also supported the program of work on the quality of patents proposed by the Delegations of Canada and the United Kingdom (document SCP/17/8). As regards their proposal contained in document SCP/18/9, the Delegation noted its positive reaction to that proposal concerning a questionnaire on quality of patents, which had taken into account the comments made by delegations during the previous SCP sessions. As to the program of work proposed by the

Delegation of the United States of America (document SCP/17/10), the Delegation supported conducting the proposed study, since the results of such a study might be used as a basis for general recommendations on the evaluation of the quality of patents. The Delegation stated that the timeliness of resolving the issues of quality of patents was dictated by the development of modern technologies for patent cooperation, based on the use of previous search and examination results obtained by the office of first filing or by the competent international authority, when deciding the grant of legal protection in accordance with national legislation. In that regard, the Delegation was of the opinion that the exchange of information on the provision of the quality of patents was an important component defining the development of national patent systems, and referred to its comment on the issues contained in document SCP/18/INF/2. With respect to document SCP/18/4 which contained additional information on administrative revocation and invalidation mechanisms, the Delegation considers that it contained a comprehensive and multifaceted analysis of the provisions of legislation of different countries, including that of the Russian Federation. The Delegation expressed its willingness to undertake constructive work in the area under consideration, and stated that the mechanisms referred to in document SCP/18/4 deserved particular attention. It noted that the system of courts of arbitration of the Russian Federation (to be established at the latest by February 1, 2013) would include a specialized patent court, the powers of which would cover, as a result of the Federal legislation, in particular, cases on disputes concerning the grant or termination of legal protection for inventions (utility models), including the decisions of the ROSPATENT, and concerning the recognition of a patent for an invention (utility model) as invalid, where a different procedure was not provided for by the Federal law for its recognition as invalid. The Delegation stated that strengthening measures for intellectual property enforcement in its country, including the creation of a specialized court, had proven to be an essential condition for the accession of the Russian Federation to the World Trade Organization. In its view, the appearance in the very near future of a specialized patent court would enable the effectiveness of the system of intellectual property enforcement in Russia to be enhanced, taking into account international standards for legal proceedings. It observed that, as part of the preparation of revised legislation in the above sphere, trends in the examination of disputes in the sphere of legal protection and enforcement of intellectual property in the Russian Federation were taken into account, together with international experiences of the examination of disputes in countries in which specialized courts for the examination of such cases had been created (for example, in Germany, the United Kingdom and the United States of America). To conclude, the Delegation confirmed its interest in further working on the subject of “quality of patents, including opposition systems”.

69. The Delegation of Hungary, speaking on behalf of CEBS, supported the launching of the questionnaires proposed by the Delegations of Canada and the United Kingdom and the Delegation of Denmark. The Delegation expressed its sympathy to the proposal made by the Delegation of the United States of America on the work program which could be complementary to the questionnaires. The Delegation reiterated its opinion that gathering more knowledge and evaluating different approaches implemented by WIPO Member States would be helpful. In its view, the SCP would greatly benefit from the answers to the questionnaires by as many WIPO Member States as possible.

70. The Delegation of the Republic of Korea expressed its belief that since the issue of the improvement in patent quality was closely connected to the effective use of the patent system, that theme was well-suited to the mandate of the SCP. The Delegation therefore supported continued discussions on the improvement of quality of patents. The Delegation noted that patent quality was a somewhat abstract concept which could not be objectively defined because of the characteristics of technology, time of judgement, specialized knowledge of a judge, differences in individuals’ view on quality, etc. Since patent quality could not be improved by focusing on just one of the aspects, the Delegation was of the view that the Committee should systematically examine the aspects that put a great influence on patent quality in order to promote the overall advancement of patent quality. The Delegation expressed its support for

the proposals by Denmark and by the United States of America, as they would contribute to the improvement of quality of patents by sharing experiences and exchanging information. The Delegation explained that, at the Korean Intellectual Property Office (KIPO), an Examination Quality Assurance Officer and Directors from each examination division evaluated the examination procedure based on the examination evaluation guidelines. Also, KIPO's Committee on Trial Quality Assessment evaluated trial decisions. In addition, the Delegation considered that international cooperation through collaborative search under the PCT and the PPH programs should be strengthened in order to improve patent quality, based on the reduced examination workload of each patent office. Moreover, the Delegation was of the opinion that relevant IT infrastructure should be expanded and improved for a better access to examination/search results of each country.

71. The Delegation of Argentina stated that the discussions on the proposals relating to the quality of patents had underscored the importance of having a high quality and balanced patent system in each of the Member States. The Delegation noted that the proposals made by the Delegations of Canada and the United Kingdom and by the Delegation of the United States of America recognized that the quality standards varied from one country to the other. The Delegation considered that various parties and players were involved in the issues relating to quality of patents, and that the Committee should bear in mind its implications to the national objectives, policies and legislation. The Delegation observed that, despite all endeavors made, it was not clear whether the quality of internal procedures for each office was at stake or not. It was of the opinion that, in general, the proposals could be subject to various interpretations and ways of viewing them. In its view, the Committee should look at the efficiency of patent systems, and that countries should be paying more attention to the way in which patents were assessed and granted, especially in terms of industrial applicability, in order to avoid granting low quality patents. Since the quality of patents was an essential feature of the patent system, the Delegation was of the opinion that high standards in examining patent applications and patents was a vital part of a balanced intellectual property system, as that avoided granting patents of low quality that could have a negative impact on innovation, competitiveness as well as the development and well-being of society in general. The Delegation underscored the fact that defining the patentability criteria according to national requirements was a vital tool that countries had at hand. It therefore considered that any endeavor to harmonize the patentability requirements among States would affect the flexibility under Article 27 of the TRIPS Agreement.

72. The Delegation of the United States of America expressed its gratitude to the Delegations of Brazil, the Russian Federation and the Republic of Korea for their constructive interventions. The Delegation expressed its belief that the Committee might be making progress towards consensus where it could share the goal of best practices regarding the evaluation of the quality of patents.

73. The Delegation of Australia expressed its support for the proposals made by the Delegations of Canada and the United Kingdom, of Denmark and of the United States of America. It expressed its willingness to share its experience on the use of foreign search reports and on its quality assurance system. The Delegation stated that the questionnaire proposed by the Delegations of Canada and the United Kingdom would be useful in exploring the various definitions of quality used within national offices. With the benefit of such additional information, the Delegation considered that the Committee would be in a better position to progress with its work. With regard to the proposal by Denmark, the Delegation was of the opinion that that proposal was a good example of a specific piece of work that fell within the process improvement component of the proposal by Canada and the United Kingdom. Noting its significant experience in using foreign search and examination results within its national examination, the Delegation considered the use of those results to be an efficient way of increasing the quality of patent offices' work. With regard to the proposal by the United States of America, in its view, that proposal complemented the work envisaged under the first and third components of the proposal by Canada and the United Kingdom. The Delegation explained that

its country placed great emphasis on the quality of patents it granted, as well as implementing a quality management system and independently reviewing the work done by examiners. It noted that Australia recently passed amendments to the Patents Act which would strengthen the quality of patents granted, and highlighted four key areas of the amendments relevant to the topic under consideration: (i) the Bill amended the Patents Act to remove restrictions on the prior art information and common general knowledge that was taken into account when assessing whether an application was sufficiently inventive to justify a grant. That would raise the standards set for inventive step in Australia to a level that was more consistent with standards set elsewhere; (ii) the amendments bolstered the requirement that the patented invention be useful, i.e., the invention worked in the way the patent said it did. Such an amendment strengthened the requirement for patents on speculative inventions that required too much work before they could be put into practice; (iii) the Act raised the standards for disclosure of an invention, where the information disclosed in a patent application, although sufficient to make one thing within the scope of each claim, was not sufficient enough to make the invention across the full scope of each claim. That particular change ensured that granted patents were not broader than the invention which had been disclosed; (iv) the Bill amended the Patents Act to increase certainty in the validity of granted patents. Currently, the Commissioner was limited in the ground she could consider when deciding whether to grant or revoke a patent after examination. In contrast, the courts in Australia could consider a wider range of grounds. As a consequence, a patent correctly granted by the Commissioner might subsequently be found invalid by the courts. The change introduced by the Bill would expand the grounds the Commissioner could consider, and apply consistent standards of proof across all grounds so that the Commissioner was not obliged to grant patents which would not pass scrutiny in a court challenge.

74. The Delegation of Denmark, speaking on behalf of the European Union and its 27 Member States, stated that good quality of patents increased the legal certainty for patent holders and third parties, guaranteed the scientific progress and ensured that the patent system performed its economic functions properly. The Delegation stated that ensuring high quality patents was heavily dependent on the high quality of patent search reports, patent examination requirements, which would ensure sufficient disclosure of inventions, well defined claims and efficient appeals systems. In that regard, the Delegation reiterated its support to advancing work on the issue of quality of patents as proposed by the Delegations of Canada and the United Kingdom, Denmark and the United States of America. The Delegation considered that those proposals were fully complementary to the mandate and the expertise of the Committee and took into account a number of the Development Agenda recommendations, in particular, recommendations 10, 11, 19, and 29. It further noted with satisfaction that some Member States, including six European Union Member States, had already contributed to the discussions on quality of patents with their comments, additional proposals and further information about the subject matter compiled in documents SCP/17/INF/2 and SCP/18/3, and it further encouraged other members to do the same. The Delegation further underlined that the adequate application of the patentability criteria, such as novelty, inventive step and industrial applicability, represented important elements of that subject. The Delegation stated that the European Union and its 27 Member States were of the view that the Committee should establish a work program on the subject of quality of patents. As the next steps to be taken by the Committee in relation to that subject, the Delegation was in favor of launching a questionnaire containing the elements of all the proposals made by 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 program proposed by the Delegations of Canada and the United Kingdom on process improvement, the Delegation supported the proposal made by the Delegation of Spain to launch studies dealing with the inventive step concept and evaluating inventive step used in Member States. In conclusion, the Delegation expressed its commitment to advancing discussions in the Committee on quality of patents in line with the proposals made by the Delegations of Canada, Denmark, the United Kingdom and the United States of America.

75. The Delegation of Ghana expressed its appreciation to the Delegations of Canada, Denmark, the United Kingdom, and the United States of America for their proposals on the issue of quality of patents. Of particular interest for the Delegation was the proposal made by the Delegation of Denmark on the use of foreign search and examination reports by national IP offices, which had also been supported by the Delegation of the Russian Federation. The quality of foreign search and examination reports were of particular importance to small IP offices, particularly small IP offices which did not conduct substantive examinations and, therefore, relied solely on foreign reports. The Delegation was of the view that the SCP should set minimum standards for examination authorities and the IP offices to ensure that they adhere to the basic criteria for patentability, i.e., novelty, inventive step, industrial applicability and sufficiency of disclosure. Such minimum standards would ensure enhanced confidence in the quality of patents granted by IP offices. That should run concurrently with ensuring access to patent information and building capacity of small IP offices to enable countries to conduct their own search and examinations of patent applications.

76. The Delegation of Spain expressed its full support for the questionnaire presented by the Delegations of Canada and the United Kingdom as part of their proposal on quality of patents. The Delegation was certain that through responses by the largest possible number of States and the subsequent analysis of those answers, a conclusion would be reached on the global situation in relation to the quality of patents and as to how WIPO could collaborate in order to improve the situation in that area. In the comments contained in document SCP/18/INF/2, the Delegation had already presented the responses to some of the questions raised in the questionnaire. With a view to the next session of the Committee, the Delegation expressed its wish to respond to the whole questionnaire and complete the responses already provided. The Delegation expressed its doubt about pursuing the question about the definition of “quality of patents” in the jurisdiction of a State. Since the legislation of many countries did not define what was meant by quality of patents, in the absence of a legislative definition, the Delegation wondered whether it would be possible to consider definitions of “quality of patents” used by patent offices, i.e., in unofficial documents or examination guidelines. The Delegation welcomed the comments made on the electronic forum by a number of countries, such as the detailed information on their quality management systems provided by the Delegations of Brazil, France, Portugal and the Russian Federation. Referring to its comment contained in document SCP/18/INF/2, the Delegation reiterated its proposal that, within the framework of the proposal by the Delegations of Canada and the United Kingdom, and more specifically, in the section entitled “process improvement”, a series of studies be conducted to improve the understanding of the inventive step requirement and the evaluation thereof. With a view to the Committee’s next session, the Delegation stated that, either individually or in collaboration with other States that might be interested in that subject, it intended to submit a document relating to the inventive step requirement and the evaluation thereof so that, if possible, work might begin on the subject. As regards the proposal by the Delegation of Denmark contained in document SCP/17/7, the Delegation expressed its support for the study by the Committee on the aspects relating to the re-use by national patent offices of the search and examination work already done by other offices. The Delegation observed that a search report, accompanied on occasions by a written opinion, was usually published together with the patent application, and a large number of Offices had databases where it was possible to consult all or a majority of the documents produced during the grant procedure. It noted that the re-use of the search and examination results produced in other offices was a routine practice in the majority of patent offices, including the Spanish Patent and Trademark Office. It explained that the first search carried out by a patent examiner, in addition to the search by the inventor and applicant, was the search of other applications already published in the same family. The Delegation expressed the opinion that the existence of searches and/or examinations already carried out on the same invention guided and facilitated the subsequent work of the examiner, even where the final decision always laid with the patent office, irrespective of the decisions taken by other national or regional patent offices. Therefore, in its opinion, the re-use of the work done was not contrary to the sovereignty of States, as was sometimes claimed. The Delegation explained that the Spanish legislation

provided for the use of the results of previous searches and examinations, thereby reducing the corresponding fee, depending on the scope within which the work done previously had been useful. Through recent experiences which the Spanish Office had had as part of the PPH program, within which it had agreements with Canada, Finland, Japan, Mexico, Portugal, the Republic of Korea, the Russian Federation and the United States of America, the Delegation observed that the main problem in benefiting from the results of searches and examinations already carried out in other national offices in relation to a patent application was the difference in languages, especially where there were languages which were very remote from the mother tongue of the examiners. It regretted the fact that automated translation systems currently available did not provide the requisite quality. Although the Delegation was aware that great efforts were being made to make progress in that field, in its view, the language issue was the main obstacle to the appropriate re-use of the search and examination results of other offices. As long as more advanced computerized translation systems were not available, the Delegation considered that full benefits would not be gained from the examination and search results of other patent offices. In its opinion, WIPO should collaborate in the efforts designed to obtain automated translation systems for patents, which were sufficiently reliable. The Delegation further noted that another situation in which the use of a previous search or examination was difficult was where the application on which such work had been done had undergone amendments with respect to the application examined by the second office. In order to circumvent those difficulties, a framework of equivalence of claims, which facilitated the use of work done by another office, should be produced as within the PPH agreements. Furthermore, the Delegation stated that national offices should work in the area of provision of databases allowing access to the search reports and examination results generated during the patent grant procedure, which were freely accessible at least to the other national and/or regional patent offices. Since it was the third session at which the Committee was dealing with the subject of quality of patents, the Delegation expressed its belief that the time had come to begin work thereon, by answering the questionnaire put forward by the Delegations of Canada and the United Kingdom, in which some of the aspects contained in the proposals by the Delegations of Denmark and the United States of America could be included in order to avoid it being necessary to respond to too many questionnaires simultaneously. In its view, it did not appear to be fair that progress in that regard continued to be delayed because of the lack of the definition of quality of patents, if, as had been stated by numerous groups, there was a desire in the Committee to achieve balanced progress on the different subjects of interest. The Delegation was of the opinion that everybody should be more flexible, and stated that delegations were not present to prevent others making progress on their subjects of interest, but for the international community as a whole to witness improvements to the patent system. The Delegation therefore considered that the lack of agreement on the definition of the quality of patents was not a sufficient excuse to delay progress on the subject of interest for so many delegations. Quoting a representative of the Brazilian industry who had highlighted the need for Brazil to have a strong patent system which provided a high quality product for the purpose of promoting innovation, the Delegation stressed the importance of the subject for a large number of States and requested delegations not to further delay the commencement of work.

77. The Delegation of Canada clarified that the objective of the questionnaire put forward by its Delegation and the Delegation of the United Kingdom was not to seek a harmonized definition of quality, but rather to gain an understanding of how different Member States defined quality of patents and the steps they took to ensure that their domestic objectives for the patent system were met. The Delegation expressed its belief that such a questionnaire would allow the work on the subject to proceed and provide benefit to all members of the SCP. The Delegation especially invited members who were requesting a definition of quality of patents to provide how they defined quality in their domestic regimes.

78. The Delegation of Algeria, speaking on behalf of the DAG, expressed its appreciation to the delegations for submitting their proposals. The Delegation clarified its position by stating that its Group was ready to discuss work of the SCP on that topic if a clear definition of what was

meant by quality of patents was provided. The Delegation, however, observed that it had not been possible to achieve that during the last three sessions. While appreciating the questionnaire proposed by the Delegations of the United Kingdom and Canada which could assist the Committee in drafting the definition, the Delegation considered that that questionnaire was based on the premise that a definition did exist, and was directed to those Member States that had a definition. The Delegation therefore was of the view that the questionnaire excluded some Member States which did not yet have a definition of quality of patents. The Delegation stated that the Committee would not be in a position to adopt a document that was not inclusive, excluding some Member States and preventing them from exercising the most basic right, which was to respond to the questionnaire. The Delegation reiterated that, in the first place, it was more than necessary to have a definition of what quality of patents was, and that without such definition, the Group could not adopt any activity of the SCP in that direction.

79. The Delegation of Algeria, speaking in its national capacity, asked the proponents whether they considered "quality of patents" to mean "conformity of patents with the criteria of patentability". The Delegation noted that, if that was the case, it related to procedural issues, and not to substantive issues.

80. The Delegation of Switzerland welcomed the fact that the issue of patent quality, which was an important subject for its country, was being discussed within the SCP. The Delegation expressed its appreciation to the Delegations of Canada, the United Kingdom, the United States of America and Denmark for their contributions to the Committee's discussions on the matter. The Delegation considered that the questionnaire submitted by the Delegations of Canada and the United Kingdom was very useful, and the responses to the questionnaire would provide the Committee with the necessary answers for the Committee to move forward. The Delegation therefore supported the continuation of the work as suggested by the Delegations of Canada and the United Kingdom.

81. The Delegation of South Africa aligned itself with the statements made by the Delegations of Egypt on behalf of the African Group and of Algeria on behalf of the DAG. In addition, the Delegation fully endorsed the intervention made by the Delegation of the United Republic of Tanzania on the importance of clarity of the issues under consideration. The Delegation, expressing its appreciation to the proponents for making proposals, reiterated that it was not opposed to any proposals, but was seeking clarity. The Delegation observed that Member States had different understanding as to what quality of patents was. It requested the proponents to clarify a number of questions it had, i.e., (i) what were the proponents trying to address? Noting the different level of developments among members and the fact that not all were international searching or examining authorities, the Delegation expressed its willingness to understand what the problems perceived by the proponents were and what the proponents wanted to address. (ii) what inspired their proposals? The Delegation considered that there should be an inspiration behind the proposals; (iii) what benefits did they envisage, not only for themselves but for everyone? The Delegation expressed its wish to understand the benefits for developed countries, developing countries and LDCs as well as for small and large offices; (iv) how did their proposals relate to the discussions in the PCT Working Group? Noting that Member States in the PCT Working Group had recognized the need for improving the quality of granted patents, and in that regard, had approved a mechanism for the review by the Quality Subgroup of the Meeting of International Authorities on that matter, the Delegation requested clarification regarding the relationship with the discussions under the PCT. In its understanding, quality of patents should primarily mean the granting of patents on a high threshold definition of quality. The Delegation observed a problem with the deterioration of patent quality largely because of the lowering of the standards of patentability and examination practices. Therefore, in its view, Member States should be focusing not on quality of patents, but rather on improving the quality of the search and examination and/or filing systems. The Delegation therefore highlighted the link between opposition systems and quality of patents, and the link with the disclosure issues. The Delegation noted that those, at least, were how it considered what

quality of patents should encompass. To move forward, the Delegation reiterated the necessity of clarity on the concept itself. The Delegation sought no definition, but a clear understanding of what the proponents wished to achieve with their proposals. With respect to the questionnaire, the Delegation reiterated that, as long as there was no clarity about what exactly would be addressed in the questionnaire, it was not in the position to move forward with it.

82. The Delegation of Iran (Islamic Republic of), speaking in its national capacity, aligned itself with the statement made by the Delegation of Algeria on behalf of the DAG. The Delegation stated that any work on patent quality should take into account the following elements: (i) the different nature and the different role of patent systems in Member States as well as the different levels of development in IP offices; (ii) the need for capacity building and training programs for IP officers. Training programs needed to be given due consideration and be developed as a separate component or as an underlying element within each component of patent quality; (iii) any discussion on patent quality should take into account the relevant Development Agenda recommendations with the objective of strengthening patent offices in granting high quality patents based on their national law; (iv) that process should be voluntary and be guided by Member States and not aimed at harmonizing patent laws. Any work on patent quality should ensure compliance with the requirements of patentability, including sufficiency of disclosure of inventions.

83. The Representative of ALIFAR, stressing the importance and relevance of ensuring the quality of patents, stated that quality of patents was absolutely fundamental for the patent system to work correctly for it to be able to achieve its objectives in terms of social and economic policies, and to allow for adequate balance between the interests of inventors and competitors. The Representative shared the view expressed by the Delegation of France on the importance of patentability criteria when assessing the quality of patents. The Representative underscored his concern about the debate that had taken place within the SCP, as the way the discussions were held could lead to harmonization of the law of patents on the patentability requirements, exclusions and exceptions. If it were to occur, he stated that harmonization would have an impact on the flexibility that the current international treaties provided, which were vital for developing countries. The Representative noted that patent offices in developing countries should be structured according to their own legal traditions and economic, political and cultural realities. He observed that training and technical assistance provided to those offices by other patent offices generally did not take into consideration the differences between those developing countries and the different interests and public policies of those countries, for example, criteria used were not adapted to the requirements of those countries. Referring to the concept of the interest of users of the patent offices, the Representative stated that not only the interests of those who requested patents needed to be considered, but also the general public should be given adequate protection. The Representative expressed his belief that automatic adoption of search and examination reports by designated officers was not adequate. He was of the view that those reports should only be used by local examiners once their own search and examination had been made. In his opinion, that process of reviewing the patentability requirements was not merely technical and neutral, but it involved national policies. Regarding a possible work program on the quality of patents, the Representative considered that it was necessary to widen the scope of the questionnaire to be carried out by Member States. He observed that the questions proposed so far could induce unilateral approach in the answers, increasing possible risks of harmonization. He therefore considered that questions that also allowed to underscore the differences in criteria and the use of flexibilities in international treaties should be also included. In his view, the Committee should be looking at the risks of an automatic adoption of the results of examinations carried out by other offices and the violation of public policies and legislations. The Representative pointed out that, in order to assess the quality of patents, its relationship with the human rights that were recognized at the international level should be taken into consideration. In his opinion, that relationship must also be included in the questionnaire for discussion. He noted that the analysis of patents in new technologies must take into consideration human rights in terms of privacy and access to

culture, amongst other things. He stated that the analysis of patents related to pharmaceutical inventions must always take into consideration human rights in terms of health.

84. The Delegation of India aligned itself with the statement made by the Delegation of Algeria on behalf of the DAG on the issue of quality of patents. It noted that the issue of quality of patents was very important for the development of any patent system and further transfer of technology. As stated in its opening statement, the Delegation underscored that patent offices across the world would not be able to maintain the quality of patents without maintaining the standards of search and examination. In its view, most patent offices in developing countries were in a transition phase and needed to upgrade their systems, in particular, the systems related to the prior art searches and the development of human resources. The Delegation proposed to take steps to build the capacity among the IP offices of developing countries to enable them to carry out their quasi-judicial functions in the best manner possible. In its opinion, the full disclosure of the invention, including the most relevant prior art on the part of the applicant, was one of the most important features in improving the quality of patents. The Delegation stated that applicants were expected to disclose the findings in search reports related to the patentability and the full outcome of their corresponding applications if their applications were rejected by another patent office. It observed that Article 29 of the TRIPS Agreement clearly mandated that disclosure including providing information concerning the applicant's corresponding foreign applications and grants. The Delegation pointed out that in order to enhance the quality of the search and examination process, WIPO should look at the possibility of providing access to value-added databases existing both in private and public domain to developing countries, either for free or with subsidies. As regards the proposal submitted by the Delegation of Denmark, the Delegation welcomed using information relating to search and examination of one country by following countries in respect of the corresponding applications. The Delegation explained that the Indian Patent Act made it mandatory on the part of the applicant to submit a statement containing the particulars about the corresponding foreign applications. The Act further empowered the controller to direct the applicant to furnish the details relating to the processing of corresponding applications in foreign countries within a certain period of time. That information included the search reports and patentability reports of the corresponding applications in foreign countries. The failure to submit such information could become a ground of opposition as well as for revocation of a patent. The Delegation clarified that, in the case that the patent had been granted in a foreign country, that fact could not be the ground for also granting the patent in India. The Delegation was of the opinion that the use or reference of foreign search in examination work should be left to each country and, therefore, should not lead to any harmonization. With regard to the challenges faced in the use of foreign search and examination, the Delegation noted that the Indian Patent Office faced language challenges in accessing the reports of the offices which did not use English as their official language. The Delegation also observed that, quite often, co-pending applications underwent radically different treatments in each jurisdiction, even with respect to cardinal issues such as novelty and inventive step. It noted that the search and examination outcomes were not consistent, even among International Search Authorities (ISAs). With regard to the potential obstacles of using foreign search in examination work, the Delegation considered that there were several issues to be resolved which involved both technical and legal components. In its view, apart from language barriers, exchange of information and common technological platforms, there were several substantive issues which needed to be resolved while owning to the needs of countries with different economic and social levels. With regard to the proposal by the Delegations of Canada and the United Kingdom, the Delegation of India recalled its view expressed in document SCP/17/13 Prov.2, paragraph 93. The Delegation further stated that the quality of patents depended to a great extent on the patentability criteria, which were determined by national laws. In its opinion, while proposing a definition and the scope of the quality of patents, proposed modalities of checking the quality of patents and the capability of the country should be given due importance. The Delegation observed that the proposal was suggesting a very broad definition, including the overall functioning of the patent office and the relationship of patent offices with clients. The Delegation was of the view that such a broad definition might not

be pertinent and might not achieve the desired goal. It pointed out that the judicial system should be excluded from the work program. The questionnaire developed by the Delegations of Canada and the United Kingdom did not consider whether the closest prior art had been disclosed by the applicant himself or not. Further, it did not take into account whether the applicant had submitted the search and examination outcome, such as the refusal of corresponding applications in other countries. Regarding the proposal of the Delegation of the United States of America, the Delegation stated that it did not examine the role of incremental inventions leading to the frivolous grant of patents with a view to so-called ever greening, which extended the lifetime of existing patents. In its view, that type of activity on the part of the patent applicant might also affect the quality of the patent. The Delegation stated that any proposal for expediting the granting of patents on the basis of the patentability criteria used in other patent offices could not be considered. In its opinion, use of promptness in examination as one of the metrics for the quality of patent, as proposed by the Delegation of the United States of America, did not always lead to a high quality of patents, but involved a very high risk if such an invention was later rejected on the basis of high quality examination in another country. It observed that such patents might be rejected on the basis of high quality of search later on by some other countries. The Delegation stated that since the degree of patent quality depended on the policy framework of the patent law of each country, it was difficult to measure the quality of patent on that basis. Further, in the pharmaceutical and chemical sector, the Delegation observed that the so-called Markush claims used by patent applicants always affected the quality of patents, as unforeseen combinations and permutations in such claims were difficult to perceive in reality. Therefore, in its view, the enforcement of such claims was doubtful and questionable. The Delegation stressed the importance of the pre- and post-grant opposition system in enhancing the quality of patents, which should be included in any discussion on improving patent quality.

85. The Delegation of the United Kingdom responded to a number of questions raised by the Delegations of India, South Africa and the United Republic of Tanzania in order to clarify their concerns. The Delegation highlighted that all of the offices with registration or full examination would apply filters in granting patents. These filters were tied into the national objectives for the respective patent systems fostering innovation and technological and social and economic development. In the broader sense, the filters Member States applied defined the quality of patents in their jurisdictions. Therefore, the Delegation was interested in learning what measures national and regional offices would take in ensuring that the patents they granted met those requirements. The Delegation stated that the work would enable the Committee to share experiences, to allow members to learn from others and to help cross the barriers that were surmounted in the past development. The Delegation invited interested Member States, especially those with concerns and reservations, to participate in drafting of a questionnaire.

86. The Delegation of Chile reiterated the importance of a functioning patent system for its country and achieving such a patent system. It noted that the quality of the procedures and other aspects played an important role in the granting of patents. In its view, the use of search and examination work carried out by other Patent Offices was valuable to improve those processes. From that point of view, the Delegation appreciated and reiterated its support for the proposal made by the Delegation of Denmark, because that proposal would maintain the independence of each of the members in applying the substantive norms on patents. Similarly, the Delegation considered that it was important to use technological tools according to open and clear standards that enabled the interoperability of computer tools and that facilitated the use by members of an integrated system of information while respecting the individual characteristics of each of the national systems at the same time. The Delegation expressed its appreciation for the proposal submitted by the Delegations of Canada and the United Kingdom, and emphasized that the intention to enhance the exchange of information on patents and the improvement of the systems was particularly positive in that proposal. In its view, patent quality was connected with the grant of rights and in that context, the Delegation highlighted the existence of regional initiatives, such as the one pursued by the Southern Common Market (MERCOSUR). That initiative involved 10 industrial property offices in Latin America and the objective was to

promote cooperation within that region on the understanding that cooperation was key for innovative factors. That unique project was a purely regional patent cooperation initiative by the industrial property offices with funding from the Inter-American Development Bank, WIPO and the European Patent Office (EPO). With reference to patents, the project had been focusing on dealing with the problem common to all offices of the growing number of patent applications. The project tried to make the work more efficient in terms of processing applications, but without neglecting quality and at a reasonable cost to offices and to States. Specifically, the project tried to achieve the sharing of search and examination reports, so that examiners of the offices involved could benefit from the work of their colleagues. In that way, it was intended to make proceedings smoother and shorten examination time, while saving resources and time by avoiding duplication of work. The Delegation clarified that it did not mean that the reports were binding to each office, because the offices would maintain their independence and autonomy. The Delegation stressed that it was extremely important to analyze the lack of resources which affected most offices, namely, resources to invest in databases or access to databases and resources to examine novelty and to ensure that the search was as productive as possible.

87. The Representative of TWN expressed that there was a need to ensure that patent offices which granted statutory monopolies exercised their authority with utmost care and caution. In other words, patents should be granted to inventions which satisfied the patentability criteria under the relevant domestic legislation. In his view, some patents, for example, were not a mere technical activity guided by the national public policy objective. Further, he stated that Member States should vary from initiatives that focus on speedy patent grants or simplifying patent grant procedures as countries were at different levels of development. Thus, he considered that the adoption and implementation of patentability criteria and the patent examination process should be guided by national objectives, and therefore, it was important to reach a shared understanding on the term "quality". The Representative stated that the work program on quality should not lead to any kind of harmonization of patent laws. According to the Representative, not only the different legal procedures but also the organization and the funding of the patent offices affected the quality of patents. In his opinion, it was an issue whether the patent office was funded through the national budget or through the revenue from patent applications. Further, the Representative was of the view that human resources policies, where staff had been pushed to grant patents and to fulfill certain targets, affected the quality of patents. In his opinion, the issue should be covered more holistically. The Representative stressed the importance to reach a shared understanding or conceptual clarity on the term "quality".

88. The Representative of AIPLA stated that quality of patents was an extremely important issue to the users of the patent system. He observed that quality was difficult to define, but it comprised the quality of applications and the quality of examination processes involving all the factors that delegations had mentioned, including the access to the full contents of prior art. In his view, without having full access to prior art, examiners could not do a quality job, no matter how good they were. The Representative informed the Committee that AIPLA, along with FICPI, would hold a joint colloquium in September 2012, specifically on the issue of quality focusing on the quality of applications and the quality of examination processes. That would gather officials from patent offices from all over the world to gain insight what they would see as ways to improve the quality of applications and of the examination process. Further, the colloquium would be complemented by users who would look into best ways to increase quality related to their business to file and to prosecute patent applications. The Representative indicated that he would provide a report on the results of the colloquium to the next session of the SCP.

89. The Chair opened the discussion on opposition systems and other administrative revocation and invalidation mechanisms (document SCP/18/4).

90. The Delegation of India noted that, with respect to paragraph 80 of document SCP/18/4, the following facts should be elaborated: (i) there was no fee to be paid by any person to file a pre-grant opposition system in India, which was very cost effective and fast track; and (ii) any

person could file a pre-grant opposition as there was no need to establish the *locus standi* of the person. The Delegation stated that such provisions would greatly improve the quality of patents. The document also highlighted statistical data on opposition and re-examination systems of some countries and furthermore, the Delegation suggested that statistical data of India about the number of applications published *vis-à-vis* with the number of pre-grant oppositions filed and also number of patents granted *vis-à-vis* the number of patents opposed to be included in the document for the benefit of members of the SCP.

91. The Chair invited the Delegation of India to submit the information in writing.

92. The Delegation of Switzerland emphasized that document SCP/18/4 was an excellent document containing many examples from member States that had opposition procedures, re-examination systems, the possibility of submission of information by third parties and also administrative systems for revocation and invalidation. It observed that those systems played an important role in order to guarantee the quality and credibility of patents. In its view, even if those systems were very different from each other, they showed the proper working of such mechanisms. Furthermore, the Delegation considered that it was a swift and cheap way for a third party to challenge a patent and thereby improving the quality of patents. In its opinion, it was crucial to continue the work on that subject at the next SCP. The Delegation proposed having a compilation of all the different mechanisms that had been described in the document so that each country could draw on them either to improve its own system or to set up such a system if it so wished. Such a publication would be of benefit to all Member States and would involve no obligation to set up such mechanisms.

93. The Delegation of the United States of America stated that the update to the study on opposition systems was informative on the benefits and problems encountered with regard to the implementation of opposition systems and other similar patent review proceedings. The Delegation observed that the document provided an informative review of the new provisions of the Leahy-Smith America Invents Act (AIA), Public Law 112-29, most of which would enter into force on September 16, 2012, having a positive effect on the quality of patents granted by the United States Patent and Trademark Office. The Delegation explained that the AIA provided an increase in the quality of patents through, for example, greater legal certainty which was obtained by providing multiple ways for parties to challenge the issuance or validity of a patent. It noted that the administrative procedures were expected to be much less complex and much less costly than resorting to patent litigation. It observed that some of the procedures implemented in the AIA affected the quality of patents, including by allowing third parties to submit printed publications of potential relevance to examination within six months after publication of the application with no fee being required, if submitting less than three documents and the current description of the asserted relevance of the documents. Furthermore, the AIA established a post-grant review before the Patent Trial and Appeal Board to review the validity of issued patents within nine months of the grant except for best mode. That review had to be completed within one year with a possible extension of six months. The Delegation explained that it was replacing the current *inter partes* re-examination with a new *inter partes* review to be conducted by the Patent Trial and Appeal Board to be completed within a year with a possible six-month extension. It noted that that procedure allowed anyone to seek to cancel claims based on Section 102 (novelty) and Section 103 (non-obviousness), using patents or printed publications.

94. The Delegation of Denmark, speaking on behalf of the European Union and its 27 Member States, welcomed the revision of document SCP/18/4 by providing additional information on opposition systems and administrative revocation and invalidation mechanisms and other similar procedures, as requested by the Committee at the last session. The Delegation was convinced of the important role of those mechanisms for ensuring the proper functioning of the patent system and, in particular, the contribution to increasing the quality of patents by providing a simple, rapid and inexpensive alternative to litigation. In that context, it reiterated that the

freedom of all WIPO Member States to decide whether or not to introduce such procedures or mechanisms into their national legislation should be preserved. The Delegation urged continuing the work on opposition systems and considering the elaboration of a reference book/handbook of the most successful models of opposition systems and other administrative revocation and invalidation mechanisms in a non-exhaustive manner in order to serve as a reference to WIPO Member States.

95. Without necessarily associating itself with the issue of quality of patents, the Delegation of the United Republic of Tanzania highlighted the importance of having a pre-grant opposition procedure. The Delegation stated that it was unfortunate that some jurisdictions did not provide for pre-grant opposition, but relied on the invalidation procedures which were costly. Noting that Section 64 of the Tanzanian Patent Act provided for invalidation proceedings but not for pre-grant opposition, the Delegation considered that it was a lacuna in the patent law which should be addressed. Therefore, the Delegation welcomed document SCP/18/4 which elucidated the manner in which patent granting procedures should be addressed. In its opinion, however, it was a different issue from the one of quality of patents.

96. The Representative of GRUR informed the SCP that Germany, an important country in terms of patent activities and economic performance, provided for a third party observation system in Section 43.3 of the Patents Act, which had existed already for decades. Furthermore, he noted the legislative changes in opposition proceedings which had taken place in Germany in the late 1970s or early 1980s: Germany had run a pre-grant opposition system from the beginning of 1977. At the beginning of January 1981, Germany changed from pre-grant to post-grant opposition in order to follow the example of the European Patent Convention (EPC).

97. The Representative of APAA, representing IP professionals within the Asian regions, considered quality of patents an important issue, particularly the opposition systems and other administrative revocation and invalidation mechanisms. The Representative observed that while recognizing considerable diversity among countries on the mechanisms, such as pre-grant and post-grant oppositions, third party observations, re-examination, and administrative revocation and invalidation, the sharing of experiences were of common interest for both, developing countries and developed countries. She noted that, for example, in the Asian countries, most of those countries, for example in India, had pre-grant opposition systems, and those mechanisms had been found helpful and workable in order to provide examiners with good pieces of prior art by way of public participation to ensure a better quality examination with limited examination resources and capacities. Meanwhile, Japan used to have a pre-grant and then a post-grant opposition system. It was utilized by third parties for challenging the validity of examined patent applications and granted patents. The Representative observed that although the present invalidation trial system was a fair and balanced system, judging from the fact that the number of demands for invalidation trial were far less than originally estimated, which was less than 10 per cent of the number of requests for opposition, opposition mechanisms, which were simple, quick and inexpensive procedures available at an earlier stage before an actual dispute could arise, were more desirable for the public. APAA observed that even in developed countries, which were facing patent thickets, broad patents and a great number of patent applications, time-bound *inter partes* procedures were a good supplement and complement to granting procedures. In her view, public opposition in ensuring quality of patents was important for sustainable patent systems, because only patent applications or patents that would conflict with third parties interests were more likely to be subject to a larger number of third parties oppositions. APAA agreed that, while recognizing the most appropriate system for each national law potentially varied from country to country, further elaboration of work on quality of patents was beneficial for all those concerned in the Committee.

98. The Representative of TWN appreciated the fact that the study had been updated with some of the information which had been requested by the Committee in May 2012. At the same time, the Representative commented on some texts in document SCP/18/4, especially the

sentence in paragraph 27, stating that "the patent system intends to promote innovation, dissemination and transfer of technology by granting a limited exclusive right to prevent others from using a patented invention without the consent of the patent owner and, at the same time, requiring the patent owner to fully disclose the invention to the public." In his view, that paragraph did not reflect the objectives listed in some of the international agreements, especially in the TRIPS Agreement which clearly stated in Article 7 that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." Similarly, the Representative noted that it was also important to reflect in paragraph 27 of document SCP/18/4 that "the procedural and substantive requirements of a patent system were also aimed at ensuring that the patent system should operate to the mutual advantage of producers and users of technological knowledge and in a manner that is conducive to the economic welfare." Similarly, in paragraph 31 of document SCP/18/4, it was stated that "viewed from the angle of innovation policy, the positive effect of the patent system on innovation can only be achieved by valid patents complying with all the requirements of the applicable law." For instance, the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) had concluded in its report of 2006 that "the fact that a patent can be obtained may contribute nothing or little to innovation if the market is too small or scientific and technological capability inadequate." From the view of the Representative, it was important that utmost caution should be taken while using that type of language. Further, the Representative indicated two possible ways of updating that report: (i) to have an appendix containing the grounds for opposition in the countries listed in the report, in order to inform other countries to borrow some of those grounds or to incorporate them in their own domestic law; and (ii) to have a section to find out about the difficulties in using the opposition system in various Member States or under various domestic laws. The Representative considered that it might be a good idea to provide an opportunity for users of the opposition system to express their views through web-based consultation.

99. The Delegation of Chile recalled that pre-grant opposition system should function in such a way that it contributed effectively to the examination process. That system was very useful as it allowed analyzing the various sources of information by examiners and offices. Any abuses that could take place during the pre-grant opposition process should be avoided, in particular, where it could be misused to delay the granting of a patent. It could create additional obstacles, both for the applicants and for the offices.

100. The Representative of KEI considered it useful to have more empirical evidence as to the amount of money it would cost to obtain a determination that a patent was issued in error in different countries, since the economics of resolving disputes about patent quality were an important part of the patent system and it related to the issue of whether or not countries or parties were affected by it could afford to resolve those issues. Since the complaints about patent quality were as old as the patent system itself, the Representative suggested that the Committee reflect on how the patent system should be implemented when the granting of bad patents was actually part of the system and predictable. Further, he questioned what happened to the patents in other countries if a patent was found to be invalid in one country due to evidence of prior art or a determination that there was no inventive step. He considered that WIPO could provide a service by having a database of such patent oppositions which could be used in evidence in any other country. In his view, that was a concrete thing that WIPO could do to reduce the expenses and difficulties of amounting patent challenges around the world and from which parties in one country could benefit from the investment that was made in resolving those disputes in a different country and could have access to sufficient information.

AGENDA ITEM 9: PATENTS AND HEALTH

101. The 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.

102. The Delegation of Egypt, speaking on behalf of the African Group, stated that the Delegation of South Africa on behalf of the African Group and the DAG had proposed a joint initiative, which looked substantially into the issue of the impact of the international patent system on the issue of public health. The Delegation further stated that the aim of the proposal was to put WIPO in the lead on those discussions. While it was aware that discussions on that issue were happening in other fora, as the leading agency on intellectual property rights, the Delegation considered that it was an opportunity for WIPO to take a lead on that issue and discuss it from various perspectives. The Delegation recalled that the main core of the matter was to ensure that the patent system was consistent with the basic goals and interests of the public, particularly when it related to the impact of the patent system on the issue of public health. It further stated that the proposal contained three elements, namely, (i) the elaboration of studies by renowned independent experts, to be commissioned by the Secretariat, following consultations with Member States; (ii) information exchange among Member States and leading experts in the field; and (iii) the provision of technical assistance to Member States, particularly to developing countries and LDCs, building upon the work undertaken in the above first two elements. The Delegation explained that the proponents of the proposal sought to enhance the capacities of states, especially developing countries and LDCs, to make full use of existing flexibilities in the international patent system to promote policies towards public health and public health considerations. Referring to the studies available in that regard, the Delegation stated that the studies indicated the need to work further on that issue and there was much substance that could be built upon within WIPO, and more specifically, under the umbrella of the SCP.

103. The Delegation of Algeria, speaking on behalf of the DAG, wished to stress that the proposal in document SCP/16/7 examined thoroughly the issue of patents and health, and proposed a work program which would be of assistance to their countries in adapting their legislation on patents to benefit from flexibilities in the area, in the light of public health priorities and especially in conformity with international obligations on the subject. The Delegation believed that the proposal was very timely. In its opinion, it was an important progress, considering the few discussions on patents and health that had been held in WIPO. The Delegation noted that the work on that issue was following along the lines of what had already been done by the international community. In that context, referring to the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) adopted by the WHO, the Delegation stated that, in the GSPOA, it was stated that intellectual property agreements contained flexibilities that could facilitate better access by developing countries to pharmaceuticals. It was of the opinion that those countries, however, might meet obstacles in the use of those flexibilities. In its view, it was necessary to solve that problem and to remedy that situation so that the countries could make full use of flexibilities in the public health area. The Delegation further stated that under the TRIPS Agreement and the agreement concluded between WIPO and WTO and the UN, WIPO's mandate and obligation was to provide guidelines or guidance on those matters. The WIPO-WTO agreement settled the legal basis for that cooperation between the two organizations. Therefore, in the context of the TRIPS Agreement, its group considered that WIPO's mandate in the area of intellectual property covered not only right holders, but also the flexibilities and their use, which were part of the system. The Delegation continued that it was necessary for WIPO to take action in that regard. The Delegation proposed the following non-binding work program. The first element of the work program was to request a study that would examine the constraints and challenges seen by developing countries and LDCs that wanted to make the best use of the flexibilities provided in the patent system. The Delegation called on the Committee to look more into details of the study which could guide the Secretariat, if the SCP decided to mandate the Secretariat to

undertake such a study. In its view, a sufficient amount of information had been provided to guide the authors of that possible study. Referring to the second element of the work program, which proposed an information exchange among Member States, the Delegation expressed its belief that inviting the UN Special Rapporteur on the Right to Health to the SCP to present his report on intellectual property rights and access to medicines that had been drawn up for the Human Rights Council would give clear information to Member States on what had been done elsewhere and, above all, what WIPO could do. The Delegation believed that such work was within the mandate of WIPO. Finally, referring to the third element of the work program, the Delegation stressed the importance of technical assistance which could be provided to its members. It particularly emphasized technical assistance programs which could clearly show the difference between compulsory licenses granted under the procedures of Part II of the TRIPS Agreement concerning patent rights and those grander under Part III of the Agreement, concerning the remedies for infringement of those rights. In its view, the proposal took a holistic approach that the SCP could agree to follow, so that countries could fully benefit from the flexibilities provided for in the international system which, in its view, could hold up access to medicines.

104. The Delegation of the United States of America stated that the availability of medicines was a topic of great importance and interest, and its country continued to be a global leader in promoting availability of medicines throughout the world. The Delegation expressed its pleasure in contributing to that discussion. Noting that some of the public health issues facing developing countries and LDCs included neglected diseases, the spread of tuberculosis, malaria and HIV/AIDS and the availability of medicines to treat those and other ailments, the Delegation considered that there was no easy solution to those problems. In its opinion, reducing patent protection was not likely to solve those thorny issues. Furthermore, it stated that the notion that all developing countries faced identical challenges and should apply the options that existed under international agreements in a single way – or that access to medicines would be enhanced by such an approach – had been rejected by many WIPO Member States, including developing nations. In its view, to the contrary, the lack of effective patent protection could be one of the many factors which prevent the appropriate medicines from reaching the neediest patients in developing countries and LDCs. The Delegation was of the opinion that weakening the patent rights granted to pharmaceutical researchers and manufacturers in certain markets not only removed or reduced the incentive to develop new medicines, but also reduced the incentives for innovative medicine developers to invest in those countries and harness their innovation to solving the public health challenges that disproportionately affected developing countries, and were not being solved in other ways. In its view, weakening patent protection for innovative medicines was not a productive approach to improving availability of health care, because many other factors, other than patents, more directly affected the availability of medicines. The Delegation observed that the proof of the weakness of that argument was that although most medicines on the WHO's List of Essential Medicines were not protected by patents, their availability in many markets, particularly in developing countries and LDCs, was still limited. According to its view, many other factors affected the availability of all medicines, patented or not. The Delegation further stated that, consequently, assessing the extremely complicated challenges of public health with respect to the patent system as the primary point of intervention, without recognizing the indisputable facts affecting access to medicines, was an imbalanced and ultimately unproductive approach. If not viewed in context, the Delegation was of the opinion that such an approach would invest WIPO's limited resources to inaccurately quantify the impact of the patenting system on the availability of medicines, and would not help Member States make informed decisions about how to view their patent systems in the context of their efforts to address the specific and unique health challenges each country must overcome. It further stated that, at the previous session of the SCP, the Delegation had set forth two basic elements for consideration by the Member States. The first element was to conducting a study on the positive impact of patent systems in providing lifesaving medicines to developing countries. The Delegation considered that the 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 generic and patented medicines available in developing countries and LDCs. The second element was to conducting a study to examine the availability of lifesaving medicines that were provided in generic form, and the reasons for their lack of availability. In the view of the Delegation, the 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 the many other important existing challenges that would not be affected by any patent regime. It further stated that alternative approaches sought to evaluate patent systems in a vacuum, and drew conclusions about patent protection and public health without acknowledging the complexity of the problem. The Delegation believed that an isolated and partially-informed inquiry could not help in the evaluation of how patents did or did not affect extremely serious and important challenges, and therefore would be an inappropriate use of limited resources. The Delegation had taken note of the preliminary comments to its proposal that were voiced during the seventeeth session of the SCP and of the comments compiled in documents SCP/18/INF/3 and SCP/18/INF/3 Add. The Delegation acknowledged that many of the comments had indicated that some issues raised in its proposal fell outside of the mandate of the SCP, as they involve aspects of national laws, infrastructure, and issues that might be better handled by other UN agencies. One example might be the trilateral cooperation framework by WIPO, the WTO and the WHO. It further stated that if the SCP chose to meaningfully address the profoundly serious and complicated issue of public health, it would be a disservice to that effort to ignore the facts that were necessary to understanding how patent regimes could advance public health. In its opinion, without gathering the information that placed the role of patent systems in context, no reliable or informed conclusion about how patent systems could or should respond to public health challenges could be drawn. Should a forum better equipped to evaluate that complicated issue be agreed upon to conduct studies on the protection of public health and on access to medicines, the Delegation would be amenable to considering the discussion in that forum. The Delegation further stated that, In light of those issues, if any work programs on health related issues were retained within WIPO and particularly within the SCP, care would have to be exercised to avoid duplication of efforts between the various WIPO Committees, in particular, with the Committees more directly addressing Development Agenda issues, such as the CDIP. In particular, the Delegation reminded the Committee that the trilateral framework was finalizing a joint study on the promotion of access and medical innovation at the intersection between public health, intellectual property and trade, which intended to provide a holistic presentation of the full set of issues, including a comprehensive consolidation of their technical cooperation activities in the field. Therefore, Delegation believed that a thorough discussion of the WHO-WIPO-WTO joint study had to take place before additional work, if any, was undertaken within the SCP on the subject of patents and health. Further, the Delegation stated that regardless of the forum chosen, it believed that work on that issue that ignored the interaction of the patent system with the many other factors affecting access to medicine was unproductive and would not result in the stated goal of understanding how patent regimes could improve public health. A balanced approach had to be at a minimum to evaluate all the contributions patents had on the availability of medicines, including the development of life-saving medicines and medicines tailored to public health challenges in developing countries. The Delegation expressed its belief that reduction in patent protection for innovative medicines was not the solution to overcoming public health challenges, as it was made clear by the challenges to access generic medicines, and that the one-size-fits-all approach advocating reduction of patent protection was inappropriate. Therefore, the Delegation concluded that given the resources and expertise of the SCP, great care would have to be taken to add value to the work done by other competent bodies in considering public health challenges, rather than making duplicative efforts.

105. The Delegation of Paraguay, speaking on behalf of GRULAC, underscored the importance of the agenda item on patent and health and supported that progress on the subject to be made, while recognizing that it was a complex issue. It welcomed the proposal submitted by the Delegation of South Africa on behalf of the African Group and the DAG, which was

designed to boost the capacity of Member States, especially developing countries and LDCs, in adopting their patent systems so that they could use the flexibilities provided for in the international patent system. After having heard the elements in the proposals, the Delegation stated that GRULAC was prepared to move forward to the first phase of that proposal. With regard to the proposal made by the Delegation of the United States of America on this agenda item, the Delegation stated that its group was of the opinion that certain elements of that proposal would make the SCP to depart from its mandate.

106. The Delegation of Switzerland stated that, in its essence, the proposal made by the Delegation of South Africa on behalf of African Group and the DAG, contained in document SCP/16/7, focused on the relationship between patents and health, in particular access to medicine, a topic that was of utmost importance to Switzerland. In addition to its intervention during the last session of the SCP on that proposal, the Delegation referred to its further comments on the proposal, which could be consulted on the SCP electronic forum. The Delegation expressed its wish to summarize the key points of its comments. Firstly, the Delegation referred to the work already undertaken or that was underway in relevant international organizations in the area of access to medicines and its relationship to patents. The Delegation reminded the SCP that, for instance, WIPO maintained a trilateral cooperation with the WHO and WTO on the topic. Furthermore, noting that those three agencies were currently co-authoring a comprehensive joint study about the promotion of access and medical innovation at the intersection between public health, intellectual property and trade, the Delegation fully supported that ongoing work which took into account of the complexity of the topic. The Delegation also referred to the discussion on patents and health that the WTO had led since 2000, as well as to the relevant work in the WHO in the context of the establishment and implementation of its GSPOA. The Delegation noted that those discussions had been very extensive and comprehensive, duplications with which were to be avoided. Therefore, should members agree to undertake further work in those fields in addition to the work already done and under way in other international organizations and also existing efforts and engagement by WIPO, the Delegation was of the opinion that an overview and thorough evaluation on the already existing activities, studies, results, information exchanges and general information on technical assistance projects would have to be established first. Secondly, the Delegation was convinced that the access to medicines challenge needed to be addressed in a sustainable manner and, thus, with a systemic and long-term perspective. In the view of the Delegation, the proposal contained in document SCP/16/7 took a short-term perspective only. A proposal for a work program which consisted exclusively of flexibilities and exceptions to intellectual property and patent rights did not do justice to the complexity of the challenge of providing sustainable access to medicine in the WIPO context, and thus from an intellectual property perspective. Therefore, should WIPO members, after a review and on the basis of an overview of the work already undertaken in the field of access to medicine, agree to engage in further work on that topic in WIPO, that would have to happen on the basis of a working document which would ensure a balanced approach, taking into account many interfaces and various factors relevant to the subject matter. In that regard, the Delegation stated that the proposal by the Delegation of the United States of America contained in document SCP/17/11 provided interesting elements. The Delegation was of the view that any meaningful discussion on the issue of access to medicines had to take into account many aspects and factors which made the access to medicines issue such a formidable challenge. In its opinion, looking at one aspect only, and in isolation, would result in an artificial discussion detached from the real world problem. Furthermore, the Delegation observed that the topic as proposed for discussion had a predominant and strong link to development issues, which was also recognized in the proposal submitted by the Delegation of South Africa. Accordingly, the Delegation was of the view that should Member States find it appropriate and agree to carry out additional work on that topic in WIPO, the appropriate place to do so would be the CDIP.

107. The Delegation of Denmark, speaking on behalf of the European Union and its 27 Member States, considered that document SCP/18/5, listing projects and activities on

patents and health undertaken in WIPO, the WHO and the WTO, provided the Committee with a valuable overview and needed information about a wide range of activities undertaken by WIPO, the WHO and the WTO in the area of patents and health, including their cooperation with other international organizations, such as UNITAID. Together with document SCP/17/4 on WIPO activities on patents and health, document SCP/18/5 was essential for the Committee's consideration on possible further work in the area of patents and health. Further, the Delegation expressed its appreciation to the Delegation of the United States of America for its proposal contained in document SCP/17/11. The Delegation reiterated its understanding of the concerns of developing countries and LDCs, as well as the challenges and constraints they faced in handling public health problems. In that regard, the Delegation expressed its support to adequate activities which might assist those countries in addressing those concerns through adapting their national patent legislation. On the basis of the overview of the work already undertaken in the field of patents and health provided in documents SCP/17/4 and SCP/18/5, the Delegation noted that numerous projects and activities within WIPO, the WHO and WTO were either completed or pending. In particular, the Delegation recalled that among activities undertaken by WIPO in that area, there was a pending CDIP project on developing tools on access to patent information which, to a certain extent, already had implemented the activities provided for in element two of the work program proposed by the African Group and some other WIPO Member. Within the framework of the CDIP, there was also an ongoing work program on flexibilities in the intellectual property system within which patent-related flexibilities and a strategy for WIPO's technical assistance in the area of flexibilities had been discussed. Two documents dealing with patent-related flexibilities in the multilateral legal framework and their legislative implementation at the national and regional levels were discussed in the CDIP. The Delegation further noted that WIPO, the WHO and WTO were carrying out a trilateral study which would support technical cooperation and dialogue on issues concerning public health, intellectual property and trade and their relationship with access to and innovation of medical technologies. Against that background, 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 for WIPO or other international organizations. In particular, the Delegation was of the view that, before moving forward, an adequate analysis of existing projects and activities in the field of patents and health as listed in document SCP/18/5 should be undertaken to identify the concrete patent-related issues which eventually could be addressed in the Committee. 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 made by the Delegation of the United States of America. As regards the WTO, the Delegation underlined the importance of putting the TRIPS flexibilities in the wider context of an efficient and adequate intellectual property system to stimulate innovation. In the WIPO context, the European Union and its 27 Member States were of the view that most concerns of the developing countries and LDCs relating to public health, and the activities proposed in the work program of the African Group and some other WIPO Member States, could be addressed accordingly either within the framework of the above CDIP projects. Furthermore, the Delegation emphasized the importance of a close cooperation with other international organizations, in particular, with the WHO and the WTO. In that respect, a parallel avenue could be to continue discussions on public health related issues at the trilateral cooperation platform among the WTO, the WHO and WIPO, which had already been carrying out work in that area. In conclusion, the Delegation stated that they remain committed to advancing work on that issue, and were ready to participate actively and constructively in the forthcoming discussion on this topic.

108. The Delegation of Monaco stated that the complexity of the issue meant that the Committee should look at it from a long-term perspective and in its entirety. In particular, the Delegation stated that, in order to guarantee a holistic and balanced approach, the SCP should look at the other aspects of the subject, inter alia, the importance of innovation and the mechanisms involved. Moreover, should the SCP decide to move ahead on that issue in the context of WIPO, the ongoing work in other organizations, namely, the WHO and the WTO

needed to be taken into account. Noting further that the issue was a cross-cutting one, which had strong implications with developmental issues, the Delegation stated that the most appropriate forum in WIPO to deal with the issue would be the CDIP. The Delegation therefore supported the comments made by the Delegation of Switzerland.

109. The Delegation of the United States of America, speaking on behalf of Group B, stated that the SCP was being asked to revisit the joint proposal made by the African Group and the DAG on a work program for patents and health contained in document SCP/16/7. The Delegation noted, however, that as had already been mentioned by some delegations, WIPO was involved in a trilateral cooperative effort with the WHO and the WTO, which was focusing on the relationship between intellectual property, trade rules and health. That collaboration sought to increase and enhance the relevant policymakers' knowledge in addressing public health issues in connection with intellectual property rights. Referring to a joint study being completed by the trilateral group on the promotion of access and medical innovation at the intersection between public health, intellectual property and trade, the Delegation stated that the study was intended to provide a holistic presentation of the full set of issues, including a comprehensive consolidation of the three organizations' cooperation activities in the field. To that end, Group B was of the opinion that a thorough discussion of the WHO-WIPO-WTO joint study must take place before WIPO undertaken work, if any, on the subject of patents and health.

110. The Delegation of the Russian Federation, referring to the proposal submitted by the Delegation of South Africa on behalf of the African Group and the DAG, noted that, on the whole, the proposed work program should be devised under the leadership of the Secretariat and with the agreement of the Member States of WIPO. The Delegation referred to its comments contained in document SCP/18/INF/3, in which its support for the proposal by the Delegation of the United States of America was expressed. The Delegation considered that an important factor of the proposed studies was the identification of the degree of influence of falsified medicines on accessibility, as well as the positive effect of patent systems in providing access to medicines. In its view, the studies in question would allow the Committee to assess the role of patent protection in stimulating scientific research, leading to the creation of innovative medicines and technology, essential for the provision of accessibility of "generics" in developing countries and LDCs. The Delegation considered it extremely important to study issues linked to the influence of the patent system on the accessibility of medicines, and to research into factors limiting the accessibility of patented and non-patented medicines. The Delegation noted that, as part of the accession of the Russian Federation to the WTO, amendments had been made to its national legislation. Thus, amendments had been made to Federal Law No. 61-FZ, of April 12, 2010, on Circulation of Medicines, providing a period of six years from the date of the State registration of a medicine, during which the following were not permitted without the applicant's consent: the receipt, dissemination, use for commercial purposes and for purposes of the State registration of medicines, of information on the results of pre-clinical trials of medicines and clinical research into medicines, provided by the applicant for the State registration of a medicine. On the territory of the Russian Federation, the circulation of medicines registered in violation of the given provision was forbidden. Failure to observe the prohibition established by that provision would incur liability in accordance with the legislation of the Russian Federation. The established period for results of pre-clinical and clinical trials of original medicines did not relate directly to the system of intellectual property protection, but gave additional guarantees to protect the pharmaceutical market for those developing innovative medicines by limiting, for the purposes of acceptance and examination, requests for the State registration of reproduced medicines. In that connection, the Delegation noted that, taking into account the period defined for the State registration to be carried out, the actual duration of the period of exclusivity of the data in question exceeded six years. The Delegation further emphasized that the issue of combating the circulation of falsified and low-quality medical products lied, in the Russian Federation, within the competence of a number of ministries, i.e., the Ministry of Health and Social Development, the Federal Service for

Supervision of Health and Social Development, the Ministry of Internal Affairs, the Office of the Prosecutor General and the Federal Customs Service. In addition, the Delegation pointed out that, as a result of the joint efforts of the international community, the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME) had been signed in Moscow on November 28, 2011, with the active participation of the Russian Federation. The MEDICRIME Convention had been signed by Austria, Cyprus, Finland, France, Germany, Iceland, Israel, Italy, Portugal, the Russian Federation, Switzerland and Ukraine. The main aims of the MEDICRIME Convention were to establish criminal liability for the falsification of medicines and similar crimes such as, production, storage and offer for sale of such products, the forging of relevant documentation and packaging materials, the protection of the rights of injured parties as a result of the offenses in question, and the development of cooperation at the international and State levels. Work was being done on further ratification of the MEDICRIME Convention which, according to the Delegation, was the first European agreement on the fight against counterfeiting of medical products, extended to legal, criminal and organizational aspects, and was also of a marked humanitarian tendency in that it strengthened as a priority the removal and prevention of the threat to public health created by crimes in that particular sphere. The Delegation further pointed out that within the WHO, a global system was being created for supervision and operational information provided to Member States of WHO on the falsified and counterfeit medical products identified as being in circulation. The Russian Federation was participating in the process of producing the draft in question. The Delegation considered that experience and integration into the system of global notification would assist the effective implementation of measures to combat the circulation of falsified and low-quality medical products as part of the MEDICRIME Convention. The Delegation was of the view that the work program proposed by the Delegation of the United States of America would allow a multifaceted analysis of all factors hampering accessibility of medicines and help to obtain objective data on the degree of influence of the patent system on the accessibility of medicines. The Delegation further stated that document SCP/18/5 was a good basis for discussing the subject under consideration at subsequent sessions of the Committee, since it reflected detailed information on the activities of all those organizations on the issue, including the conduct of different measures and also their status and current results.

111. The Delegation of Canada expressed its appreciation to the Delegation of South Africa for its proposal on behalf of the African Group and the DAG contained in document SCP/16/7, and to the Delegation of the United States of America for its proposal contained in document SCP/17/11. The Delegation also expressed its gratitude to the Delegation of Switzerland for its comments on the proposal submitted by the Delegations of South Africa, and it supported the point of view expressed by the Delegation of Switzerland about the need to avoid any duplication of work or to redo studies that had already been done. The issue of patents and health and access to medicines had already been the subject of much research, particularly, in WIPO, the WTO and the WHO. The Delegation considered that looking into the duplication issue before starting any new studies would make the discussions as useful as possible, while recognizing the limited resources. The Delegation was of the opinion that access to medicines should be tackled on a sustainable basis based on the long-term perspective in a systemic way. The Delegation believed that using patent-related flexibilities would not in itself ensure greater access to medicines. In its view, patents were only one of the factors influencing access to medicines. It further underlined that a comprehensive and global approach was required to respect the complexity of the issue. Otherwise, the Committee would be collectively responsible for paradoxical situation, such as having customs duties counteracting the very purpose of patent-related flexibilities with respect to compulsory licenses. While emphasizing that the Committee should not concentrate just on the issue of flexibilities, the Delegation stated that the use of patent-related flexibilities should be encouraged, particularly the flexibilities provided in the TRIPS Agreement. Noting that its country had been a leader in implementing them, the Delegation stated that the issue of patents and health should be dealt with in the CDIP rather

than the SCP. It added that there should be more coordination between the WTO and the WHO on patents and health.

112. The Delegation of Iran (Islamic Republic of), speaking on behalf of the Asian Group, stated that the issue of public health and patents and having access to medicines at an affordable price was an important issue for the Asian Group, and that the Committee should explore practical ways to respond to existing challenges, including the use of flexibilities available under international agreements. It welcomed the preparation of document SCP/18/5 which listed the projects and activities, including their status or outcome, on patents and health in WIPO, the WHO and the WTO. In its view, that information was useful in developing a focused work plan on patents and public health in the Committee.

113. The Delegation of Iran (Islamic Republic of), speaking in its national capacity, noted that extensive work had been done in the WHO to investigate the linkage between IP, public health and innovation, which had led to the adoption of the GSPOA. In its opinion, the SCP should build on that work, commensurate with its mandate and recognize and then address the existing challenges created by the patent system to public health. The Delegation supported a joint proposal of the DAG and the African Group and the implementation of its three elements, namely, carrying out the framework study by independent experts, information exchange and provision of technical assistance to Member States. In its opinion, following the outcome of the studies and information exchange, Member States should be in a position to fully utilize the flexibilities accorded to them under international agreements and WIPO should give advice on the basis of those findings to the Member States in order to make appropriate revisions in their national laws to enjoy those flexibilities. Further, it stated that other components could be added to the work program, such as establishing a panel of independent experts on patents and health to review the patent provisions on health, which would report to the SCP at a later stage. It was also of the view that any work program on health and patents should be balanced and based on a long-term approach. Therefore, while the Asian Group recognized the importance of the effective patent system in the promotion of innovation and producing life-saving medicines, in its view, the work program of the SCP should also provide the possibility of analyzing the potential impediments and obstacles created by that system in accessing medicines, and coming up with practical solutions to address such challenges. The Delegation also supported inviting the UN Special Rapporteur on the Right to Health to the next session of the SCP to share his findings with the Committee. On the issue of the inter-relation between patents and the right to health, it also believed that WIPO's cooperation and contribution to the work of the WHO on the issue of patents and health should be reported and discussed in the SCP. The Delegation further stated that WIPO should represent the consensus view of its Member States in providing advice to the WHO, particularly in the course of the norm-setting process. In relation to the proposal by the Delegation of the United States of America, the Delegation was of the view that the proposal had not observed a balanced approach and had looked at the problems from one angle. In its opinion, it was not the mandate of the SCP to address the problem of enforcement and falsified medicine or its safety. It also did not share the view that the patent system did not at all constitute a problem for accessing medicines on affordable price. The Delegation noted that there were two different approaches to the problem. The study proposed by the African Group and the DAG could shed light on that issue and analyze the obstacles as well as the incentive provided by patent system in access to medicine. It was of the opinion that any kind of study on the subject should not be one-sided and focus only on the positive or negative role of the patent system. Referring to the statement that most of the essential medicines were not protected by patents, the Delegation referred to the report of the UN Special Rapporteur on the Right to Health to the Human Rights Council, in which it was emphasized that nearly two billion people lacked access to essential medicines and such inability of the population to access medicine was partly due to high costs. The report also stated that IP law had an impact on the right to health and product patents could create absolute monopolies as they could restrict the use of a product.

114. The Delegation of Spain expressed its support to the statement made by the Delegation of Denmark on behalf of the European Union and its 27 Member States on the subject under discussion. It further stated that it was studying with great interest the proposal by the African Group and the DAG on access to medicines, a subject of great interest to its country. Referring to documents SCP/17/4 and SCP/18/5, the Delegation noted that WIPO had already been collaborating with the WHO and WTO on subjects related to access to medicines, and in its view, it was under that tripartite cooperation that access to medicines should be dealt with. The Delegation stated that, in any case, should the final decision of the Committee be to study the issue of patents and health, it would be necessary to avoid any duplication of effort. In particular, regarding the study on compulsory licenses, the Delegation stated that the Committee should avoid duplicating efforts in respect of the work done within the proposal of the Delegation of Brazil on exceptions and limitations. Furthermore, it pointed out that the Committee would have to avoid any duplication of work done by the CDIP, in particular, as regards documents CDIP/5/4 and CDIP/7/3. The Delegation reminded the SCP that, at the request of Member States, the CDIP was already running a program on flexibilities in intellectual property rights and also holding several seminars on the matter. In addition, WIPO's web page contained a database on national experiences with flexibilities. Furthermore, in relation to element 3 of the proposal by the African Group and the DAG on technical assistance, the Delegation noted that the workshops and seminars were held periodically on the subject in cooperation with the WTO and the WHO. In view of what it had stated, the Delegation expressed its belief that the SCP should confine itself to studying those matters that were within its limit, and therefore, it should identify which issues in the proposal corresponded to its mandate. In its view, the proposal by the African Group and the DAG laid too much stress on flexibilities as a means of facilitating access to medicines. The Delegation stated that its position was more in line with what had been expressed by the Delegation of the United States of America in its proposal contained in document SCP/17/11, where it was stated that weakening patent-related protection for innovative products was not a productive approach in improving accessibility to medicines or in improving availability of health care. The Delegation further stated that although the proposal by the Delegation of the United States of America was laudable, the SCP was not the proper forum for its implementation, and in its opinion, the same applied to the proposal by the African Group and the DAG. However, should the decision be to move forward with the African Group’s and the DAG’s proposal, the Delegation proposed to also move forward with the proposal of the United States of America, at least with regard to the study of examining the role of patent systems on providing life-saving medicines to developing countries. In conclusion, the Delegation stated that the assumption implied in the proposal that the impact of the patent system in providing life-saving medicines to developing countries would be a positive one should be avoided, even though that might be expected to be the outcome of the study.

115. The Delegation of Chile stressed the importance of patents and public health. The Delegation believed that that was one of the most relevant items on the agenda of the Committee. As a general comment, the Delegation stated that due to the complex nature of the subject, progress should be made gradually, on a step-by-step basis, without establishing major targets. Supporting the proposal by the African Group and the DAG, the Delegation stated that no one could deny that studying the way in which national legislations use flexibility mechanisms offered by the international patent system was a laudable objective and one of importance. In its opinion, the use of flexibilities in the patent system was not in any way to be construed as weakening patent protection, quite to the contrary. The Delegation observed that the use of flexibilities was simply using legitimate mechanisms established in various legal texts and instruments. In that context, the Delegation considered that the first phase proposed by the African Group and the DAG, that is, carrying out studies, was the right way to start and make progress. Turning to the proposal by the United States of America, the Delegation stated that that proposal too contained interesting elements. Especially, the Delegation considered that there were relevant elements identified in the proposal that did affect access to medicines. However, the Delegation was of the view that the work of the SCP should focus exclusively on

the elements that pertained to patents and public health and not digress on other elements that could be taken up by other international bodies in order to avoid duplication. In conclusion, the Delegation stated that it was possible to progress on the subject, starting on the first phase of the African Group and the DAG proposal by avoiding overlapping with other efforts being made in the Organization. The Delegation stated that what should not happen was that the SCP, which was the main multilateral forum on patent law, prevented itself from studying the issue and from recognizing the link between patents and public health, which was one of the most important issues to be considered.

116. The Delegation of Argentina expressed its support for the proposal by the African Group and the DAG on patents and health. In its view, it was a good working basis and was relevant to the Committee's work. The Delegation stated that the proposal tackled substantive matters concerning the patent system and public health so that countries could make full use of the flexibilities contained in the TRIPS Agreement and the intellectual property system. Supporting the statement made by the Delegation of Chile, the Delegation was of the opinion that since public health did require special attention when applying the TRIPS Agreement, the SCP should give meaningful consideration to public health issues. In its opinion, access to medicines was an essential issue and the SCP was the adequate forum for that discussion. The Delegation further stated that the impact of patent law on access to medicines was great, and that the monopoly that it accorded in relation to essential medicines led to imbalance between the public and private sectors. In its view, since that affected not only corporations but the access to an essential right, i.e., the right to health and medicines, the public health issue was dealt with in various international and regional instruments. The Delegation further stated that although it was said that patents were a stimulant of innovation, and therefore specific medicines existed due to the patent system, the situation in real life was far different. The Delegation noted that very often, cost was a barrier to access to those medicines, and whereas intellectual property agreements could be an instrument to innovation, they could also be an impediment to access. Noting that the impact of the TRIPS Agreement was recognized and that it could have effects on health, the Delegation underlined the need to balance public and private interests. In its view, the proposal of the African Group and the DAG was useful in order to guide the work of the Committee in the right direction. It was essential for the Delegation that the Committee looked further into flexibilities in the TRIPS Agreement. Supporting the position of the GRULAC, the Delegation stated that it was committed to work constructively on that issue and that the Committee could begin with the first phase of the proposal by the African Group and the DAG. In relation to the proposal by the Delegation of the United States of America relating to the issue under discussion, the Delegation stated that while there were general elements that were very interesting, its scope was different from the African Group’s and the DAG’s proposal and it minimized the fact that patents could be an impediment to access to medicines for the LDCs. It was further stated that, for instance, the phrase “measures that weaken patent protection systems through greater use of flexibilities are not useful in securing better availability of medicines” required more thinking. The Delegation noted that abundant literature had indicated that flexibilities allowed governments to alleviate impediments to access to health and medication through adoption of appropriate laws. The Delegation further stated that if there was no recognition of those elements as constituent elements in the problem, it would be difficult to find any possible solution to those problems. Noting the importance of the Doha Declaration on TRIPS and Public Health, the Delegation stated that any positive move forward should bolster access to public health. It was of the view that voluntary licenses and differentiated treatment could help such access. While it was aware of the alternatives which could contribute to resolving the issue, the Delegation considered that those alternatives depended on the goodwill of the holders of rights and, therefore, could be questioned from the sustainability aspect. Referring to document SCP/18/INF/3 which included observations from certain members, the Delegation stated that while it recognized the value a of voluntary system, member States should not depend only on voluntary systems, as they were insufficient to offer sustainable solutions to the problem of access to medicines. Further, referring to the proposal by the United States of America, the Delegation raised the question as to the extent falsified medicines

prevented access to genuine medicines and generic medicines. The Delegation stated that the falsification of medicines was a reprehensible issue harmful for health and threatened the access to decent medicines. However, in its view, the adequate forum to look at the methodology for quality control and efficiency of those medicines was the WHO, which was the proper forum to give objective replies assessing the risks and magnitude of danger. More specifically, in the context of the WHO, the Delegation stated that a Working Group had been set up to start work on defining treatment of falsified medicines, spurious medication and substandard drugs. In addition, the Delegation acknowledged that there was no definition of falsified medicines, and that was an ongoing work in WHO. In conclusion, the Delegation supported the statement made by the Delegation of Paraguay on behalf of GRULAC that the specific discussion on those issues could go beyond WIPO's mandate and the SCP, and thus, should that work program be implemented, it would constitute a duplication of efforts.

117. The Delegation of India expressed its concern relating to issues of public health. It stated that, recognizing the importance of that issue, the TRIPS Agreement provided as an objective under Article 7, that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology in a manner conducive to social and economic welfare and to a balance of rights and obligations. The principles provided under Article 8 also stated that members could take necessary measures in formulating and amending their laws and regulations to protect their interest. The Delegation noted that the TRIPS Agreement provided for much flexibility to ensure that access to medicines was available at reasonable prices at the earliest after the grant of patents. The TRIPS Council, in its meeting at Doha, also recognized the importance of protection of public health. The Delegation explained that the Indian Patent Act took care of the public health aspect very comprehensively and holistically, and made provisions for compulsory licensing in various situations. For example, compulsory licensing could be granted if the patented products were not available at reasonable prices, in case of emergency situations, and 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 public health problems of that country. The Delegation further stated that there was no denial of the fact that public health was of paramount importance to all, including both developed and developing countries. The Delegation was of the view that the effective utilization of the flexibilities afforded under the TRIPS Agreement could also greatly contribute to providing access to medicines at reasonably affordable prices to the poor of the world. In that context, the Delegation expressed its satisfaction to note that the Secretariat was organizing a seminar on compulsory license, price control and access to patented products. However, in its opinion, it was essential that a study be conducted by WIPO documenting the compulsory license practices among its Member States. In that context, the Delegation suggested that the study focus on the manner in which Articles 30, 31 and 44.2 of the TRIPS Agreement had been implemented by Member States. Further, the Delegation fully aligned itself with the statement made by the Delegation of Algeria on behalf of the DAG, and fully supported the proposal submitted by the Delegation of South Africa on behalf of the African Group and the DAG. While the Delegation appreciated the work of the Secretariat in compiling the projects and activities on patents and public health undertaken in WIPO, the WHO and the WTO, the proposal of the Delegation of South Africa was substantially different from that document prepared by the Secretariat. In particular, the African Group and the DAG's proposal aimed towards the better utilization of the flexibilities afforded under the TRIPS Agreement or better access to health care. As regards document SCP/17/11 containing a proposal submitted by the Delegation of the United States of America, the Delegation stated that the observations made in the document that new drug was more likely to be launched where patent protection was more strong was lacking any evidentiary support. On the contrary, in its view, it may be true that where there was more demand or market for a drug, the sooner it would be launched there. The Delegation was of the opinion that there was a need not only to study the flexibilities under the TRIPS Agreement and effective implementation or utilization of compulsory licensing provisions under patent laws in order to provide life-saving drugs at an affordable price, but also

a need for a study measuring the impact of the grant of the compulsory license and the consequential impact on prices of patented drugs. The Delegation was of the opinion that document SCP/17/11 did not propose a balanced approach towards the flexibility offered by the TRIPS Agreement. Further, the Delegation stated that the governments of developing countries and LDCs were engaged in providing medicines to the poor with their limited resources. Therefore, the proposal for a contribution to the fund might be beyond their capacities and their limitations. In conclusion, the Delegation stated that the comments of the members and observers contained in document SCP/18/INF/3 needed to be examined seriously, noting that the suggestion of the Delegation of the Russian Federation had not clearly elaborated how a patent pool system reduced the transaction cost, eliminated the barriers to use medicines and facilitated the availability of medicines.

118. The Delegation of Hungary, speaking on behalf of the CEBS, stated that the issue under the discussion was very important and complex. It noted that WIPO, together with other relevant international organizations such as the WTO and the WHO, had started extensive work on that topic. Those different organizations had been working closely together trying to give their specific added value and expertise to the different layers of the question on access to medicines. The Delegation welcomed the joint study currently being prepared by the trilateral group of WIPO, the WTO and the WHO on the promotion of access and medical innovation and the intersection between public health, intellectual property and trade. In its opinion, that exercise would allow delegations to learn more about the factors that had impact on the access to medicines. The Delegation further noted that some elements of the work program proposed by the African Group and the DAG were also being dealt with in other WIPO Committees, such as the CDIP. In its view, the challenge in the Committee was to find out what kind of added value it could add to the work already ongoing on that question, and, at the same time, to respect and realize the core mandate of the SCP. For that reason, before going into the possible duplication of work, the Delegation would find it useful that the Committee was provided with more information about the concrete, strictly patent-related problems that individual Member States might have encountered and which did not fall under the WTO mandate and the instruments developed in that fora. With such experience sharing, the Committee would be in a better position to have a detailed discussion and decide on the possible next steps. As to the proposal by the Delegation of the United States of America, the Delegation was of the view that it could add a relevant layer to the discussion and have a potential to enrich the debate in the Committee. Finally, the Delegation emphasized that any discussion on that issue should be balanced and take into account the positive impacts of patents, in particular, on the availability of medicine. Thus, the Group also highlighted the important role of the patent system in the field of research and innovation and the development of new medicines.

119. The Delegation of China, referring to document SCP/18/5, stated that the document provided a very sound foundation and had clearly shown insights of what the international community had done for public health. In its view, building a balanced patent system was very meaningful for all Member States, and the patent system should ensure a good balance with the State's public policies. Referring to the proposal made by the African Group and the DAG, the Delegation stated that the proposal was very positive and meaningful for developing countries and LDCs to resolve the public health problems they were facing. In its view, since the SCP was one of the most important platforms to discuss patent-related developments and to promote international cooperation on patents, it should have a good balanced work program on patents and public health. Therefore, the Delegation considered that the SCP studies should be very comprehensive and objective, showing the role of patent systems to promote innovation and the full picture of patents and public health so that they could provide guidance for all Member States. The Delegation was of the view that work could be focused on the patent systems in relation to public health, for example, compulsory licenses, government use and parallel import of medicines, to improve the legislation and practice on those matters by perfecting the patent

system in promoting innovation and new technology on medical health. It also noted that providing flexibilities on patent use could help countries dealing with public health issues.

120. The Delegation of Egypt considered that the proposal by the African Group and the DAG was a very balanced proposal, identifying the problem, providing further process and suggesting the end goal or the objective of the initiative. Referring to some statements made by other delegations on the need to ensure that there should be no unnecessary duplication, the Delegation stated that their proposal did not duplicate with other processes within or outside WIPO. However, if the proposal was going to be considered as duplication, the Delegation considered that it was necessary duplication because the elements of the proposal, despite the title, were very pertinent elements and they were different from other processes that WIPO was engaged in. The Delegation continued by stating that that view had been supported by the documents presenting activities that WIPO had been engaged in. The Delegation further pointed out that the proposal put forward by the Delegation of the United States of America constituted duplication with the other processes outside of WIPO, and it had also elements that fell outside of the mandate of the SCP and WIPO. Referring to the history of the GSPOA of the WHO, in particular, how and why it had ended in its results, the Delegation noted that one of the identifications was that there was lack of proper research and development in order to develop pharmaceuticals and medicines for diseases that were harshly impacting and prevalent in developing countries. Therefore, the Delegation stated that the patent system should help and serve public health considerations, as was mentioned previously by the Delegation of India. In addition, the Delegation stated that there was no evidence to support the fact that when there was a patent system, there was innovation and, hence, access to medicines. Further, the Delegation recalled that their proposal was not limited to access to medicines but went beyond that by covering also diagnostic tools and the health care system at large when they related to patents. In its view, there was an interplay and direct link between how patents worked and how public health considerations worked. If the discussions were about coordination of and consistency in policies, the Delegation was of the opinion that the SCP could discuss mainstreaming of human rights in the UN system. In its view, the discussions on public health considerations could be spoken also in human rights language about the right to health and, therefore, it would be beneficial for the Committee to listen to the input by the UN Special Rapporteur on the Right to Health when it related to the issue of intellectual property and public health and how it impacted the right to health. The Delegation recalled that when the report had been submitted to the Human Rights Council in March 2009, it had been argued that it had not been the mandate of the Human Rights Council to discuss that issue. The same views and the same argument that it was not the mandate of WIPO to discuss the right to health was heard when the issue was brought to the SCP. The Delegation stated that, since it was a global issue, Member States could try to create a transcendent global body that would deal with those issues that were of global nature. However, so far, since the relevant bodies were within the UN system providing multilateral fora, in its opinion, their activities were confined to their own boundaries. Therefore, the Delegation considered that the SCP with its specific expertise should provide its input to the process, and the WHO and the WTO could provide their inputs to the process. In its opinion, through policy coherence and consistency, those bits and pieces could be drawn up together to provide the big picture of how the issue could be addressed. The Delegation was of the view that, if it was left to pharmaceutical companies and businesses, their goodwill and the voluntary activity of such businesses could not be relied upon, because they did not have an obligation as such to promote public health. In its opinion, if they relied on voluntary activity, developing countries would not get benefits. In addition, the Delegation pointed out that innovation also related to the absorptive capacity of developing countries not only to incorporate flexibilities in their legislation, but to put them into action. In its opinion, that would require capacity building, technical assistance and technology transfer so they could make use of such flexibilities that were inherent in the system rather than putting them aside and working on something else to promote the interests of businesses in face of the public interest.

121. The Delegation of Japan aligned itself with the statements made by the Delegations of the United States of America, on behalf of Group B, and of Denmark, on behalf of the European Union and its 27 Member States. The Delegation noted that, while it recognized the necessity and importance of approaching health issues in a general context, many activities providing technical assistance had been already carried out by WIPO, the WTO and the WHO in collaboration with other international agencies. The Delegation was of the view that it was important to review and carefully investigate the existing activities so that there was no duplication of work.

122. The Delegation of the United Republic of Tanzania supported the proposal by the African Group and the DAG contained in document SCP/16/7. The Delegation stated that since the issue of public health was of a paramount importance, due consideration should be given to the issues as alluded to in the above document. The Delegation disagreed with those delegations which had stated that as parallel work was undertaken in other fora, there was no use in discussing those matters in the SCP and that the SCP had no mandate to do so. Noting that committees were supposed to complement and not contradict each other, the Delegation stated that it did not recognize any point of contradiction on that issue, and complementarity of issues provided an added value to the work that was being undertaken in other fora.

123. The Delegation of Zambia expressed its full support for the proposal by the African Group and the DAG. It also added that although there were other external factors limiting the availability of medicines in developing countries and LDCs which needed to be ascertained, the utilization of voluntary licenses as proposed by the Delegation of the United States of America did not in most cases work effectively in those countries. In its view, those schemes were not in most cases sustainable, in the sense that they normally laid conditions which adversely affected the countries that were in need of those medicines. Further, the Delegation referred to the case in its country involving the Global Fund. In relation to the issue of falsified medicines, the Delegation was of the view that since those issues were not within the ambit of WIPO but rather the WHO, the SCP had no mandate to discuss them. Finally, the Delegation stated that there was a need to have a holistic, well balanced, practical and sustainable approach in an effort to resolve the issue of patents and public health.

124. The Delegation of Brazil recalled that the universal access to healthcare was a right guaranteed by the Brazilian Constitution and therefore, any discussion impacting health policies was of interest to Brazil. The Delegation noted that it had actively participated in the discussions on that issue in many fora dealing with the subject, taking into account the complex ways it influenced health policies. The Delegation further stated that providing access to essential medicines at affordable prices was a goal of countries, and a necessary step for the achievement of the United Nation's Millennium Development Goals. In its view, WIPO, as a specialized UN Agency, should make an important contribution to its proper execution. The Delegation observed that the relationship between the patent system and health also offered a clear picture of the inherent trade-off of intellectual property, that was, governments offered the incentives for innovation while controlling eventual negative effects on competition, ensuring an adequate balance between rights granted and access to the products. In addition, it noted that the Doha Declaration on the TRIPS Agreement and Public Health conveyed the understanding that health products were different from other products and should not be treated as a commodity. Further, the Delegation reiterated its support to the proposal by the African Group and the DAG, and shared the views expressed by the Delegations of Argentina, Chile and others, stating that the Committee should adopt the first phase of their proposal. The Delegation further stated that that proposal provided 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 right balance between rights and flexibilities according to the national reality. In its view, the scope and the goals of that work program showed that it would not lead to duplication of efforts. With regard to the proposal of the United States of America, the Delegation was of the opinion that some of its details brought challenges for the acceptance by the Committee.

The Delegation explained that firstly, it included aspects unrelated to the patent system, such as the discussions of sanitary aspects and substandard medicines under the subtopic of enforcement. In its view, WIPO's mandate and the objectives of the SCP did not pertain to those debates, since those matters had already been discussed in the WHO. The Delegation further stated that, while it was fully against the production and commercialization of substandard or spurious medicines, a debate in the SCP on such issues would overlap with those carried out in established fora, unnecessarily duplicating the work. Further, the Delegation stated that the percentage of patented substances in the WHO Essential Medicines list might be a misleading data if the conditions of inclusion of those medicines in the List was not considered. It noted the known fact that antiretrovirals, which formed a large part of the patented chemicals of the mentioned list, were included in the List only after great efforts by governments and activists. In addition, it observed that other relevant medicines, such as those for cancer, had only recently been included, and only in part. Alternative mechanisms as suggested by the Delegation of the United States of America, such as "tiered pricing" and voluntary licenses, were adequate for very specific cases, but should not be seen as the generic solution for access to medicines. The WHO's Commission on Intellectual Property Rights, Innovation and Public Health had reported the obstacles and strategies for the use of such alternative mechanisms and the extent to which those policies depended on the voluntary cooperation of the rightholder. In its opinion, sound health policies demanded certainty in the provision of medicines, especially life-saving ones. Lastly, the Delegation stated that the recently published report of WHO "Consultative Expert Working Group on Research and Development: Financing and Coordination" clearly showed that current financing mechanisms for pharmaceutical research were not aligned to the needs of developing countries in that matter. More than ten years after the Doha Declaration on the TRIPS Agreement and Public Health, in its opinion, it was time that the SCP further explored the issue in order to overcome the great obstacles Member States faced.

125. The Delegation of Indonesia expressed its support to the joint proposal of the African Group and the DAG, i.e., adapting the patent regimes to make full use of patent flexibilities related to public health through deliverance of studies from independent experts, information exchange and the provision of technical assistance. The proposal, in its view, did not necessarily mean duplication on the work done in other UN bodies. It was of the opinion that the proposal merely enforced efforts to provide better understanding and efforts to address the issues related to patents and public health. The Delegation was also of the view that in relation to the patents and public health issue, a greater flexibility should be recognized in the discussion, including in the SCP. The Delegation also appreciated the proposal made by the Delegation of the United States of America on the matter. While that proposal contained some interesting information, in its opinion, the SCP should focus on addressing issues related to patents and impediments to the availability of medicines, and should not go beyond it.

126. The Delegation of South Africa associated itself with the statements made by the Delegations of Egypt on behalf of the African Group and of Algeria on behalf of the DAG. The Delegation stated that paragraph 153 of document SCP/17/13 responded to the questions raised by some delegations in general, while paragraph 157 of that document responded to the counterproposal by the Delegation of the United States of America on patents and health. The Delegation emphasized that, as some delegations had already stated, the proposal did not intend to weaken or reduce patent protection. In its opinion, the proposal reinforced what was already there in international agreements, as reflected in paragraph 153 of document SCP/17/13. In relation to the issue of duplication, the Delegation stated that while there was no duplication in the proposal, if some delegations were convinced about it, they should point out exactly where such duplication occurred. The Delegation also emphasized that the Secretariat had a role to play in identifying if there were any duplication. In addition, the Delegation noted that during the CDIP meeting in relation to the issue of flexibility, the same Member States who were raising the issue of duplication at the current session of the SCP had stated that the right forum for addressing the issue had been the SCP. Therefore, the Delegation expressed its

confusion as to the right forum for discussion. Further, the Delegation stated that at the last session of the SCP, the Delegation of Egypt had suggested to have the trilateral briefing as a standing agenda item at the SCP because they had appreciated the wealth and depth of the information provided in document SCP/17/4 on the issue of cooperation between WIPO, WHO and WTO. However, at the current session, the Delegation was surprised by the fact that the same delegations which were emphasizing the need to hear the results of the trilateral cooperation, had been opposing to having such trilateral briefing at the last session. The Delegation did not support the idea that the Committee should wait for the results of the trilateral study. In that regard, the Delegation emphasized the issue of the mandate. In particular, it stated that Member States had not mandated WIPO to undertake that study, and that WIPO was doing that study *de facto* because of recommendation 14 of the Development Agenda. Since Member States had not mandated that study, in its view, they could not justify holding up work on that agenda item until the completion of that study. Further, the Delegation agreed that balance should be respected. It noted that the proposal by the African Group and the DAG, which emphasized the needs of developing countries and LDCs, was not the end of the process, and that other countries could, and were encouraged, to make their proposals. In that regard, the Delegation expressed its appreciation to the Delegation of the United States of America for its proposal. Regarding the issue of the time frame for implementation of the proposal, the Delegation referred to paragraph 154 of the report of the seventeenth session of the SCP, where the Delegation of Zimbabwe had supported the Delegations of Switzerland and the United States of America in their statements that the planning had to be on a long-term basis and it also welcomed other interventions which supported the long-term perspective for that project. The Delegation appreciated such perspective as it did not want that agenda item to disappear. It further stated that while the Secretariat had been proactive in undertaking certain activities, that was due to the fact that WIPO had delayed discussing it in an intergovernmental forum. Turning to the question as to how to move forward, the Delegation expressed its appreciation for the comment made by the Delegation of Paraguay on behalf of GRULAC. The Delegation stated that it could accept moving forward with the first phase of the proposal by the African Group and the DAG, and expressed its willingness to look into certain elements within the proposal of the United States of America. In addition, the Delegation observed that, although it might not agree with everything, the comments made by the Delegation of Spain, contained in document SCP/18/INF/3 Add, were constructive and fair in their critique of both proposals. The Delegation recalled that the Delegation of Spain had suggested that the Committee could go forward by looking into Markush claims as a first element of the African Group and the DAG's proposal, and by conducting a study examining the impact of patent systems on providing lifesaving medicines to developing countries, as contained in the proposal of the Delegation of the United States of America, avoiding the assumption implied in the proposal that the impact would be a positive one.

127. The Delegation of Venezuela (Bolivarian Republic of) stated that the proposal of the African Group and the DAG was a good basis on which the SCP could start to work. The Delegation recalled that WIPO was part of the UN system, and had the undertaking to achieve the United Nation's Millennium Development Goals. The Delegation stated that while the issue of health was of basic importance for its countries, this should be the case for all SCP members, because it involved issues of human rights, the right to health, the right to life, etc. It observed that many delegations had stated that discussions should not take place in the SCP due to the discussions held in other fora, and in those other fora, they would prevent discussions there because they were being discussed in the SCP. The Delegation expressed its concern about getting into a vicious circle and about the final intention of those delegations. In particular, it recalled that, on the subject of flexibilities discussed in the CDIP, it had been stated that the issue had been exhausted. Therefore, it was surprising for the Delegation that the same delegations were stating at the ongoing session of the SCP that the issue should be looked at in the CDIP. In its view, there was much to be discussed on the subject of flexibilities so that developed countries that used those flexibilities could promote the development by explaining how they had used it on an ongoing basis. In conclusion, the Delegation, supporting the

statement made by the Delegation of Paraguay on behalf of GRULAC, stated that the project should not be delayed any longer and that the first phase of the African Group and the DAG`s proposal should be adopted and moved forward.

128. The Delegation of Norway supported the statement made by the Delegation of the United States of America on behalf of Group B. It reiterated its statement made at the seventeenth session of the SCP by stating that it was within each country's freedom to fully apply the flexibilities in the patent system within its national framework. Considering the nature of the SCP, the Delegation considered that the issue of patents and health lay within the scope of what might be discussed in the Committee. However, in its view, one should avoid duplication of work in relation to other organizations as well as other WIPO Committees.

129. The Delegation of the Republic of Korea stated its appreciation for the proposals submitted by the Delegations of South Africa on behalf of African Group and the DAG, and the United States of America, which were included in documents SCP/16/7 and SCP/17/11, respectively. It stated that both proposals had provided interesting and helpful aspects on that very crucial issue. The Delegation attached great importance on the patents and public health issue while, at the same time, recognizing that that was extremely complicated issue. Supporting the statements made by the Delegations of Spain and Denmark on behalf of the European Union and its 27 Member States, the Delegation expressed its concern about duplicating efforts in the SCP. It continued by stating that the issue relating to access to medicines was an ongoing topic discussed in many other fora in WIPO, the WHO and the WTO. In particular, the Delegation referred to the trilateral study on “Promoting Access and Medical Innovation: Intersections Between Public Health, Intellectual Property and Trade”, and the ongoing discussions within the framework of the CDIP. The Delegation further stated that since only limited resources were available to deal with a number of issues in the patent system including patents and health, it believed that any conclusions derived from the discussions or studies already undertaken by WIPO, the WHO and the WTO could form a better basis for the further development of the issue in the SCP in an efficient manner. While the Delegation was well aware of the importance of better utilizing the flexibilities provided in the international patent system, it emphasized that developing innovative medicines required a tremendous amount of time and cost. Therefore, giving incentives to inventors in the framework of the patent system was a reasonable measure to promote development of innovative medicines. In that regard, the Delegation shared the view expressed by the Delegation of Hungary on behalf of the CEBS that the issue should be balanced and take into account the crucial role of the patent system in the process of research and innovation of new medicines, which was more desperately needed in developing countries and LDCs.

130. The Delegation of Algeria, speaking on behalf of the DAG, stated that the proposal by the Delegation of the United States of America was interesting, and that it proved their commitment and constructive attitude. Referring to the phrase in the proposal that a number of factors influenced the availability of medicines in developing countries, the Delegation noted that even if that were the case, it was important to recognize that the price factor was a determining factor for the life and death of people who did not have access or who could not have access to medicines, not because they were not available but simply because the cost was too high. The Delegation considered that it was a factor that should be primordial in the study that WIPO should undertake. In its view, the influence of the other factors on the health system, did not rule out studying the issue of access to patented medicines, as the WHO Secretariat itself had recognized that patents could have an influence on access to medicines. The Delegation further referred to the WHO website on which reports and discussions on the issue were available. The Delegation stated that the Doha Declaration recognized the concerns about the TRIPS Agreement and its effect on prices. It noted that a number of governments had intervened to circumvent that barrier of patents in order to improve access to medicines. In its view, it had been proven that patents were an obstacle to access to medicines in particular countries. Furthermore, the Delegation considered that the proposal by the Delegation of the United States

of America could jeopardize the role of flexibilities, particularly the grant of compulsory licenses provided for in the TRIPS Agreement to improve access to affordable medicines. The Delegation further reminded the Committee that the compulsory licensing mechanisms were not only used by developing countries but by developed countries as well, for example, in the United States of America and Canada. The Delegation was of the view that that mechanism, which was useful and necessary, should be examined in a WIPO study. Furthermore, regarding the view of the United States of America that rather than flexibilities, other options such as voluntary licenses and tiered pricing should be considered, the Delegation noted that voluntary licenses were obligations negotiated between private parties and such licenses depended on the terms of the license. Therefore, in its view, voluntary licenses were less useful to the countries of DAG than compulsory licenses. Regarding the tiered pricing solution proposed by the United States of America, the Delegation referred to a Report of the Commission on Intellectual Property Rights, Innovation and Public Health of WHO which stated that the use of preferential pricing to solve difficulties of access might not turn out to be as useful as compulsory licenses. Further, regarding the statement that weakening the patent rights granted to pharmaceutical researchers and manufacturers in certain markets not only removed or reduced the incentive to develop new medicines, but also led manufacturers to keep already developed medicines out of those markets, the Delegation stated that no statistical data was submitted to support that statement. Further, according to its observation, it was well-known that the present system of encouragement was incapable of stimulating R&D needed by many people in developing countries. The Delegation stated that it was fully committed to long-term activities as suggested by the Delegations of Switzerland and Canada. It explained that although its proposal established three levels of programs that could be undertaken in the short-term, it was also prepared to undertake as many long-term activities as they could. Further, referring to the position expressed by the Delegation of the United States of America on behalf of Group B that the SCP should await the results of the work being done by WIPO, the WTO and the WHO, the Delegation emphasized that WIPO was an independent organization which did not have to wait for the results of the activities undertaken in other organizations before establishing its own activities. Finally, on the subject of duplication, the Delegation was concerned about the meaning of the term “duplication”, since on the one hand, during the CDIP meeting, it had been told that the issue of flexibilities had already been taken into account by the SCP, and on the other hand, during the current session of the SCP, they were being told that it was being dealt with by the CDIP. The Delegation stated that looking at the document describing WIPO's activities on the matter, there was no activity that might duplicate its proposal. If that were the case, the Delegation requested other delegations to indicate where exactly such duplication occurred.

131. The Representative of the CSC stated that the patent system involved not just the rights of patent holders but also flexibilities such as, exhaustion of rights, compulsory licenses and patentable subject matter, among many others. In her view, WIPO's mandate on patent issues extended not just to the issue that affected right-holders but also flexibilities that were part of the system, including their use in specific sectors. The Representative stated that it was worth recalling Article 8 of the TRIPS Agreement which stated that Members may, in formulating or amending their laws adopt measures necessary to protect public health and nutrition. Accordingly, she observed that the TRIPS Agreement contained flexibilities that Members could take to protect the public health interest as envisaged by Articles 7 and 8 of the TRIPS Agreement. In her view, such flexibilities were found in, for example, Article 6 on “Exhaustion”, Article 7 on “Patentable subject matter”, Article 8 on “Exceptions”, Article 31 on “Other use without authorization of the right-holder”, and Article 44 on “Injunctions”. The Representative considered that the issue of patents was interlinked with the ability to take measures to protect public health, as was well noted in above Articles as well as in the Doha Declaration on the TRIPS Agreement and Public Health. According to her observation, the SCP until recently had spent most of its time focusing on development of patent law to protect the rights of the patent holders. In her opinion, it was time to reflect on its implications for health. Referring to the statement of some delegations which had suggested that using flexibilities amounted to

weakening of patent rights, she stated that flexibilities were an integral part of the patent system and their aim was to balance public and private interests. Taking into account the fact that developed countries, such as the United States of America, used flexibilities on a regular basis, it was puzzling for the Representative to hear the same countries described flexibilities used by developing country governments as "weakening of patent rights". She continued by stating that the use of flexibilities by some developing country governments as well as public interest groups and other entities had been positive. For instance, in 2006, public interest groups filed a pre-grant opposition against Glaxo Smithkline(GSK)'s application on Combivir, which was an important ARV product, arguing that it was an obvious combination of two ARV drugs in one pill and they had not been entitled to a patent under the Indian patent law. Following the filing of the pre-ground opposition, GSK had withdrawn its pending patent application in India as well as in other countries, enabling improved access to generic versions of Combivir. The Representative stated further that another example was that of Malaysia issuing a compulsory license to import three products from India to supply public hospitals which had led to an average cost reduction of about 81 percent per month per patient for the Ministry of Health, and the number of patients that could be treated in government hospitals increased from 1,500 to 4,000. Interestingly, the compulsory license had also resulted in reduction of prices by the originating companies. She continued by stating that by 2004, GSK had reduced the price by 50 to 80 percent and Bristol Meyers Scripps had reduced the price from 50 to 90 percent. Further, the Representative stated that the proposal by the Delegation of the United States of America was one-sided, as it only focused on the positive role of the patent system. She noted that the WHO Commission on Intellectual Property, Innovation and Public Health had released a detailed report in 2006 on the linkage between IP, innovation and public health. The report had concluded that patents were not a relevant factor or effective in stimulating R&D in diseases that disproportionately affected developing countries. It was also noted in the report that the monopoly cost associated with patents had limited the patented healthcare products required in developing countries and could be a barrier to further R&D efforts as well. In view of all those observations, the Representative was disappointed with the observations made in the proposal by the Delegation of the United States of America, as well as the statements made by 12 members of the SCP. Thus, the Representative strongly urged the Delegation of the United States of America to reconsider its proposal and urged Member States to develop a concrete plan on patents and public health on the basis of the African Group and the DAG's proposal.

132. The Representative of ALIFAR agreed with the proposal submitted by the Delegation of South Africa on behalf of the African Group and the DAG. He stated that the patent system should serve to promote and protect public health, as was indicated in the above proposal. He noted that the regulations in the area of patents should be compatible with the people's right to health and, in particular, access to medicines. Because of the compromise in the objectives of conciliating patents with the promotion of public health, he objected to the proposal of the Delegation of the United States of America. The Representative stated that ALIFAR rejected the claim that linked greater access to medicine with patent rigor. In his opinion, there was an extensive international opinion on the negative impact of patents on public health in developing countries, which could result from legislation that sought to establish a rigorous patent system. In that regard, he particularly noted the WHO Report on Public Health, Innovation and Intellectual Property Rights of 2006. Further, he also noted his disagreement with seeking to attribute to the patent system the responsibility for the lack of medicines in certain markets with conclusions such as, "much more products would have been made available to developing countries in which IP rights had been strengthened". He stated that it seemed clear that the matter of access to medicines in developing countries did not arise from whether or not a medicine was available, but rather whether those medicines were affordable and whether the people had access to public health. He noted with the conviction that one of the most important aspects was the extensive use of flexibilities to improve access to medicine. The Representative stated that there was no doubt that compulsory licenses had proven themselves to be an effective mechanism for having access to patented medicines. With respect to the trade of falsified goods and substandard medicines, ALIFAR and its associated laboratories

supported actions of authorities of respective countries in eradicating that scourge. However, he stated that that issue would go beyond the mandate of the SCP and WIPO, and had no link with patents, inventions and enforcement. He noted that the WHO had shown that the problem of falsified medicines and substandard medicines affected medicines that were covered by patent protection as well as generic medicines. While reiterating that the fight against falsified medicines was not part of patent enforcement, the Representative stated that strict applications of laws, including criminal sanctions, if they were provided for in national legislation, were needed. In conclusion, ALIFAR wished to see the Committee to continue making progress, and supported the proposal of the African Group and the DAG with the objective of furthering the work plan. He further stated that a framework study by independent experts should include a cost-benefit analysis with respect to public health for certain types of patent claims of pharmaceutical patents. The Representative referred to the so-called "Markush claims" and also to patents on selection inventions, diagnostic and surgical methods, first and second medical use claims, patents on formulas and composite pharmaceuticals, salts, esters and other already known derivatives and substances, patents on polymorphs and analogous sediments actives, antonyms, active metabolites and other drugs which were already known, as well as patents on the administration of medicines and doses of certain pharmaceutical. The Representative noted that the Argentinean authorities had regulated the issues following the recommendations issued by WHO, ICTSD and UNCTAD in the working document on the assessment of pharmaceutical products. Noting that the objectives of the Argentinean regulations were protecting public health, regulating pharmaceutical patents and accelerating competition in pharmaceutical markets, the Representative believed that those criteria should be applied to other developing countries.

133. The Representative of MSF reiterated its support to the proposal of the African Group and the DAG. The Representative expressed its concern in relation to the proposal by the Delegation of the United States of America, as MSF considered it as a step backward in the promising discussion in the SCP. He stated that the proposal by the Delegation of the United States of America seemed to be based on several assumptions on the relationship between patents and global health, which did not reflect the MSF experience providing medical care in many developing countries where it worked. The Representative further explained that, in those countries, they were confronted with a range of access barriers related to the patent system. Its field experience showed that accessing affordable quality drugs could be distracted due to patents. As an example, he referred to Tenofovir used for the treatment of HIV/AIDS. He further stated that that problem was increasing with the full implementation of the TRIPS Agreement in countries which had existing and prospective generic drug capabilities. Therefore, in its opinion, it was vital that all developing countries make full use of flexibilities as one of the tools that allowed such barriers to be overcome to continue to have access to affordable medicines. He stated that the proposal by the United States of America contradicted the Doha Declaration on TRIPS Agreement and Public Health and WHO GSPOA. MSF highlighted three areas for consideration by the Committee and its Member States as part of ongoing work. First, the issue of transparency and access to patent related information was critical for them and other treatment providers to make decisions about treatment options and procurements. For example, MSF had an extensive experience of treating people living with HIV/AIDS and it had been reporting continuously in publications and the web that tracking information about which patents were in force in a particular country was often extremely difficult. There could be multiple patents on specific drugs making it difficult in finding relevant patents because of lack of uniformity in how patents were described in various countries and jurisdictions. Furthermore, the patent situation of different drugs could be so complex that drug procurers, like MSF, often did not get full information about patent status in countries where it worked. The Representative further suggested that WIPO, building on its work it had already done with Medicines Patent Pool and other patent offices, consider the development of a patent database for all medicines, and/or offer on demand assistance to procurers to identify relevant patents with the help of patent offices. Second, referring to the Committee's discussion on different aspects of quality of patents, the Representative stated that it was particularly important in the field of medicines that

the patents were only granted to those inventions which met the robust patentability criteria. Noting that, however, a number of developing countries did not undertake substantive patent examination, the Representative stated that without such examination system, developing countries could not fully benefit from different flexibilities under in the TRIPS Agreement, such as the capacity to define the patentability criteria that promoted the public health and prevented evergreening practices or bogus patents being granted in developing countries. There was little information on the ways in which developing countries could implement feasible and functional examination systems suitable for their domestic needs and public health priorities. In the view of the Representative, It would be useful for a study to be undertaken on the different costs and structures of examination systems in developing countries. Further, the Representative stated that the important role of patent opposition systems should be noted as an important mechanism to increase patent quality. The opposition systems, both pre-grant and post-grant, were crucial to ensure that all information was reviewed and thoroughly scrutinized by national patent offices. The Representative stated that, in India, for example, the use of opposition systems had led to the rejection of patent applications of doubtful quality on vital HIV drugs for example tenofovir, darunavir and child friendly versions of nevirapine in syrup form, allowing generic companies manufacture, supply and export those AIDS medicines to the rest of the developing world. In his opinion, the incorporation of an opposition system in developing country's patent law was a key public health safeguard.

134. The Representative of KEI expressed his support to the proposal by the African Group and the DAG. He expressed his opposition to the proposal of the Delegation of the United States of America, as indicated in his submission compiled in document SCP/18/INF/3. He further stated that the latter proposal was an effort to ignore the fact that patents caused problems. He was particularly concerned about the comments made in relation to the WHO's List of Essential Medicines, a topic which had been a subject of a meeting between the USPTO and several public interest groups. He further referred to his personal case to illustrate why he thought that a legal regime under which it was not possible for patients to access to life-saving drugs due to an artificial scarcity around the patent system was not acceptable. He further stated that there were problems of barriers to access in the United States of America. Referring to the AIDS problem in the United States of America, he stated that there were thousands of people on waiting lists that could not get access to government-funded programs for the treatment of AIDS. He observed that there were 1.2 million people who were HIV positive and there were 50,000 new infections per year in the United States of America. He noted that those drugs not just saved lives of people but evidence had shown that they increased the risk of infection by 95 percent. In addition, he noted that there were States which had made it harder to get on to the waiting lists and there were about 20 States that had imposed certain kinds of cautionary mechanisms designed to restrict access to drugs. Thus, in his opinion, sustainable access to AIDS drugs for the expanding population could not be provided in the United States of America. The Representative further observed that only about a third out of over a million sick people in the United States of America were getting those drugs, and that the head of the AIDS program of the Health Department in Washington, D.C. had testified that the AIDS drugs were a budget buster because of the patent issue. In addition, the winner of the Nobel prize in economics, John Stiglitz had testified at the hearing that the United States of America needed a fresh, new, radical approach to eliminate the exclusive rights around patents for AIDS drugs and replace it with inducement prices, with a way of delinking R&D incentives from the prices of drugs. The Representative further stated that the World Health Assembly of the WHO was debating the idea of such delinkage in the context of diseases found in patients in developing countries, such as malaria and tuberculosis. The Representative concluded by stating that when it came to public sector research that could be delinked from drug prices, the United States of America had opposed to that at the World Health Assembly, and at the SCP, it had mounted a big attack on the African Group and the DAG's proposal. The Representative expressed his disappointment in the way the Obama administration was dealing with that issue.

135. The Representative of TWN stated that while it might be the case that a number of factors

affected the availability of medicines in developing countries, it was also important to acknowledge that the price factor could be determinative of whether a patient would have access to the treatment it required or not. He stated that there was a major success in treating HIV/AIDS due to the fact that the prices for ARV drugs had dropped dramatically in the last decade from more than $10,000 per person per year in 2002 to less than $150 per person per year. That price reduction had made life saving drugs accessible to millions of people in developing countries, as by the end of 2010, 6.6 million people in low and middle income countries had received access to ARV therapy and ahad been 300,000 people in 2002. That had been a result of competition from suppliers of generic drugs mainly from India, as the transitional period in place in India allowed firms to produce affordable generic versions of ARVs and, more importantly, to produce easier combinations of ARVs. He continued stating that that single example showed how the removal of patent barriers, as well as the use of the TRIPS flexibilities had had enormous positive impact in improving access to medicines in developing countries. The Representative further stated that the proposal by the United States of America undermined those flexibilities, particularly, in providing access to affordable treatments. The proposal had deliberately chosen to ignore concrete evidence available today on the positive impact of relevant flexibilities on public health. He further stated that there were ample evidence to show that use of compulsory licenses in many countries improved access to medicines, especially after the adoption of the Doha Declaration on Public Health and the TRIPS Agreement. He observed that, most recently, the government of India had granted a compulsory license on a patented drug on the ground that the drug was not available to the public at a reasonably affordable price. The patented version costed 5,600 USD per month while the generic version produced under the compulsory license would only cost 176 USD, making the price reduction by nearly 97 percent. The Representative further observed that, as a result of the compulsory license, other producers had also put down prices of other key cancer drugs by more than 50 percent. In his opinion, the compulsory license would improve access to affordable medicines for cancer patients in India. Referring to the proposal by the Delegation of the United States of America noting that only about 4 percent of the medicines in the WHO's List of Essential Medicines list had been protected by patents, he stated that it was a well-known fact that drugs for HIV/AIDS were only added to that list after extensive campaigning by AIDS activists. In his view, the fact that other factors, including the weakness of the health system, could affect access did not preclude the need to address also patent barriers. He noted that the WHO itself had recognized that patents could impact access to medicines and had issued or commissioned various publications on the matter. In his opinion, that encouraged the use of the TRIPS flexibilities to overcome the patent barrier. Further, in relation to the issue of falsified and other substandard medicines, the Representative stated that that issue had no connection with patent issues. A product was granted a patent on the basis of whether it fulfilled the patentability criteria used nationally and not on the basis of quality and safety of medicines. Since that was an issue being debated in the WHO, WIPO, in his view, did not have the mandate to handle it. The Representative noted that over 30 civil society organizations in their open letter to Member States participating in the SCP had expressed serious concerns with regard to the proposal by the Delegation of the United States of America on patents and health and had requested its withdrawal. He further stated that those organizations expressed their support for the African Group and the DAG’s proposal on patents and public health, and called on all WIPO Member States, including the United States of America, to support that proposal. He stated that civil society organizations had also called upon WIPO Member States to make all efforts to agree to a work plan as outlined in the African Group and the DAG proposal. Further they had encouraged all countries to urgently enact and use patent flexibilities to further their public health objectives. In his opinion, LDCs should also seek further extension of their transitional period, especially with respect to pharmaceutical product patents and data protection.

136. The Delegation of Venezuela (Bolivarian Republic of) stated that the proposal by GRULAC to take up the first phase of the African Group’s and the DAG’s proposal had been supported by its Delegation and had not been opposed by any Group. The Delegation therefore considered that that proposal was presumed to be accepted by the Committee.

137. The Delegation of the United States of America clarified that its statement on behalf of Group B had indicated that no work should be done on the proposal until the trilateral study from WIPO, the WHO and the WTO was available.

138. The Delegation of Denmark stated that it was totally in line with the statement made by the Delegation of the United States of America on behalf of Group B.

139. The Delegation of Egypt, speaking on behalf of the African Group, requested a clarification as to whether the Delegations of Denmark and the United States of America were against the agenda item under discussion or against the proposal put forward by the African Group and the DAG. If their position was against or a postponement of the proposal by the African Group and the DAG, the Delegation sought clarification from the Delegation of the United States of America whether it withdrew its own proposal under the same agenda item.

140. The Delegation of Algeria, speaking on behalf of the DAG, stated that the DAG and the African Group represented more than 70 countries. Those countries stated that it was not necessary for WIPO to wait for work that had been initiated in other organizations in collaboration with WIPO. It stated further that WIPO was an independent organization and the SCP was a WIPO Committee, not a joint WIPO-WTO-WHO Committee. Therefore, in its view, the Committee should not wait for the results from the trilateral work before undertaking its work. The Delegation stated that the question was not whether WIPO should or should not undertake work, but rather, what it should undertake. In its view, there was a consensus on the fact that there should be a study, whatever the study was. It was of the opinion that the time had come to discuss the theme of the study. The Delegation expressed its readiness to re-examine the first stage of its proposal in order to have a study together with its partners.

AGENDA ITEM 10: CONFIDENTIALITY OF COMMUNICATIONS BETWEEN CLIENTS AND THEIR PATENT ADVISORS

141. The discussions were based on document SCP/18/6.

142. The Delegation of the Russian Federation emphasized the high quality of the work on the subject of the “right of a patent advisor not to disclose information obtained from a client” in document SCP/18/6. The Delegation observed that the document reflected the approaches and possible remedies to cross-border aspects of confidentiality of communications between clients and patent advisors, including the search for minimum convergence of national standards of substantive law, which were able to effectively prevent the disclosure to third parties of the content of a confidential service in the sphere of intellectual property, irrespective of the citizenship or place of registration of the patent advisors and the place where the service was provided. Taking into account the significant divergences in the legislation of different countries regarding the establishment for a patent attorney of the privilege not to disclose client information, the Delegation had previously put forward a proposal on the need to further study the issue of a minimum international standard in that area, which coincided with the proposal of the International Association for the Protection of Intellectual Property (AIPPI) on the development of an international basic standard, as reflected in paragraphs 54 to 57 of document SCP/18/6. The Delegation explained that, in the Russian Federation, a limited privilege existed for patent advisors, since confidential information available to a patent advisor may be supplied to third parties on a court decision and/or where that was directly established by federal law. The Delegation therefore noted that national standards of professional secrecy of a patent advisor, i.e., confidentiality of client relations, significantly lagged behind the standards of certain countries, both those governed by common law and civil law systems. In addition, the Delegation pointed out that the accession of the Russian Federation to the WTO had given rise to the need to revise the standards in question. The Delegation considered that the most

appropriate way to implement a system of cross-border protection for patent-advisor confidentiality, i.e., the establishment of privilege, might be the development of an international agreement envisaging the recognition, for foreign patent advisors, of the right to client confidentiality and the protection thereof from compulsory disclosure in the Russian Federation on a mutual basis. It considered that the subsequent incorporation of an international agreement in the national legislation of the Russian Federation and, consequently, the unification and mutual recognition of the right to client confidentiality for a patent advisor, would promote both the interests of Russian companies and inventors abroad and the interests of foreign companies using the services of foreign and Russian patent advisors for the provision of cross-border relations in relation to legal protection and enforcement of intellectual property. Therefore, the Delegation favored continuing the work on the subject in question.

143. The Delegation of Switzerland highlighted that document SCP/18/6 provided a comprehensive explanation of approaches and remedies in the area of confidentiality of communication between clients and patent advisors at national, bilateral and international levels. The Delegation supported the statement made by the Delegation of the Russian Federation, considering the importance of the confidentiality of communication between clients and patent advisors in cross-border cases, and the fact that only a few countries provided a clear legislation in that field. Therefore, the Delegation strongly supported the work on that topic within the SCP. During the last session, the Delegation had supported the idea of minimum standards which should not be mandatory but should give WIPO Member States guidelines on how to best address that topic and define national standards. Those minimum standards should also reveal how countries that had solved those problems with cross-border communication and confidentiality on a national level had addressed the issue. Document SCP/18/6 provided an excellent basis for the establishment of possible options of minimum standards or of common principles as potential, not mandatory, mechanisms for solving the still existing problem of cross-border issues. Therefore, concerning future work, the Delegation supported continuing the work on the cross-border aspects of the confidentiality of communications between clients and patent advisors by the SCP. The Delegation suggested that the Secretariat, taking into account the views expressed in the contributions made and based on document SCP/18/6, prepare a guide with possible options as well as minimal standards which could be used as templates for the national legislation or as tools for the mutual 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 Committee.

144. The Delegation of India reiterated its concern about the proposal made by the ICC on respecting the privileges of other countries. The Delegation reaffirmed its view expressed during the past meetings that such a move imposed extra-jurisdictional powers, which was a clear violation of the sovereign authority of a country and was recognized by neither the TRIPS Agreement nor the Paris Convention. The Delegation reiterated that the Indian Patents Act provided no provision for such attorney-client privileges. In India, persons who had graduated in science were qualified for practicing as a patent agent, even without having a law degree. There was a privilege for the advocates under the Indian Evidence Act which protected lawyers from such discovery proceedings. In its view, however, the patent agent being a person of scientific ground, having qualified the patent examination under the Indian law did not fall under such protection. The Delegation emphasized that, since the discovery related to not only technical information but also other relevant information concerning patent applications, for example, most relevant prior art, such information might be very relevant, and at the same time, detrimental to the determination of novelty and inventive step. The Delegation therefore considered that such information was a substantial element of the patent system. The Delegation was of the opinion that one of the important duties of the patent attorney was to promote the dissemination of information about the patent application, and, therefore, any effort to formalize the client-attorney privileges would ultimately lead to a defective and unenforceable ground of patents. The Delegation considered that any confidentiality of the information between a client and his attorney could be protected through a non-disclosure agreement. It noted that the Indian

Patents Act provided for the power to the Controller of requiring the discovery and production of any document.

145. The Delegation of Australia considered that document SCP/18/6 gave a very useful summary of the cross-border aspects of confidentiality, including remedies and practical approaches. That information was useful to SCP members in order to provide them with the benefit of others' experience, when deciding how to deal with those issues. The Delegation continued to support further study of that issue at the international level. It considered that free and frank communication between clients and their patent advisors was essential to the patent prosecution process, as it helped patent advisors in delivering high-quality services to their clients. In the context of the global patent system, the Delegation considered that high quality professional representation led to high quality patent specifications, giving greater certainty in the validity of granted patents, and importantly, an increase in the quality of information which was disseminated to the public. Referring to a recently passed intellectual property reform Act, the Delegation explained that among the amendments was a change to the provisions relating to the confidentiality of communications between clients and their patent advisors. The Act extended the privilege to communications between applicants and their foreign patent advisors. As foreshadowed in paragraph 28 of document SCP/18/6, that had been achieved by expanding the definition of patent attorney to include an individual authorized to do patents work under the law of another country or region. Under the amended Act, the privilege only applied to the extent that the attorney was authorized to provide intellectual property advice. The Delegation pointed out that those changes were necessary to reflect and support the global nature of trade and intellectual property, where patents for the same invention were often sought simultaneously in a number of jurisdictions.

146. The Delegation of Algeria, speaking on behalf of the DAG, reminded the Committee of its position concerning agenda item 10. The DAG did not agree with the view that the Committee could come to an agreement on that matter. In its view, following the previous sessions, it was clear that there was no consensus on undertaking activities in that area, because confidentiality of information had to be managed at the national level, based on the national interests and modalities that were provided for in each State. The Delegation stated that in many States, the issue was not dealt with in the patent law, but in civil or criminal procedures, and in some countries, in the law that governed discovery. The Delegation considered that it was the duty of each country to deal with such a sensitive and important issue as the confidentiality of communications. The Delegation expressed its preference that that item did no longer appear on the agenda of the SCP. In its opinion, too much time had been spent on that issue without reaching any consensus.

147. The Delegation of Hungary, speaking on behalf of CEBS, reiterated its position expressed in the opening statement. Being a strong proponent of confidentiality of communications between clients and their patent advisors, the Delegations highlighted that the relevant topic needed further substantive examination. In that regard, it supported the statements made by the Delegations of the Russian Federation and Switzerland. It considered that document SCP/18/6 contained practical approaches and solutions, and that finding remedies with respect to the identified problems in relation to the cross-border aspects would be of benefit to users of the patent system. It also thanked the non-governmental organizations (NGOs) for their valuable contributions to the debate. It strongly supported continuation of the work on that issue, and stated that the adoption of common non-binding principles regarding possible remedies and practical solutions could be a way forward.

148. The Delegation of Denmark, speaking on behalf of the European Union and its 27 Member States, highlighted that document SCP/18/6 provided the Committee with a useful overview of possible remedies identified with respect to the cross-border aspect of preserving the confidentiality of communications between patent advisors and their clients, including rules regarding the foreign patent advisors by national laws, choice of law rules and practical

approaches. The Delegation expressed its conviction that the convergence of existing diverse systems in the area of confidentiality of communications between clients and patent advisors among WIPO Member States would be beneficial for users of the patent system, irrespective of the level of development of individual WIPO Member States. In its opinion, the time was ripe to consider concrete mechanisms to address the recognition of foreign patent advisors' privilege. The Delegation expressed the view that, to avoid the need to amend national legislation or change national judicial systems, a soft law approach should be considered, whereby WIPO Member States could adopt minimum standards or common non-binding principle that could be applied at the national level in line with the proposal made by the Delegation of Switzerland. The Delegation supported the continuation of the work on that issue in the Committee.

149. The Delegation of Egypt, speaking on behalf of the African Group, supported the statement made by the Delegation of Algeria on behalf of the DAG by expressing its belief that whatever the outcome of the proposed process could be, whether guidelines, whether those were voluntary, whether it was a toolkit, at the end of the day, it gave the impression that that was some sort of a supra-national approach. The Delegation stated that that approach would cut down the policy space and the sovereignty to design national laws and policies in that regard. The Delegation pointed out that the studies undertaken by WIPO in that regard had clearly stated that there were various legal systems at the national level and that those could not in any way be harmonized or synchronized. In its opinion, the studies that had been done in that area were sufficient enough to indicate that there was no room for future action on that issue.

150. The Delegation of Iran (Islamic Republic of) pointed out that the issue would fall in the purview of national laws within the scope of civil procedure law and regulations of each country. Given the fact that there was a wide discrepancy among the national laws, the Delegation believed that the SCP was going too far, if it discussed common and international standards or any kind of norm-setting at that stage. Furthermore, on the issue of cross-border aspects of confidentiality of communications between clients and patent advisors, the Delegation informed the Committee that its country did not recognize any kind of privilege in its national law.

151. The Delegation of Spain noted that the lack of harmonization in the recognition of confidentiality of communications between clients and patent advisors gave rise to serious problems. The Delegation stated that, in the intellectual property sphere, the freedom of communications between clients and patent advisors was necessary so that the advice given would be of the highest possible quality. In its view, freedom of communication would not exist if the confidentiality was not recognized at the international level. The Delegation observed that the international situation was changing ever more swiftly, and the number of inventors from emerging countries who were becoming technological powers, for example, in renewable energies, bio-fuels and other green technologies, and who wished to protect their inventions in other countries had been increasing. In its opinion, such countries would also benefit from international recognition of confidentiality of communications between clients and patent advisors. The Delegation suggested that the SCP continue working on that matter, especially with respect to extension of confidentiality at the international level. Aligning with the statement made by the Delegation of Denmark on behalf of the European Union and its 27 Member States, the Delegation urged the Committee to adopt an approach through which WIPO Member States would adopt a number of non-binding principles or minimum standards to be implemented at the national level, in accordance with the proposal made by the Delegation of Switzerland.

152. The Delegation of South Africa aligned itself with the statements made by the Delegations of Algeria on behalf of the DAG and of Egypt on behalf of the African Group. It noted that the Committee had heard that that was an issue to be dealt with by national laws. The Delegation fully agreed with the position that that issue should no longer be on the agenda of the SCP in order to make progress.

153. The Delegation of Djibouti stated that the issue under consideration superseded the

national jurisdictions and that the Committee had spent more than enough time on it. It therefore supported the position that the issue should be removed from the agenda in the future.

154. The Delegation of Japan stated that permitting patent advisors to claim confidentiality might enhance reliability and stability of the intellectual property system both in developed and developing countries, which would contribute to the interests of all the relevant parties. Noting that various solutions might be possible in order to afford confidentiality in cross-border cases, the Delegation stressed the importance of putting into practice a system where an applicant could file patent applications across different jurisdictions in a safe manner. The Delegation therefore expressed its hope to advance the discussion on that topic in a constructive manner in order to ensure confidentiality of communications between clients and their patent advisors.

155. The Delegation of the Republic of Korea highlighted that, as the work of patent advisors has become more globalized, partly also due to the Patent Cooperation Treaty (PCT), each office could not separately deal with the issue of confidentiality. Besides the acknowledgment of the privilege or confidentiality obligation, in its opinion, the issue should be resolved globally. The Delegation expressed the view that the common interest between States should be further shared in order to globally deal with confidentiality of communications between clients and their patent advisors. The Delegation therefore requested to continuously work on the study by further analyzing actual cases.

156. The Delegation of Brazil stated that document SCP/18/6 provided a good overview of the discussions in the Committee. The Delegation reiterated that, in the Brazilian legislation, there was no provision for a different treatment of foreign lawyers and patent agents when compared to Brazilian professionals. To the best knowledge of the Delegation, no difficulties were reported so far in the Brazilian jurisdiction. The Delegation observed that the debates under that agenda item had provided for different approaches to that issue. Some countries were in favor of a basic international standard and others were of the view that bilateral arrangements would best suit their needs. Further, some members showed sensibilities 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, the Delegation expressed its belief that the best approach for the moment would be to leave it to the countries to define their own standards.

157. The Delegation of the United States of America, speaking on behalf of Group B, considered that it was important to maintain a balanced work program in the SCP. In its view, the issue was to further address the cross-border aspects. In response to the concerns that continuing work might lead to harmonization of national law, it pointed out that, as the Delegation of Switzerland and others had stated, any guidance or compilations would be non-obligatory. The Delegation urged that the confidentiality of communications between clients and their patent advisors remained on the agenda of the SCP and that work should proceed.

158. The Delegation of Romania aligned itself with the statements made by the Delegations of Spain and Switzerland. The Delegation stated that cross-border issues were issues of interest for patent attorneys from Romania and other countries, and highlighted that the preparation of non-binding principles by the Secretariat did not mean any interference with national legislation.

159. The Delegation of Germany endorsed the statements made by the Delegations of Denmark on behalf of the European Union and its 27 Member States and Hungary on behalf of the CEBS. The Delegation expressed its belief that that topic should remain on the agenda. It noted that, as the Delegation of the United States of America on behalf of Group B had pointed out, the principles should be non-binding.

160. The Delegation of Chile stated that, as could be seen from document SCP/18/6, there was a great deal of difference in the rules governing the different aspects related to confidentiality of communications. It noted that, in the case of Chile, there was an obligation to maintain

confidential those matters with which attorneys were acquainted when providing services to their clients. At the same time, lawyers had the protection of professional secrecy when they faced any inquiries from authorities or judges. The infringement of the duty of confidentiality was considered an offense under the civil code. In the case of patents, the requirement of novelty highlighted the importance of maintaining the information confidential. The Delegation, however, expressed the view that, in order to protect confidentiality among patent advisors and their clients, it was sufficient to have national rules and also any private contracts that might be signed between parties. It considered that that subject had been discussed at length at various sessions of the Committee. At the same time, the Delegation noted that the agenda should be balanced as there were delegations who wished to continue studying that subject. While the Delegation considered that the analysis done had been sufficiently thorough, if the Committee would continue to discuss that subject, in its opinion, the discussion should not disregard the various particularities of the legal systems of members.

161. The Delegation of Argentina stated that taking serious note of the concerns expressed by the Delegations of Algeria on behalf of the DAG, Chile, Egypt, Iran (Islamic Republic of), South Africa, Sudan and others, that subject was of interest to many delegations. It observed that the various documents produced by the Secretariat had highlighted the considerable diversity of rules in national legislations. The Delegation questioned how progress could be made on a common understanding when the reality showed that there was a great difference in approaches and coverage. If the Committee proceeded, the Delegation stressed the importance of proceeding with great caution, because in several countries, such as Argentina, that issue was part of public law.

162. The Delegation of Indonesia endorsed the statement made by the Delegation of Egypt on behalf of the African Group.

163. The Delegation of China stated that document SCP/18/6 enabled the Committee to better understand the information on confidentiality of communications between clients and their attorney or patent advisor. The Delegation noted that, while confidentiality played a role in guaranteeing the quality of services to protect public interests, the Committee should take into account that there were great differences among national laws. In its opinion, the issue should be dealt with by the legislation of each country. The Delegation considered that information should be exchanged, but wondered whether that should be on the agenda of the SCP. It stated that the Committee should give a careful thought to make a decision on it.

164. The Delegation of the United States of America, speaking in its national capacity, supported further work on that topic in the Committee and further analysis of the information compiled by the Secretariat, as well as further discussion between Member States regarding best practices, national experiences and solutions to the problems arising under that important topic, which could eventually be adopted on a fully voluntary basis by Member States. For example, the Delegation supported exploring non-binding international minimum standards for privilege applied to communications between clients and their patent advisors, which could be considered on a voluntary basis by Member States.

165. The Delegations of Poland associated itself with the statements made by the Delegations of Denmark on behalf of the European Union and its 27 Member States, Hungary on behalf of the CEBS, Germany and Switzerland. As the topic was extremely important for its country, the Delegation strongly supported keeping the subject on the agenda and continuing discussions thereon.

166. The Delegation of Portugal endorsed the statement made by the Delegation of Denmark on behalf of the European Union and its 27 Member States in favor of the continuation of the work on that important item. The Delegation observed that patent advisors were often subject to distinct rules which called into question the confidentiality of communications. In its view, the

international patent system would benefit from the achievement of a common solution between the different Member States to ensure confidentiality of communications.

167. The Delegation of France aligned itself with the statements made by the Delegations of Denmark on behalf of the European Union and its 27 Member States and Hungary on behalf of the CEBS. Since the topic under consideration was a very important subject, the Delegation suggested that it stay on the agenda of the Committee.

168. The Delegation of the Czech Republic aligned itself with the statements made by the Delegations of Hungary on behalf of the CEBS and Denmark on behalf of the European Union and its 27 Member States. The Delegation highlighted that discussing that topic and developing non-binding principles or minimum standards to be applied on a voluntary basis would not represent a breach upon national legislations or legislative actions. The Delegation believed that the Committee could progress on that issue by discussing the topic and by developing a possible guide as suggested by several delegations.

169. The Representative of FICPI stated that he was looking forward to continuing the work on the issue within the SCP. The Representative highlighted that FICPI had over 5,000 members in 86 countries throughout the world. Its members were active in prosecution, in litigation as well as in legal and technical advice with respect to IP rights, such as patents, trademarks and designs. He noted that, in their professional practices, its members and the clients were confronted with the issue of client-IP advisor privilege: clients invoking the privilege as well as clients confronted with the privilege invoked against them. He observed that, more importantly, they were confronted with different approaches which were taken by the different jurisdictions with respect to the client-IP advisor privilege. The Representative explained that in many court proceedings, that could lead to the situation that documents of parties from different nationalities were treated differently by the same court. That could be the case, for example, because the client-IP advisor privilege of a foreign party was not recognized by the court, whereas that of a national party was recognized. In his view, such a situation was undesirable and should not be acceptable in a world in which IP prosecution and litigation became more and more internationally oriented and were no longer confined to a single jurisdiction. For that reason, the Representative was in favor of the recognition of client-IP advisor privilege in all jurisdictions throughout the world. He stressed the importance of maintaining the client-IP advisor privilege on the agenda of the SCP. The Representative had offered to provide assistance in any possible way in order to get that topic forward to a solution that was acceptable to all Member States of the SCP. Noting that one of the concerns raised by some delegations during the previous meetings were the qualification of IP advisors and extra-territorial aspects involved with the privilege, the Representative emphasized that the client-IP advisor privilege was a right awarded to the client, not to the advisor, and therefore that right could not be invoked or abused by the advisor. In his view, that clarification was important, because in international litigation or prosecution, the client was always the same, whereas the advisors would change. In his opinion, it was a universal right that parties before a court had to be treated the same, with the same rights and obligations. The Representative was of the view that by denying one of the parties the right to invoke privilege for documents and allowed the other party to invoke the privilege for similar documents, a fundamental and universal right would be violated. That might even be the case for two parties from the same country appearing in their own court, because one of them had obtained legal advice from a foreign IP advisor. The Representative recognized the concerns of some delegations that, for example, patent attorneys did not have a legal qualification in all Member States, and that the qualifications for becoming a patent attorney were not the same in all Member States. In order to address that, the Representative considered that the SCP would benefit highly from defining at least a minimum standard for IP advisors for whom the client could invoke the client-IP advisor privilege. By providing clients with confidentiality for sufficiently qualified IP advisors and for specific documents and communications, in his opinion, clients would be allowed to freely seek advice from such advisors in different jurisdictions without running the unnecessary risk of undue disclosure in

court proceedings. The Representative was of the view that that would improve protection of relevant inventions and innovation, and would moreover help ensuring the full disclosure of inventions in patent applications because of the involvement of qualified professionals in all of those jurisdictions. While FICPI was well aware that client-IP advisor privilege was a sensitive issue in many members of the Committee, the Representative suggested that the Committee keep the topic on the agenda and be open for discussion, because internationally recognized minimum standards for such a privilege would promote innovation.

170. The Representative of GRUR supported the position of AIPPI, FICPI and others regarding the issue of protection of confidential communications between clients and their patent attorneys, giving special legal advice in the field of industrial and intellectual property. He considered that the importance was constantly growing in view of the globalization of the economies and the protection of intellectual property. In his view, the legal status and privilege of lawyers and attorneys related to confidential information should be accorded or extended without discrimination also to patent attorneys, which was the current legal situation in Germany. The Representative observed that the contribution of patent attorneys to qualified legal advice to individual inventors in small and medium-sized enterprises was immeasurable and indispensable for a high quality of patent applications and patents granted by the German National Patent and Trademark Office (DPMA) and by the European Patent Office (EPO) and for the proper conduct of oppositions and invalidation proceedings before the competent courts and offices. The Representative considered that they were in most respects better qualified for such proceedings than other lawyers or attorneys at law. He further noted that patent attorneys also played an important role in the infringement proceedings before the ordinary courts and, in particular, also in the international prosecution of patent applications. The Representative reiterated that attorneys at law and patent attorneys had to be placed on the same footing as far as the protection for confidential communications between attorneys and clients was concerned. He appreciated the frank manner in which the Delegations of India and South Africa had introduced their legal traditions belonging to the family of common law countries in previous meetings. As a continental lawyer, the Representative expressed his great respect for those traditions. As the United Kingdom, or rather, at least, England and Wales, were considered to be the mother country and the origin of the common law system, the Representative noted that the example of the United Kingdom and provisions on the attorney-client privilege in its Patents Act might serve as a model for their national legislations. In his view, the members of the patent attorney profession in those common law countries should be encouraged to actively fight against the discriminatory effect of the current legal situation in many of their countries. The Representative suggested that the topic be at least maintained on the agenda of the Committee, as WIPO was the specialized agency for intellectual property.

171. The Representative of the ICC reiterated his support for the continuation of the work by the Committee on the topic of confidentiality of communications between clients and their patent advisors, especially regarding the cross-border aspects.

172. The Representative of IPIC highlighted that, in Canada, there was a split profession that comprised lawyer IP advisors and non-lawyer IP advisors. Since no legislation provided a privilege for confidential communications between IP owners and their IP advisors, she explained that IP owners in Canada suffered from the inherent weaknesses that the lack of statutory privilege presented for the split of the profession. In her view, cross-border issues were exacerbated by the lack of legislation, as jurisprudence continued to expose those inherent weaknesses for all IP owners in Canada. The Representative considered that national efforts were required to remedy the situation, ensuring that the national approach addressed the proposals and remedies set out in document SCP/18/6 with respect to cross-border issues. The Representative expressed full support the work of the Secretariat and encouraged further work on those issues of importance to IPIC, and renewed its continuing efforts to persuade the Canadian government to enact appropriate legislation to ensure that IP owners were not disadvantaged in Canada.

173. The Representative of AIPPI highlighted that the report in document SCP/18/6 added to the previous documents on that issue in providing a concise and thorough overview of the cross-border issues of the topic. He stated that AIPPI had engaged in significant efforts in respect of that issue on behalf of its over 9,000 members consisting of academics, IP owners, and IP practitioners from over 100 countries. The Representative stated that the attention and the efforts that AIPPI had paid in that regard simply reflected how important that issue was to AIPPI, its members, national and regional groups and IP advisors and IP owners in general. In his view, if one was in the practice of intellectual property, it could not be overstated how significant an issue that had become for IP owners and their IP advisors on a worldwide basis. The Representative fully supported the work of the Committee to date and the content of the preliminary discussion in document SCP/18/6 on possible remedies in respect of cross-border issues. In his opinion, that was a very helpful start in analyzing and considering potential solutions to the problems that had been well documented and identified by the previous work of the Committee. The Representative encouraged the Committee to continue with its examination of possible remedies to cross-border issues. The results of that work had already been helpful to others outside of the context of the Committee. The Representative recalled that the issue was not a domestic one. He observed that businesses and companies of any nation could be confronted with issues of that kind when they traded at the international level, whether it was in respect of their own IP rights or the rights of others. Therefore, in his view, it was important to keep in mind that the issue was about preserving the confidentiality of those communications and advice that had been provided in respect of documents and facts and not about suppressing the production of documents, for example, prior art or the suppression of facts. With that in mind, the Representative expressed his belief that valuable results could be achieved through the Committee's ongoing leadership role in further examining the potential remedies and solutions in respect of cross-border difficulties. Those cross-border remedies might include detailed solutions or approaches tailored to meet the different requirements in both civil law and common law countries. In his view, the details that applied in those countries did not greatly differ between the two legal systems. In terms of future work, the Representative considered that such possible solutions might include model provisions, possible legal frameworks, suggested minimum standards, which was the preference of AIPPI, or non-binding guidelines. The basic position of AIPPI, as also expressed by FICPI, was that the same level of protection should be provided to communications between patent attorneys and their clients as for communications between lawyers and IP owners. The Representative pointed out that, since the last session of the Committee, AIPPI had further examined certain national approaches that had addressed the issue of preserving the confidentiality of communications, which the Committee could consider in terms of possible remedies. That work had included reviewing in detail some civil law jurisdictions, such as Japan and France, where legislative changes had been adopted creating a protection against forced disclosure that had been recognized by certain courts, for example, in the United States of America. In terms of common law jurisdictions, the Representative stated that common law countries might consider the options provided by the law in New Zealand and the recent amendment in the law of Australia. The Representative encouraged the Committee to continue investigating potential remedies and solutions, taking a leadership role in that regard. Even if that work was without any norm-setting goals, the work had proven to be very valuable in helping to address the issues and the problems that IP owners faced at the worldwide level.

174. The Representative of JPAA noted that there might be a misunderstanding about the main purpose of confidentiality between clients and patent advisors. He explained that the main purpose of confidentiality between clients and patent advisors was not to conceal important prior art from the patent office, but to prevent corporate secrets being leaked to the outside, especially to competitors. He explained that the confidentiality of communications between clients and their patent advisors was not linked to important prior art that affected the validity of a patent, but included other information, such as corporate secrets or the secrets of a client. The Representative noted that, without the privilege of confidentiality of communications and

protection of its cross-border aspects, IP owners might face a risk of losing its profit through its IP advisors, which would be significantly detrimental to the interests of clients, the quality of IP rights and any costs associated therewith. In his view, that issue was very important for both developing and developed countries. Since the issues had many international aspects and related to certain international agreements between Member States, the Representative expressed strong support to the position of the Delegation of Switzerland at the last session that minimum standards on cross-border aspects should be determined.

175. The Representative of TWN highlighted that, considering public policy concerns as well as the asymmetry existing in terms of intellectual property ownership at the international level, it was important to maintain absolute transparency around the granting of patents and litigation around patents, since society could not afford any layer of secrecy around patent specifications. The Representative was of the view that the extension of privilege to patent advisors compromised the transparency requirement, which included both patent prosecution procedures as well as litigation of patents. As the issue of privilege could always play out when there was a judicial process as for the discovery of documents or the request to produce such documents, in his opinion, that would prevent courts from discovering quality evidence. The Representative noted that there was no confusion regarding the confidentiality and the privilege. The privilege was of evidentiary value to the documentation between the client and the patent attorney. In his view, the demand for a cross-border privilege was facing the fact that, in many countries, such kind of privilege for patent attorneys had never existed. The Representative questioned whether it was possible to create a privilege that extended to cross-border situations that had not even existed in many WIPO Member States. In his opinion, the issues needed to be considered in the context of trade of services. He considered that if one would recognize such a privilege, that was a particular kind of service which was mutually agreed and thereby opening up the service sector. Therefore, in his view, the SCP was not the right forum to discuss such trade in services. In many countries, the practices of patent attorneys were only open for citizens and not for foreign nationals. Therefore, the Representative was of the opinion that extending such a privilege was not going to serve the purposes. In his view, any kind of such privilege required changes in national law. Against that background, the Representative stated that the item, having been discussed in the last three or four sessions of the Committee, should ideally be dropped from the agenda to move forward with other agenda items.

176. The Representative of APAA supported the previous statements made by NGOs, with the possible exception of the statement made by the Representative of TWN. He noted that the position of APAA on the topic under consideration had been stated during previous sessions of the Committee. The Representative stated that it looked forward to a further study of that topic in the manner generally outlined earlier by the Representatives of AIPPI and FICPI.

AGENDA ITEM 11: TRANSFER OF TECHNOLOGY

177. The discussions were based on documents SCP/18/7 and SCP/18/8.

178. The Delegation of the Russian Federation stated that the revised document SCP/18/7, which related to WIPO's activities on technology transfer and focused on the problems of such transfer in the development context, was of interest to the Russian Federation, in particular as regards the establishment and development of Technology and Innovation Support Centers, which were referred to in the document in question. The Delegation noted that the International Bureau of WIPO, together with the ROSPATENT, had undertaken additional steps to promote an international pilot project aimed at establishing and developing Technology and Innovation Support Centers in the Russian Federation. An agreement on the opening of a network of centers in the Russian Federation, which might become one of the most important elements of the nascent national innovation system in Russia, had been signed between WIPO and ROSPATENT on April 17, 2012. The basic aims of that international project were to train users

to conduct patent search, to use patent information when marketing new inventions and provide broader access for inventors to specialized databases and other information resources relating to intellectual property, in order to enhance the creation and effective use of the results of intellectual activities. The Delegation further stated that the creation of Centers would ensure: increased awareness of the benefits provided by legal protection of the results of intellectual activities and the use of patent information; active dissemination of knowledge relating to patent law at the regional level; increased exchange of technologies; and, provision of information for domestic users relating to the creation, enforcement, possession and management of their intellectual property rights. The main forms of the Center's activities were: providing access to patent and non-patent databases; increasing potential through the training of local users by means of distance learning and study programs in the sphere of intellectual property; provision of information and study materials; and dissemination of advanced experience of Centers' activities by conducting conferences and seminars in the regions. The organizational structure of the Centers was set up on a regional basis with coordination and scientific and method-related guidance provided by ROSPATENT. The potential entities which would provide services relating to the Centers' activities were universities and scientific institutions, sectoral scientific research organizations, scientific and technical information centers, libraries and regional chambers of commerce and industry. The services provided by the Centers would be supplied on the basis of a modular approach, beginning from the basic level and upwards, in accordance with the needs of local users. In that regard, the basic level included training on the conduct of database searches; access to patent and non-patent databases; and provision of assistance in the search for technical information when conducting patent search on the basis of databases. Additional services were: providing general information on intellectual property legislation; providing information on where to obtain consultation from intellectual property specialists and patent advisors on the preparation of national and international applications; and basic recommendations on licensing. The Delegation further informed the Committee that as of April 16, 2012, 72 economic entities of the Russian Federation had officially declared their willingness to participate in the creation of Centers. Measures to open up a network of Centers had been combined with an initial study seminar which was planned to be held in May 2012, in Saint Petersburg. Further development of the network of Centers was intended to be coordinated with the WIPO Action Plan as part of an international pilot project. As regards document SCP/18/8, the Delegation expressed its willingness to continue working on that particular issue. The Delegation stated that practical experience in relation to the role of patents in technology transfer was extremely important for its country, since it had a task of building an economy which rationally combined State regulations with market mechanisms, aiming at stimulating scientific and innovation activities. It noted that intellectual property mechanisms were becoming one of the key aspects of the activities of economic entities. The Delegation considered that the institution of intellectual property allowed, in a limited fashion, intellectual and innovation activities to be incorporated in the general-economic system in the Russian Federation. In its view, intellectual information products should be adapted to the realities of the market, and a balance of interests should be ensured between society and the creator of an intellectual product. The Delegation further stated that it was essential for the intellectual property system to continue to serve the most important aim – the promotion of innovation and creativity - so that the benefits of the system became accessible to all, thereby helping to bring the world closer together. In its opinion, the modern intellectual property system was designed not only to grant documents providing protection for the results of intellectual activities and support in the legal enforcement thereof, but to play a significant role in the strategic planning devised by economic subjects and in their orientation towards the creation of new technologies and the further commercialization of intellectual property subject matter. The Delegation observed that the resolution of the tasks in question depended on many factors which, together with the economic situation, defined the technical policy of organizations and, in the final analysis, the generation of results from the innovation activities they carried out. Taking into account the above, the Delegation was in favor of continuing work on the subject of technology transfer.

179. The Delegation of Iran (Islamic Republic of), speaking on behalf of the Asian Group, stated that its Group was interested in the continuation of discussion on the subject of transfer of technology in the SCP including impediments to transfer of technology. In its opinion, consideration should be given to flexibilities and their role in transfer of technology.

180. The Delegation of Algeria, speaking on behalf of the DAG, recalled that, at the seventeenth session of the SCP, the Secretariat had been requested to prepare a document listing the various WIPO activities in the area of technology transfer and expand its study on patent-related incentives and impediments to transfer of technology through practical examples and experiences. In the view of the Delegation, however, the study contained in document SCP18/8 merely sought to present some case studies on how patents had been useful in transfer of technology, and its analysis on the barriers to transfer of technology were limited to factors such as difficulty in identifying partners, lack of infrastructure, patent information, absorbing capacity, etc. The Delegation expressed the opinion that the study did not undertake any effort to analyze situations where patents had actually acted as a barrier to transfer of technology even where potential licensing partners with adequate infrastructure and absorptive capacity were easily identifiable. Therefore, the Delegation requested that the study be revised to clearly address practical cases where technology transfer could not take place due to patent barriers and address how such issues could be addressed, *inter alia*, by using patent flexibilities.

181. The Delegation of Brazil, referring to document SCP/18/8, stated that it was certainly commendable that success cases were studied, thus bringing encouraging signals for developing countries with regard to the results accruing to them by the patent system. Nevertheless, it was of the view that failure cases were at least as important as success cases for analysis, for they had the potential of providing feedback to members and therefore assist the improvement of the public policies. The Delegation observed that directly related to the discussion of transfer of technology was the capacity of absorption by national industries. Thus, in its view, the mere existence of a patent system did not automatically imply that a successful transfer of technology would take place, since many other factors influenced it. Additionally, the Delegation reiterated its view that anti-competitive practices which might be found in license agreements should be effectively countered by governments. It further stated that the discussion on transfer of technology and patents had a long history. In 1961, Brazil had made a proposal to the General Assembly of the United Nations instructing the Secretariat to elaborate a report on “The role of patents in transfer of technology to under-developed countries”. Recently, those debates were again on the agenda of the United Nations’ Framework Convention on Climate Change. Therefore, the Delegation was of the opinion that continuing work on the subject in the SCP would benefit all members.

182. The Delegation of Egypt, speaking on behalf of the African Group, thanked the Secretariat for its efforts in revising the original study. Supporting the statement of the Delegation of Algeria on behalf of the DAG, the Delegation stated that while the part on incentives was quite elaborate, the part on impediments lacked in depth analysis on how the patent system acted as a barrier to the technology transfer. It stated that they were not denying that some of the factors identified in the study were of importance and of relevance. However, the study should have been directly related to how the existing patent protection regime acted as an impediment to the transfer of technology, and ways how to overcome such impediments including, but not limited to, the use and utilization of existing flexibilities in the patent system in order to enhance transfer of technology.

183. The Delegation of South Africa supported the statements made by the Delegations of Algeria on behalf of the DAG and Egypt on behalf of the African Group. While acknowledging the efforts of the Secretariat in preparing the useful document given the short period of time, the Delegation was of the view that the examples were limited as that had been pointed out by the DAG and the African Group. In addition, the Delegation requested that the document be clustered by appropriate topics in line with the incentives and impediments to transfer of

technology described in Chapter XI of document SCP/14/4/Rev.2. In conclusion, supporting the statement made by the Delegation of the Russian Federation, the Delegation stated that the important issue under consideration should be maintained in the agenda of the Committee.

184. The Delegation of India expressed its appreciation to the Secretariat for providing comprehensive information on WIPO's activities on transfer of technology contained in document SCP/18/7, and also for providing information on technology platforms to facilitate sharing of information in particular, WIPO Green on green technology and WIPO Re:Search for sharing information in the field of health. Further, the Delegation requested the Secretariat to undertake a study on how and with what measure the technology transfer could be promoted to developing countries. In its view, it was quite evident that sophisticated technologies were owned and protected by persons from developed countries who did not seem to be inclined to transfer the technology unless strong patent protection existed in developing countries. It further stated that there was a need to study the various impediments in licensing agreements relating to transfer of technology to developing countries and LDCs in greater details for the benefits of not only the members of the SCP but also for those who were interested in developing their business and investments in those countries. In its opinion, the provided examples relating to developing countries were very few and did not reflect the correct picture. It was also pointed out that paragraphs 27 and 28 of document SCP/18/8 had mentioned very limited obstacles to licensing out patents. The Delegation, supporting the statement made by the Delegations of Egypt on behalf of the African Group and Algeria on behalf of the DAG, stated that the study should examine in more detail the obstacles being faced in he transfer of technology.

185. The Delegation of Denmark, speaking on behalf of the European Union and its 27 Member States, expressed its appreciation to the Secretariat for the preparation of documents SCP/18/7 and SCP/18/8, and noted with satisfaction the systematic approach and objectivity shown in the latter document listing various activities on the transfer of technology undertaken by WIPO. In general, that document showed that all efforts to improve the patent system had a positive impact on the contribution of the patent system to technology transfer as 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, technology infrastructure and tools, capacity building or raising awareness. In that respect, a high quality of patents, the sufficient disclosure of inventions in patent applications and an adequate scope of patent protection, and the well functioning PCT system had been mentioned by the Delegation as essential elements of the patent system to fulfill its objectives also in terms of innovation and transfer of technology. Further, the Delegation stated that, as regards the WIPO Development Agenda projects concerning transfer of technology, there were five pending projects listed in document SCP/18/8. In particular, it noted that extensive work was to be undertaken under the project on "Intellectual Property and Technology Transfer: Common Challenges - Building Solutions", implementing recommendations 19, 25, 26, and 28 under the WIPO Development Agenda. It further reiterated that until the completion of that project and its follow-up analyzes, it was not in favor of launching new initiatives on transfer of technology within the SCP. While the European Union and its 27 Member States were of the view that the work of the SCP on transfer of technology should be discontinued for the time being, they expressed their readiness to reopen the issue on the basis of analysis of results of those projects, if appropriate.

186. The Delegation of Egypt stated that since the revision of the study was of a specific nature, it did not duplicate or coincide with the work done in the CDIP. In its view, what was being done at the SCP was analyzing incentives as well as impediments to the transfer of technology as it related to the patent system, which was a very specific area of study. It recalled that the basic purpose of the WIPO Development Agenda, for which the CDIP was established at the later stage, was the mainstreaming of development in all WIPO activities and bodies, including substantive bodies, i.e., taking the development perspective in all areas of WIPO activities,

including the discussions on the patent system within the SCP. The Delegation deemed it important and appropriate that the SCP considered that issue under the umbrella of the SCP.

187. The Delegation of South Africa recalled that, at the last session of the SCP, there had been an agreement that the SCP might consider organizing a seminar to complement the study in the future.

188. The Delegation of Argentina expressed its appreciation to the Secretariat for producing the two documents SCP/18/7 and SCP/18/8. However, referring to the statements made by the Delegations of Algeria on behalf of the DAG and Egypt on behalf of the African Group on that subject matter and based on other comments, the Delegation stated that it seemed necessary to complete document SCP/18/8 with practical examples and experiences with respect to patent-related impediments to transfer of technology. Further, it stated that impediments and incentives in the form of clusters in document SCP/14/4 Rev.2, needed to be kept in the study. In conclusion, the Delegation suggested that, for the time being, the above revision of the study be conducted, and the next step be determined at the next session of the Committee.

189. The Delegation of the United States of America thanked the Secretariat for having updated the background paper on transfer of technology SCP/14/4 Rev.2, and for preparing documents SCP/18/7 and SCP/18/8. The Delegation associated itself with the statements made by the Delegation of Denmark on behalf of the European Union and its 27 Member States. The Delegation stated that document SCP/14/4 Rev.2 increased the understanding of that complexity, and identified the fact that though patent protection played a significant role in technology transfer, it was only one among many factors influencing such transfer. Thus, in its view, that study provided valuable insights into the complexity and interplay between the patent system and many of the other factors implicated in technology transfer. The Delegation was of the opinion that the document led to the conclusion that technology transfer could not be increased by simply using patent flexibilities, but many other factors also had to be addressed at the same time before effective technology transfer could take place. Referring to paragraph 65 of document SCP/14/4 Rev.2, the Delegation noted that the simple existence of a patent for particular technology was not a barrier in itself to the transfer of technology, nor did it guarantee that the technology would be fully exploited by the patentee in all possible beneficial ways. Conversely, the absence of an enforceable patent right did not in itself provide any guarantee of technology transfer. In its view, some form of technology transfer took place whenever a patent or a patent application was published, because the technology could be obtained by reading what was listed in the patent. The Delegation observed that intellectual property protection gave companies the confidence to engage in foreign direct investment, joint ventures, partnerships and licensing arrangements with local partners to establish local operations and work with local manufacturers and suppliers and to open research facilities in markets abroad. In its opinion, intellectual property protection fostered creativity and innovation and contributed to economic development and improved quality of life around the world.

AGENDA ITEM 12: CONTRIBUTION OF THE SCP TO THE IMPLEMENTATION OF THE RESPECTIVE DEVELOPMENT AGENDA RECOMMENDATIONS

190. The Secretariat informed the delegations that, in connection with agenda item 12, the following text had been agreed by the Committee at its sixteenth session, and was recorded in the Summary by the Chair as well as the Report of that session: “A number of Delegations made statements on the contribution of the SCP to the implementation of the respective development agenda recommendations. The Chair stated that all statements would be recorded in the report for the sixteenth session of the SCP, and that they 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."

191. The Delegation of Algeria, speaking on behalf of the DAG, stated that it attached great importance to agenda item 12, and expressed its pleasure in noting that the Committee was taking stock of how it had so far contributed to the mainstreaming of the Development Agenda in its area of work in keeping with the decision of the General Assembly. The Delegation noted that the patent system was a key element in the intellectual property framework, which impacted directly on national socio-economic development and societal welfare. In its view, the fundamental premise of the patent system was that a country conferred an artificial and temporary monopoly to the inventor, in exchange for disclosing the invention to benefit the larger interests of society. The Delegation observed that there was a growing acknowledgement that the current IP system focused heavily on ensuring rights to IP title holders, without adequately ensuring that the other side of the trade-off was taking place as it should, consequently leading to the concern that the patent system was not working as it had been originally intended. The Delegation considered that if the IP system had to thrive and encourage innovation and growth – a goal that was shared and supported by all, that could only happen if its shortcomings were effectively addressed. While the Delegation noted with satisfaction that there had been a tentative initiation of discussions in the Committee on some of those aspects, it was of the view that the Committee should have a more open and frank discussion about some of the current deficiencies in the patent system and try to recover the essential balance that ought to be inherent in the patent system. In its opinion, that could only happen if there was a willingness and a commitment to improve the system, where needed, both for the benefit of Member States and for the future viability of the system itself. To that end, the Delegation welcomed the discussions that had taken place during the previous sessions of the SCP on a wide range of issues, including exceptions and limitations to patent rights, anti-competitive practices, other models of innovation, etc. The Delegation considered that they had actually contributed to a more balanced and comprehensive approach taken on many complex aspects of the international patent system. The Delegation, however, expressed the opinion that the Committee must go beyond the theoretical debate and address the actual practices – what actually happened in the outside world on the issues that were the subject of intense debates outside of WIPO but had not yet been addressed in the context of the Committee. In its view, the Committee should not be afraid of discussing and better understanding how patents were used in the market, and how those uses promoted or hindered innovation, technological growth and development. The Delegation observed that it was only through such frank discussion Member States could expect to generate the collective will and actions needed to improve the system. The Delegation noted that the issue of patent quality was one such key issue to be addressed, if Member States sought an effective and credible international patent system. The Delegation, however, considered that the Committee should have a shared and common understanding of what was meant by ‘patent quality’ before it would proceed to discuss and finalize a work program in that regard. The Delegation further noted that another critical area was the issue of patents and health, which had seen animated discussions in the public realm and had led to many concrete actions in other organizations, such as the WTO and WHO. In its view, WIPO had been conspicuously silent and continued to do so. The Delegation expressed its hope that the delay by WIPO in the treatment of that issue would be filled by taking concrete and useful steps in the work program of the SCP, on the basis of the joint proposal of the DAG and the African Group. The Delegation explained that that proposal intended to develop a work program aimed at strengthening the capacities of Member States, especially developing countries and LDCs, to adopt a patent system that took full advantage of the flexibilities provided by the international system of patents in order to promote the priorities of public health policy. The Delegation considered that that proposal was broadly in line with Development Agenda recommendation 22 which stated that WIPO’s norm-setting activities should be supportive of the development goals agreed within the United Nations system, including those contained in the Millennium Declaration. Similarly, the Delegation was of the opinion that more tangible discussions were needed in the SCP on how patents could contribute to better addressing the key challenges facing humanity today - in areas such as food and energy security, environment, disaster management, climate change and education. The Delegation expressed its hope that in the days ahead, there would be open and constructive

engagement on those important issues. In its view, the long prevalent and naïve assumption that providing patent holders with stronger rights would, by itself, foster innovation and attract investments had been rejected in the light of global economic realities and experiences. The Delegation observed that how countries could optimally calibrate the level of IPR protection using exceptions and limitations and other tools as well as flexibilities had so far been an academic discussion in the Committee. It considered that the establishment of an analysis on exceptions and limitations and how to use them as a step towards establishing a non-exhaustive manual on exceptions and limitations that would serve as reference to Member States, would allow WIPO to play its due role in assisting countries in evolving tailor-made IPR policies. The Delegation stated that, finally, and most importantly, the issue of transfer of technology was at the heart of the fundamental trade-off inherent in the patent system. The Delegation considered that an objective assessment of how the patent system had so far enabled or impeded technology transfer and identification of ways by which WIPO could help the patent system contribute to that goal, was at the heart of the work of the Committee. Noting that the SCP had not yet taken concrete actions in that regard, the Delegation stated that Development Agenda recommendation 25 (which called on WIPO to study the policies and initiatives related to the IP necessary to promote the transfer and dissemination of technology) required more effort by the SCP for its implementation. The Delegation looked forward to translating those discussions into useful elements of the SCP's work program. In conclusion, the Delegation stated that the SCP had started an important and necessary discussion on various development-related aspects of the patent system, which had been hitherto not addressed, and welcomed that positive step. It also expressed the hope that many critical issues that had not yet been addressed in the Committee would become the subject of honest and constructive consideration, leading to their integration in a holistic, development-oriented and balanced work program for the SCP.

192. The Delegation of Egypt, speaking on behalf of the African Group, shared the views expressed by the Delegation of Algeria on behalf of the DAG. The Delegation expressed its belief that it was their task, within the Committee as well as in other WIPO fora, to ensure the implementation and mainstreaming of the Development Agenda and to ensure coherence and coordination of the relevant activities within the respective mandates of WIPO bodies. The Delegation stated that, against that backdrop and in line with the decision made by the WIPO General Assembly to institutionalize the coordination mechanism of monitoring, reporting and assessing to the WIPO General Assembly by the other WIPO bodies, it had supported the inclusion of that agenda item. The Delegation expressed the opinion that not to include that agenda item as a standing item on the agenda of the SCP was inconsistent with the decision of the WIPO General Assembly, which was the mother body that governed the work of the SCP. The Delegation expressed its belief that it was necessary to assess how discussions within the Committee contributed to and were consistent with the relevant Development Agenda recommendations in order to ensure, in the international system, balance and equilibrium between IP holders and public interests at large. The Delegation observed that the relevant agenda items discussed until that moment reflected more or less specific recommendations of the Development Agenda. The Delegation noted that a cross-cutting recommendation would be the one to mandate WIPO, upon the request of Member States, to undertake studies and impact assessment studies and evaluation, which came under Cluster D of the Development Agenda and, specifically, its recommendation 35, providing for an impact assessment to evaluate the economic, social and cultural impact of the use of the intellectual property system. Considering that the SCP was the Committee specialized on patents, the Delegation was requesting such impact assessments in various areas. The Delegation specified that, in particular, such assessments related to the question of exceptions and limitations and how the exceptions and limitations presented in the existing international patent system helped development and the public policy consideration within the respective Member State as well how those countries could be assisted in incorporating and implementing exceptions and limitations in their national systems. The Delegation recalled that it was also within WIPO' s mandate to provide the States with technical assistance, capacity building and advice in that area, taking into consideration its

agreement of cooperation with the WTO in order to implement the TRIPS Agreement. In its view, that was in line with the proposal by the African Group and the DAG that had been put forward on patents and public health. The Delegation explained that the joint proposal concerned how the existing patent system impacted the public health considerations of States and how to assist States in raising their capacities, including the implementation and incorporation of flexibilities, in order to achieve their public health policy objectives or to face the national public health challenges. Furthermore, the Delegation pointed out that transfer of technology was another cross-cutting issue, and in the field of patents, they were requesting within the Committee, impact assessment studies in order to individuate what provided an incentive to and what constituted an obstacle to technology transfer. The Delegation, to conclude, stated that the development perspective had to be taken into account by the Committee, and that the African Group were focusing on impact assessment studies and its request for capacity building as a final goal in all of those areas in order for it to make use of the patent system for the favor of development.

193. The Delegation of the United States of America, speaking on behalf of Group B, expressed its pleasure to contribute to the discussion on the SCP's implementation of the respective Development Agenda recommendations. The Delegation believed that the five topics that formed the balanced work program had the potential to make a meaningful contribution to the Development Agenda recommendations. The Delegation, however, observed that, unfortunately, the Committee had made little progress with its work. The Delegation reiterated its position that agenda item 12 should not be a standing or permanent item. The Delegation considered that, unfortunately, at that stage, due to disagreement within the Committee, there had been little progress to report both respective implementation of the Development Agenda and more generally. It expressed the wish of Group B to progress in the SCP in line with the mandate of the Committee, which was to serve as a forum to discuss issues, facilitate coordination and provide guidance concerning progressive international development of patent law, including the harmonization of national laws and procedures.

194. The Delegation of South Africa aligned itself with the statements made by the Delegations of Egypt on behalf of the African Group and Algeria on behalf of the DAG. The Delegation expressed its concern and disappointment that the reporting of the SCP to the WIPO General Assembly about the implementation of the Development Agenda recommendations, which was inherent to its work, was subject to discussions and disclaimer by some Member States. The Delegation recalled that the WIPO General Assembly adopted a decision instructing relevant WIPO bodies to include, in their annual reports to the Assemblies, a description of their contribution to the implementation of the respective Development Agenda recommendations. In its view, according to that decision, there should be a standing agenda item in every session of the Committee preceding the WIPO General Assembly. The Delegation recalled that the WIPO Development Agenda, including its coordination mechanism, was adopted by the WIPO General Assembly, the highest decision making body in WIPO. The Delegation therefore expressed its belief that it was fundamental for all Member States to demonstrate political will and adhere to the decision of the WIPO General Assembly. The Delegation highlighted the importance of a balanced intellectual property system which would take into account public policy issues and public interests. The Delegation observed that the Development Agenda provided for that balance should be pursued. It considered that the impact of the patent system on development, particularly on industrial development, could not be overemphasized. In its opinion, innovation could play a central role in addressing some of the key global challenges, such as health, food security and climate change, and the Delegation recognized the role the Committee could play in enhancing the understanding and adoption of a patent law suited to a Member State in respect to the different levels of development of the countries. In relation to the issue of enhancing the capacity to innovate, the Delegation was pleased that the Committee was undertaking work on patents and health, technology transfer, exceptions and limitations and opposition systems. The Delegation pointed out that those issues related to a number of Development Agenda recommendations related to flexibilities, transfer and dissemination of

technology, access to knowledge, access to information, technical assistance and capacity building. The Delegation recognized the significant progress made by the Committee in addressing exceptions and limitations, opposition systems and transfer of technology, and appreciated all the activities undertaken by the Committee on the issues to that moment. The Delegation, however, expressed its belief that more work was still needed to be undertaken on those issues, especially in the area of transfer and dissemination of technology and flexibilities. The Delegation was of the opinion that more interactive engagement involving relevant stakeholders was desirable at that field of intellectual property. The Delegation considered that innovative and practical solutions to overcome technologies partialities were needed for the Committee to fulfill the Development Agenda recommendations, particularly those under Cluster C, as a means to ensure the long-term preservation of and continued access to information. Regarding the topic of patents and health, the Delegation recalled that three sessions had been held since the joint proposal of the African Group and the DAG on patents and health had been formally submitted to the Committee. The Delegation explained that that proposal aimed to address challenges faced by developing countries in utilizing patent flexibilities. Contrary to the arguments that the SCP should not address that issue, the Delegation expressed its belief that the Committee was the appropriate place to address that issue. The Delegation encouraged the Committee to expedite its work and adopt a work program on patents and health. The Delegation expressed its appreciation for the interactive briefing and discussions on the trilateral cooperation between WIPO, the WHO and the WTO on matters of health. The Delegation proposed to the Committee to have a standing agenda item on the trilateral cooperation between WIPO, the WHO and the WTO on issues related to health in order to facilitate the implementation by the SCP of the Development Agenda recommendations, especially recommendation 40. To conclude, the Delegation expressed its hope that the Committee would continue to work on the basis of the balanced existing program to advance the development of the international patent system in a balanced manner for the benefit of all Member States, especially developing countries and LDCs, giving consideration to the Development Agenda recommendations.

195. The Delegation of Brazil expressed its support to the statements made by the Delegations of Algeria on behalf of the DAG and Egypt on behalf of the African Group, as well as the statement made by the Delegation of South Africa. The Delegation stated that it attached great importance to the coordination mechanism of the Development Agenda approved in 2010. According to that decision, in its view, the SCP was one of the relevant bodies to report to the WIPO General Assembly and had proceeded accordingly in 2011. The Delegation therefore stated its understanding that such agenda item should be made permanent in order to implement correctly the decision of the WIPO General Assembly. The Delegation observed that the SCP had diversified its work program since the Development Agenda had been approved. The Delegation pointed out that the agendas of the sessions were not one sided and aimed at involving subjects of interest of all members. The Delegation expressed its belief that such balance was necessary to ensure that the Committee did not pursue in a single-minded way, the interest of ever higher level of protection of patent rights and harmonization, because that would leave aside development needs, while welcoming a one-size-fits-all approach. The Delegation considered that 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 of the Development Agenda which stated that WIPO’s activities should take into account the flexibilities contained in international intellectual property agreements. The Delegation noted that the discussions on quality of patents might relate to recommendations 8 and 10, if it would bring to light the need for providing access to patent databases and assistance to Member States to improve their national intellectual property institutional capacity through further development of their infrastructure, thus stimulating an efficiency which in turn played an important role in quality of patents. The Delegation pointed out that much was to be done in other areas. It considered that Cluster C on transfer of technology still demanded further work, since the obstacles and initiatives necessary to promote the transfer and dissemination of technology continued to be unclear to some Member States.

Furthermore, the Delegation stated that recommendation 17 did not appear to be implemented within the subject of patents and health, which had among its goals to explore the flexibilities which were useful to improve the policies with regard to health. In its opinion, the adoption of the proposal by the African Group and the DAG was a good step towards such implementation. The Delegation expressed its hope to see the work of the Committee continuing with a balanced agenda that took into account the needs of all Member States, while supporting the goals of the Development Agenda.

196. The Delegation of Denmark, on behalf of the European Union and its 27 Member States, recalled that the SCP, according to document SCP/1/2, page 2, paragraph 3, had been 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. The Delegation pointed out that in fulfilling its mandate, the Committee could 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. In its opinion, since relatively little progress had been made on the different items on the agenda of the Committee due to divergent views on how to move forward, it might be difficult to give a full picture at that stage of the implementation of the relevant Development Agenda recommendations. The Delegation, from a procedural perspective, underscored that in reporting to the WIPO General Assembly on its contribution to the implementation of the respective recommendations of the Development Agenda, the SCP should follow the modalities already agreed in the form of reporting. The Delegation expressed its belief that, according to the established WIPO practice, agenda item 12 should not be a permanent item on the agenda of the Committee. The Delegation pointed out that, when implementing a balanced work program of the SCP, the duplication of work with other WIPO Committees and other international organizations should be avoided.

197. The Delegation of Egypt, speaking on behalf of the African Group, expressed its wish to react to some views expressed on the topic in order to make sure that the Committee was in line with the decision of the WIPO General Assembly. The Delegation considered that any step taken within the Committee should be a step forward. It pointed out that, when a study was proposed, it was in order to reach the final goals of the SCP, among which there was also the implementation of the recommendations of the Development Agenda relevant to the Committee. In its opinion, delegations should be working in line with the established mandate of the Committee, but keeping in mind that the Development Agenda, when it had been established through a long process of negotiations within WIPO, was meant to be a transcending issue. The Delegation therefore considered that whatever came from the Development Agenda into the Committee would be in line with the decision made by WIPO in its large and comprehensive constituency. It expressed its belief that the Development Agenda should be mainstreamed in all WIPO bodies and activities, and thus tailored to the original mandate of the SCP. The Delegation noted that when some delegations made some proposals, as the one advanced by the African Group, for example, they had kept in mind to achieve, or striving to achieve the goals of implementing the Development Agenda in line with the respective mandates of each WIPO body. The Delegation drew attention to the fact that the Committee should be reporting to the General Assembly on any kind of progress, and regretted that some delegations had the impression to have had no progress. The Delegation considered that the discussion in itself, whether achieving a consensus or not, would be a step forward, because it would allow delegations to discuss and explore the issues that were present on the non-exhaustive list of issues that should form the work program of the Committee. The Delegation considered that the issue should remain open for discussion in order to improve the international patent system not only for the purpose of making the patent system to be more efficient, but also making it operating well for the purpose of development.

198. The Delegation of Hungary, speaking on behalf of the CEBS, supported the statement made by the Delegations of Denmark on behalf of the European Union and its 27 Member

States and the United States of America on behalf of Group B. The Delegation pointed out that, within the work program concerning patent law and the international patent system, there should be a balance between the fulfillment of the SCP mandate to serve the well-functioning of the patent system, promotion of innovation and technology transfer, on the one hand, and the contribution to the implementation of a number of recommendations of the Development Agenda, on the other hand. The Delegation observed that, looking at the discussions which had took place within the Committee during the last sessions, the Committee was following WIPO' s General Assembly decision in relation to development goals. The Delegation pointed out that the Committee's work program was still under deliberation, and therefore, the exact evaluation of its contribution to the Development Agenda could not be carried out at this stage.

199. The Delegation of South Africa observed that some delegations had quoted the rules of procedure of the Committee. The Delegation recalled that in 2009, the Committee was coming from a hiatus because an agreement on the work program had not been reached. The Delegation noted that the non-exhaustive list should be the starting point. It drew the attention of the Committee to the fact that the Development Agenda had been adopted in 2007 and that the decision of the WIPO General Assembly concerning the implementation of the Development Agenda recommendations within other WIPO' s bodies had been taken in 2010. Looking at the work that the Committee had undertaken, the Delegation was of the view that the SCP had done some substantial work, such as commissioning studies. The Delegation observed that, for example, the studies on transfer of technology and opposition systems provided a good overview. In its opinion, no agreement on an issue, such as quality of patents, did not mean that there was no progress in terms of realizing the Development Agenda recommendations. The Delegation stated that, looking at the five issues on the work program, it appreciated all the studies prepared by the Secretariat in the past years. The Delegation noted that the trilateral coordination between WIPO, the WHO and the WTO should also be taken into consideration. The Delegation observed positive outcomes during the last twelve months, and expressed its belief that when there was something positive, there was room for improvement. The Delegation stated that it was not sharing the view that there was no or slow progress in the Committee.

200. The Delegation of Spain supported the statement made by the Delegation of Denmark on behalf of the European Union and its 27 Member States. The Delegation expressed its wish to contribute to striking a balance in relation to the Committee's contribution to the implementation of the WIPO Development Agenda. The Delegation was of the opinion that the discussion had been enriched through the consideration of the particular circumstances of the different Member States, and that the resulting approach was reasonably satisfactory. The Delegation observed that the agenda for the SCP sessions held since the last session of the Assemblies included matters such as exceptions and limitations, patents and health, transfer of technology, quality of patents. In its view, within a relatively short period of time, efforts had been made to include development aspects into the discussions on patents. The Delegation deemed that the SCP had been enriched by the consideration of a great number of aspects of the social and international reality. The Delegation expressed its regret that because of the lack of progress within the Committee caused by the failure to agree on how to move forward, at that moment, it was not able to provide a more detailed overview of the implementation of the Development Agenda within the Committee. The Delegation pointed out that such an intensive process had given rise to a number of questions to be addressed in the near future: for example, the distribution of tasks between committees in order to better use the resources of the organization and enable a smoother progress on substantive patent-related matters. Furthermore, the Delegation considered that the development perspective should not impede the discussions of the Committee on other issues, since the loss of the balance in the discussion might result in the Committee becoming an unnecessary replica of other committees.

201. The Delegation of Venezuela (Bolivarian Republic of) supported the statement made by the Delegation of Algeria on behalf of the DAG. The Delegation stated that since the inclusion

of the matter in the agenda was very important for them, it should be maintained on the agenda. The Delegation considered that maintaining that item was in the mandate of the WIPO General Assembly, and supported by the coordination mechanism of the Development Agenda decided by the General Assembly. The Delegation was of the opinion that much still remained to be done in the area of patents, because in its view, patents were closely connected with mankind's challenges affecting not only developing, but also developed, countries. The Delegation expressed its belief that issues such as food security and climate change were important not only at present, but also for the future. Concerning climate change, the Delegation stated that the enterprises that were responsible for the current ecological disaster were the ones holding the patents that were able to provide the solution to that problem. It pointed out that the inclusion of the item in the agenda was of vital importance not only for developing countries, but also for developed countries, if the latter wished to look forward to the future. The Delegation expressed its belief that the Committee needed to continue its work with a mandate which implied obligations for all Member States.

202. The Delegation of Djibouti supported and endorsed the statements made by the Delegations of Algeria on behalf of the DAG and Egypt on behalf of the African Group. The Delegation expressed its belief that the inclusion of the item in the agenda of the Committee was in line with the decision of the WIPO General Assembly which had called for the mainstreaming of the implementation of the Development Agenda in all WIPO bodies. The Delegation stressed the importance of the report by the SCP to the General Assembly, in view of its mandate given by the WIPO General Assembly. The Delegation, therefore, supported the retainment of the item on the agenda of the Committee.

203. The Delegation of the United Republic of Tanzania supported the statements made by the Delegations of South Africa and Egypt on behalf of the African Group. The Delegation observed that although discussions were unavoidable within a larger group such as the SCP, the importance of the topics addressed in the Committee made delegations gather in the meeting room. The Delegation expressed its belief that the agenda item under consideration was crucial, and that the SCP could not avoid the item of the implementation of the Development Agenda for the impact it had on everyone. In its view, having a larger discussion and detailed information in order to reach a consensus on concrete actions were very important. The Delegation considered that the Committee had a complementary role to play in the implementation of the Development Agenda recommendations. It invited delegations to iron out the emerged impediments and obstacles through the discussion rather than depending on the actions of other bodies. In its view, there was no duplication of work. The Delegation supported the Committee to continue doing its work, considering other WIPO bodies complementary to, and not in contradiction with, the SCP.

204. The Delegation of Indonesia supported the statements made by the Delegations of Egypt on behalf of the African Group and Algeria on behalf of the DAG in relation to the fact that the issue should remain a standing agenda item in the Committee. The Delegation observed that during the current session of the SCP, some problems that needed to be addressed in relation to patents and health had emerged. It expressed its belief that that item should remain in the agenda of the Committee.

205. The Delegation of Ghana aligned itself with the statements made by the Delegations of Egypt on behalf of the African Group and Algeria on behalf of the DAG. The Delegation deemed the topic of the implementation of the Development Agenda crucial in relation to other topics discussed within the Committee. The Delegation expressed its belief that the issues raised by the above Groups presented some aspects related to the Development Agenda, such as technical assistance and capacity building, linked to other aspects such as the quality of patents. For that reason, the Delegation expressed its opinion that it was important to keep those items on the agenda, together with the other topics that were being discussed within the Committee.

206. The Delegation of Peru, in view of continuing to protect intellectual property rights, expressed its appreciation for the Secretariat's effort in compiling information on important subjects such as exceptions and limitations, opposition systems, quality of patents and, above all, the effort to bring within the discussion of the Committee public health issues that were connected with patents. As the Delegation of Spain, the Delegation expressed its belief that those issues were very important, but that they presented many nuances with respect to the interests of governments of Member States. Furthermore, the Delegation observed how difficult it was to reach harmonized conclusions or results. The Delegation suggested that the Committee continue its efforts to keep those items, such as technology transfer and quality of patents, on the agenda of future meetings.

207. The Delegation of El Salvador expressed its wish to deal with two topics, public health and transfer of technology, addressed in the Committee the previous day, given their involvement in Development Agenda issues and the importance the Delegation was attributing to them. The Delegation emphasized the importance of continuing discussion on public health as part of the work of the Committee. Noting that its statement was general and far from being exhaustive, the Delegation stated that Member States should adopt legal provisions that fully used the flexibilities available in the international patent system in order to resolve possible public health issues related to patents. The Delegation considered that Member States should have focused more on how those legal provisions could have been implemented in order to meet public health needs. The Delegation proposed to start exploring in a practical way what those real needs were in order to allow developing countries to use more frequently those flexibilities. The Delegation was of the opinion that attention should be drawn to the difficulties that developing countries were facing in the effective implementation, for instance lack of information, technical capacity or trade measures, in order to help those countries improve their systems. The Delegation expressed its belief that a positive experience to be taken into account was the one of Rwanda, which availed itself of the flexibility concerning a compulsory license to export pharmaceuticals produced under a compulsory license under the TRIPS Agreement. The Delegation noted that it was the first case that a WTO member used the system of compulsory licenses established by the decision of the General Council of August 30, 2003 to export pharmaceuticals to a requiring country. The Delegation, in particular, mentioned that Canada was the first country to notify the WTO its request for authorization to produce and export to Rwanda the generic version of a patented medicine. The Delegation thanked the African Group and the DAG for their proposal, and welcomed the submission of more contributions in order to intensify the work of the Committee. The Delegation considered that continuing the work of the SCP using studies on topics such as the obstacles that countries were facing in implementing flexibilities was very relevant to its country. In relation to item 10 of the agenda on technology transfer, the Delegation considered that topic very important and necessary to address dissemination of patented inventions as a first means of transferring technology in areas such as the pharmaceutical sector. The Delegation noted that since generic drugs were produced in El Salvador, it was interested in knowing how good manufacturing practices were applied and how the critical pharmaceutical production criteria in the production of pharmaceuticals required by WHO might be resolved. The Delegation stressed the importance of the work of the Committee in seeking to promote transfer of technology so that developing countries would be able to meet their main needs.

208. The Delegation of India fully aligned itself with the statements made by the Delegations of Algeria on behalf of the DAG, Egypt on behalf of the African Group and South Africa. The Delegation considered that issues such as patents and public health, exceptions and limitations, transfer of technology and opposition systems were very important for all Member States. In its view, all the proposals submitted by the DAG, the African Group and South Africa should be carried forward. The Delegation expressed its belief that those issues were important not only for developing countries but for all Member States.

209. The Delegation of Congo supported the statement made by the Delegation of Egypt on behalf of the African Group. The Delegation encouraged the Committee to handle all questions associated with development, notably, the issues of patents and health, technology transfer and opposition systems.

210. The Delegation of Zambia supported the statement made by the Delegation of Egypt on behalf of the African Group. The Delegation stated that the decision of the General Assembly on the coordination mechanism was very clear with regard to the contributions to the implementation of the respective Development Agenda recommendations expected from relevant WIPO bodies, of which the SCP was one. In its opinion, the SCP had important contributions to make to the implementation of the Development Agenda, and should therefore have a firm position and present its agenda to facilitate the representation of its achievements.

211. The Delegation of Iran (Islamic Republic of) stressed the importance of agreeing on the ways and modalities for reporting, and of making the coordination mechanism functional. In its view, that would be imperative in complying with the decision of the General Assembly and realizing the mandate of the CDIP. The Delegation considered that the SCP could play an important role in bringing balance to the IP system and mainstreaming of the Development Agenda in the work of all WIPO bodies. It noted that while one of the objectives of the patent system was to assist transfer of technology, the actual patent system did not work properly as was originally intended. Therefore, in its opinion, the Committee should analyse that aspect in its work. The Delegation further stated that the Committee should have an open discussion about all the issues in respect of global challenges, such as food security, climate change and health. It considered that those issues were of paramount importance for developing countries, and should be incorporated in the work program of the Committee. Furthermore, the Delegation stated that, at one point, the Committee should go beyond theoretical discussions and begin a norm-setting process in those areas in order to properly address the existing challenges. The Delegation observed that the patent system was the result of a long-term process, which was not fully perfect. In its opinion, Member States should utilize its advantages and try to solve its associated implications for the benefit of public policy.

212. The Chair stated that all statements would be recorded in the report for the eighteenth session of the SCP and that they 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.

AGENDA ITEM 13: FUTURE WORK

> 213. The Committee agreed that the non-exhaustive list of issues would remain open for further elaboration and discussion at the next session of the SCP.

214. The Delegation of Brazil noted with satisfaction that many delegations had shown interest in knowing more on how to proceed with the second phase of its proposal, and expressed the wish to share its ideas with the Committee. The Delegation noted that not less than 72 Member States had replied to the questionnaire by the Secretariat and shared their experience on exceptions and limitations to patent rights. In its view, the compilation made by the Secretariat in document SCP/18/3, which was a very rich material, organized the answers in a systematic and logical way, making it easier to study the vast amount of available data. Having concluded the stage of information gathering, the Delegation considered that it was time to move to the next phase of the program proposed in 2010. While it had been the individual work of delegations up to that moment, in its opinion, from now on, there could be more integration and interaction among Member States. Referring to paragraph 26 of document SCP/14/7 which stated that “the second phase shall investigate what exceptions and limitations are effective to

address development concerns and what are the conditions for their implementation, it is also important to evaluate how national capacities affect the use of exceptions and limitations", the Delegation expressed the wish to share its preliminary thinking on elements to be included in the second stage. It also added that it was open to suggestions. The Delegation had two closely linked elements in mind: 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 10 clusters of the questionnaire. The Delegation stated that 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. In its opinion, it should also consider the obstacles Member States encountered when implementing such exceptions and limitations. The second element was a one-day seminar to be held at the next session of the SCP. The Delegation noted that 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 of diverse affiliation on, *inter alia*, the effectiveness of exceptions and limitations when addressing developing concerns and how national capacities affected the use of exceptions and limitations; and (iii) presentations by Member States of case studies on the implementation of exceptions and limitations. The Delegation observed that that 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 volunteered to make a presentation and share its experience in that field. The Delegation further stated that the outcome of the analysis by the Secretariat and of the discussions of the seminar would become additional material for the continuation of the work program.

215. Following a suggestion by the Chair, the delegations held informal consultations in order to address the future work of the Committee.

> 216. Failing agreement otherwise, following a proposal by the Chair, the Committee agreed to carry on discussions at its next session on the basis of the agenda of its eighteenth session, except agenda items 2 and 12 in document SCP/18/1. Member States may submit proposals on the work of the Committee prior to its next session.

217. The Secretariat informed the SCP that its nineteenth session would be held from November 26 to 30, 2012, in Geneva.

AGENDA ITEM 14: SUMMARY BY THE CHAIR

218. The Chair introduced the draft Summary by the Chair (document SCP/18/11 Prov.).

> 219. After some discussion, the Summary by the Chair (document SCP/18/11) was noted.

220. 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 15: CLOSING OF THE SESSION

221. The Chair closed the session.

222. In accordance with the procedure previously adopted by the Committee (see paragraph 220 above), Committee members and observers are invited to comment on this draft report, which is being made available on the SCP Electronic Forum. The Committee will be invited to adopt the report at its next session.

[Annex follows]

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II. ORGANISATIONS INTERGOUVERNEMENTALES/INTERGOVERNMENTAL ORGANIZATIONS

SOUTH CENTRE

Nirmalya SYAM, Programme Officer, Innovation and Access to Knowledge Programme, Geneva

Kevon SWAN, Intern, Innovation and Access to Knowledge Programme, Geneva

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

Wéré GAZARO (Mme), directeur de la protection de la propriété industrielle, Yaoundé

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

Aurelia CEBAN (Ms.), Head, Division of Appeals and Quality Control, Moscow

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

Eugen STOHR, Director, International Legal Affairs (PCT), Munich

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

Peter BEYER, Senior Advisor, Department of Public Health, Innovation and Intellectual Property, Geneva

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

Roger KAMPF, Counsellor, Intellectual Property Division, Geneva

UNION AFRICAINE/AFRICAN UNION

Georges-Rémi NAMEKONG, Counsellor, Permanent Delegation, Geneva

UNION EUROPÉENNE (UE)/EUROPEAN UNION (EU)

Zusana SLOVÁKOVÁ (Mrs.), Legal and Policy Affairs Officer, Industrial Property Rights, Directorate General for the Internal Market and Services, Brussels

III. ORGANISATIONS NON GOUVERNEMENTALES/NON-GOVERNMENTAL ORGANIZATIONS

Association allemande pour la propriété intellectuelle (GRUR)/German Association for the Protection of Intellectual Property (GRUR)
Alfons SCHAEFERS, Attorney-at-Law, Bonn

Association américaine du droit de la propriété intellectuelle (AIPLA)/American Intellectual Property Law Association (AIPLA)
Albert TRAMPOSCH, Deputy Executive Director, International and Regulatory Affairs, Arlington, Virginia

Association asiatique d'experts juridiques en brevets (APAA)/Asian Patent Attorneys Association (APAA)
Greg BARTLETT, Member, Patents Committee, Adelaide
Kei KONISHI (Ms.), Member, Patents Committee, Tokyo

Association française des spécialistes en propriété industrielle de l'industrie (ASPI)
Mathieu PORCHET, trésorier adjoint, Paris

Association international du barreau (IBA)/International Bar Association (IBA)
Guillaume DE CANDOLLE, Reporter to the IBA, Geneva

Association internationale pour la protection de la propriété intellectuelle (AIPPI)/International Association for the Protection of Intellectual Property (AIPPI)
Stephan FREISCHEM, Secretary General, Köln
Alain GALLOCHAT, Co-Chair, Q228 Patents, Paris
Steven GARLAND, Chair of Q199, Zurich

Association japonaise des conseils en brevets (JPAA)/Japan Patent Attorneys Association (JPAA)
Kasuhiko TAMURA, Patent Attorney, Kisaragi Associates, Tokyo
Setsu SASAMOTO (Ms.), Attorney-at-Law, The Tokyo-Marunouchi Law Offices, Tokyo

Association latino-américaine des industries pharmaceutiques (ALIFAR)/Latin American Association of Pharmaceutical Industries (ALIFAR)
Rubén ABETE, Secretario General, Buenos Aires
Alfredo CHIARADIA, Asesor, Buenos Aires
Luis Mariano GENOVESI, Asesor Propiedad Intelectual, Buenos Aires

Centre international pour le commerce et le développement durable (ICTSD)/International Center for Trade and Sustainable Development (ICTSD)
Pedro ROFFE, Senior Associate, Châtelaine
Alessandro MARONGIU, Programme Assistant, Châtelaine

Chambre de commerce internationale (CCI)/International Chamber of Commerce (ICC)
Heinz HAMMANN, Senior Vice President, Global Head of Patents, Boehringer Ingelheim GmbH, Rheinland-Pfalz
Thaddeus BURNS, Senior Counsel, IP and Technology Policy, General Electric, Geneva
Daphne YONG-D'HERVÉ (Ms.), Chief Intellectual Property Officer, Paris
Ivan HJERTMAN, European Patent Attorney, IP Interface AB, Stockholm
Zeynep BIRSEL (Ms.), Technology Transfer Manager, *Sabanci Universitesi*, Tuzla-Istanbul
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Jennifer BRANT (Ms.), Consultant, General Electric, Qualcomm, Microsoft, Geneva

Chamber of Commerce and Industry of the Russian Federation (CCIRF)
Elena KOLOKOLOVA (Ms.), Representative in Switzerland, Geneva

Civil Society Coalition (CSC)
Tessel MELLEMA (Ms.), CSC Fellow, Geneva

Fédération internationale de l'industrie du médicament (FIIM)/International Federation of Pharmaceutical Manufacturers Associations (IFPMA)
Jon SANTAMAURO, Senior Director, Global Government Affairs IP/Biologics, Abbott Laboratories, Washington D.C.
Andrew JENNER, Director, Innovation, IP and Trade, Geneva
Guilherme CINTRA, Manager, Geneva

Fédération internationale des conseils en propriété intellectuelle (FICPI)/International Federation Of Intellectual Property Attorneys (FICPI)
Eric LE FORESTIER, President, Study and Work Commission, Paris
Leo JESSEN, Chair, Group 6, The Hague
Jerome COLLIN, Paris

Fundaçao Getulio Vargas (FGV)
Koichi Kameda CARVALHO, Researcher, Center for Technology and Society, Rio de Janeiro

Institut de la propriété intellectuelle du Canada (IPIC)/Intellectual Property Institute of Canada (IPIC)
Joan VAN ZANT (Mrs.), Chair, Privilege and Self-governance Committee, Toronto

Institut des mandataires agréés près l'office européen des brevets (EPI)/Institute of Professional Representatives before the European Patent Office (EPI)
Francis LEYDER, Secretary, Harmonisation Committee, European Patent Institute, Seneffe (Feluy)

Institut Fridtjof Nansen (FNI)/Fridtjof Nansen Institute (FNI)
Morten Walløe TVEDT, Senior Research Fellow, Lysaker

Knowledge Ecology International, Inc. (KEI)
James LOVE, Director, Washington, DC
Thiru BALASUBRAMANIAM, Geneva Representative, Geneva

Médecins sans frontières (MSF)
Hafiz AZIZ UR REHMAN, Legal and Policy Adviser, Geneva

Third World Network (TWN)
Nopakumar KAPPOORI, Geneva

IV. BUREAU/OFFICERS

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

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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

Giulia RAGONESI (Mlle/Ms.), consultante/Consultant, Section des conseils législatifs et de politique générale/Legislative and Policy Advice Section

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