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Standing Committee on the Law of Patents

Seventeenth Session
Geneva, December 5 to 9, 2011

REPORT

adopted by the Standing Committee

INTRODUCTION

1. The Standing Committee on the Law of Patents ("the Committee" or "the SCP") held its seventeenth session in Geneva from December 5 to 9, 2011.

2. The following States members of WIPO and/or the Paris Union were represented: Afghanistan, Algeria, Argentina, Australia, Austria, Azerbaijan, Bangladesh, Bahrain, Barbados, Belgium, Bosnia and Herzegovina, Brazil, Burundi, Cameroon, Canada, Chile, China, Congo, Costa Rica, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Dominican Republic, Ecuador, Egypt, El Salvador, Estonia, Finland, France, Georgia, Germany, Greece, Holy See, Honduras, India, Indonesia, Iraq, Ireland, Italy, Japan, Jordan, Kuwait, Lithuania, Malaysia, Mexico, Morocco, Nepal, Netherlands, Nigeria, Norway, Pakistan, Panama, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovenia, South Africa, Spain, Sudan, Sweden, Switzerland, Thailand, The former Yugoslav Republic of Macedonia, Togo, Trinidad and Tobago, Turkey, Uganda, Ukraine, United Kingdom, United States of America, Uruguay, Viet Nam, Zambia and Zimbabwe (83).

3. Representatives of the African Union (AU), the Cooperation Council for the Arab States of the Gulf (GCC), 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 Bar Association (ABA), American Intellectual Property Law Association (AIPLA), Asian Patent Attorneys Association (APAA), Centre for International Intellectual Property Studies (CEIPI), Chartered Institute of Patent Attorneys (CIPA), Civil Society Coalition (CSC), Computer and Communications Industry Association (CCIA), European Law Students' Association (ELSA International), German Association for Industrial Property and Copyright (GRUR), Institute of Professional Representatives before the European Patent Office (EPI), Intellectual Property Institute of Canada (IPIC), Intellectual Property Owners Association (IPO), International Association for the Protection of Intellectual Property (AIPPI), International Centre for Trade and Sustainable Development (ICTSD), International Chamber of Commerce (ICC), International Federation of Intellectual Property Attorneys (FICPI), International Federation of Pharmaceutical Manufacturers Association (IFPMA), IP Federation, Japan Patent Attorneys Association (JPAA), Knowledge Ecology International, Inc. (KEI), Medicines Patent Pool (MPP) and *Médecins sans Frontières* (MSF) (22).

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: "Transfer of Technology" (SCP/14/4 Rev.2), "Quality of Patents: Comments received from Members and Observers of the Standing Committee on the Law of Patents (SCP)" (SCP/17/INF/2), "Patents and Health: Comments received from Members and Observers of the Standing Committee on the Law of Patents (SCP)" (SCP/17/INF/3), "Report on the International Patent System: Revised Annex II of document SCP/12/3 Rev.2" (SCP/17/2), "Responses to the Questionnaire on Exceptions and Limitations to Patent Rights" (SCP/17/3), "Addendum to the Compilation of Responses to the Questionnaire on Exceptions and Limitations to Patent Rights" (SCP/17/3 Add.), "WIPO Activities on Patents and Health" (SCP/17/4), "Information on Cross-border Aspects of Confidentiality of Communications between Clients and Patent Advisors" (SCP/17/5), "Revised Rules of Procedure" (SCP/17/6), "Proposal by the Delegation of Denmark" (SCP/17/7), "Revised Proposal from the Delegations of Canada and the United Kingdom" (SCP/17/8), "Opposition Systems" (SCP/17/9), and "Addendum to Opposition Systems" (SCP/17/9 Add.).

7. In addition, the following documents prepared by the Secretariat were also considered by the Committee: "Revised Rules of Procedure (SCP/17/6 Rev.), "Proposal by the Delegation of the United States of America" (SCP/17/10), and "Patents and Health: Proposal by the Delegation of the United States of America" (SCP/17/11).

8. The following related documents were also considered by the Committee: "Proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group" (SCP/16/7), "Corrigendum: Proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group" (SCP/16/7 Corr.), "Proposal by the Delegations of Canada and the United Kingdom" (SCP/16/5), "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.).

9. 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

10. The seventeenth session of the Standing Committee on the Law of Patents (SCP) was opened by Mr. Francis Gurry, Director General, who welcomed the participants. Mr. Philippe Baechtold (WIPO) acted as Secretary.

AGENDA ITEM 2: ADOPTION OF THE REVISED DRAFT AGENDA

11. The SCP adopted the revised draft agenda (document SCP/17/1 Prov.2) as proposed.

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

12. The Committee adopted the draft report of its sixteenth session (document SCP/16/9 Prov.2) as proposed.

AGENDA ITEM 4: REPORT ON THE INTERNATIONAL PATENT SYSTEM

13. The discussions were based on documents SCP/12/3 Rev.2, SCP/12/3 Rev.2 Add., SCP/17/2 and 2 Add.

14. The SCP agreed that this agenda item would remain on the agenda of the next session of the SCP. Document SCP/17/2 will be updated based on the comments received from Member States.

GENERAL DECLARATIONS

15. The Delegation of Algeria, speaking on behalf of the Development Agenda Group (DAG), stated that the questions on the agenda for the seventeenth session of the SCP would enable participants to have a very fruitful exchange of views on a wide range of subjects related to patents. Discussions within the Committee were of particular interest for the members of the DAG given that intellectual property rights related to patents had a very considerable and direct impact on innovation, economic growth and social development. The DAG continued to urge that in the work of the SCP, the fundamental balance which should be maintained in the patent system between the private interests of right holders and the interests of the broader public, should be strengthened. That was why the activities of the SCP should help to facilitate transfer and dissemination of technology in responding to the public interest related thereto, and to ensure that the patent system contributed to promoting progress and innovation. The Delegation observed that the consideration of the questions relating to exceptions and limitations, transfer of technology, anti-competitive practices and patents and health shed further light on challenges developing countries were facing regarding economic and social development, and furthermore contributed to a better understanding of the complex nature of the patent system. In so doing, it would help to understand how better to adapt the system and adjust it to respond to national development needs. The DAG was convinced that it was more essential now than in the past to make intellectual property a tool for development which would contribute to economic and social growth and development in developing nations. The Delegation welcomed the first contribution of the SCP on its work to the General Assembly on the implementation of the Development Agenda in accordance with the coordination mechanism and modalities for follow-up to the Committee on Development and Intellectual Property (CDIP). That use of the coordination mechanism would enable the SCP to contribute effectively to the real inclusion of the development action plan in all the activities of WIPO. The Delegation had the following preliminary comments on the agenda of the 17th session of the SCP: first of all, it attached considerable importance to the elements of flexibility provided in the intellectual property system: the recommendations of the Development Agenda meant that that was a fundamental issue for the DAG. The development of the concept of intellectual property and the gradual involvement of developing countries in intellectual property rights had had a direct effect in throwing overboard the dogma that the area of patents and patent law automatically generated innovation. Developing countries were aware of the need to adapt the national patent legislation depending upon their individual economic and social situations and of the importance

of exceptions and limitations for countries that had the intention to develop their intellectual property system. Therefore, the Delegation stated that the 17th session of the SCP should make it possible to advance in considering the proposal by the Delegation of Brazil. The Delegation expected that the questionnaire of the Secretariat and the contributions of other Member States should make it possible to draw conclusions about the type of exceptions and the limitations needed to meet the concerns expressed as part of the development action plan. It hoped that it could contribute to preparing a non-exhaustive handbook of exceptions and limitations which could then be used as a reference tool for the Member States of WIPO. At the same time, in its view, it was necessary to look at the definition of the conditions for the implementation and application of those exceptions and limitations. Secondly and turning to quality of patents, while recognizing the importance of the topic for developing countries, the Delegation wished to put on record that the difficulty in giving a focused definition of the term "quality of patents" had made it difficult to understand the proposals on that subject. In its opinion, it was therefore important that an agreement be achieved on a definition of what was understood by quality of patents. The quality of patents depended to a great extent on the criteria of patentability which were determined on the basis of the development goals of each country. The Group, however, wondered whether it might not be possible to improve the quality of patents simply by adopting the practice of one office as had been suggested. DAG was of the opinion that such an initiative would not only fail to meet the goal, but it might lead to harmonization of practices in the area of patent law, and that might impinge upon the flexibility provisions in various countries' national legislation on patents. The Delegation observed that, on the subject of patents and health, the proposal co-sponsored by the African Group and the DAG, included in document SCP/16/7, covered a work program, the purpose of which was to assist Member States, particularly developing and least developed Member States to adopt and adjust their patent systems so as to take full advantage of the flexibility elements included in the international patent system and thereby to promote their public health policies. The Delegation was of the opinion that it was essential to settle that problem and to remove the obstacles which developing countries were facing when they wished to make full use of the flexibility elements included in respect of public health. In its view, WIPO as a specialized agency of the United Nations concerning the intellectual property system was in a better position than anyone to pursue that role. The Delegation stated that in looking at convergence between the patent system and public health goals, the SCP was the best possible setting for discussing that issue and dealing with patents. The public health issue was becoming increasingly important worldwide and indeed had been the subject of a quite heated debate particularly for the last 10 years or so after the entry into force of the TRIPS Agreement. The DAG was aware of the work that had been done by WIPO in the area of health and expressed the opinion that, since health was a very essential area, WIPO should step up its commitment and involvement by building on its already ongoing activities so as to achieve international goals set for public health. The DAG and the African Group welcomed the reaction of Member States to their proposal, and they believed that it showed once again the determination of Member States to make a constructive contribution to the implementation of the recommendations of the Development Agenda.

16. The Delegation of South Africa, speaking on behalf of the African Group, observed that the SCP had advanced a balanced work program in the past few sessions, discussing issues equally important to Member States. The African Group was particularly interested in the following substantive agenda items of the 17th session of the SCP: patents and health, quality of patents, technology transfer, exceptions and limitations to patent rights and future work. The mainstreaming of the Development Agenda in WIPO bodies was imperative. The Delegation expressed its hope that the discussions and work of the Committee would be guided by the relevant Development Agenda recommendations. The Delegation recalled that the African Group had requested the SCP at its 15th session to include in its future work the topic "patents and health" which had been already in its non-exhaustive list of issues. It was one of the key priorities of its continent. Empirical evidence indicated that nowhere a global public 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. Although the Delegation acknowledged that those challenges were not confined to intellectual property, in its

view, an integrated solution was needed 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 believed that WIPO could play a vital role in that regard by promoting the understanding on the relation between patents and costing and procurement practices related to the access to medical products. Furthermore, WIPO could facilitate the understanding on the challenges countries encounter using patented products for their research and development of new medicines or for improving access to those medicines. Most importantly, WIPO could ensure that the patent system was being used optimally by all developing countries, especially regarding its built-in flexibilities. The Delegation expressed its understanding that the patent system was created not only to protect the right holders but also to transfer and disseminate technology. Therefore, the joint proposal of the African Group and the DAG in document SCP/16/7 presented at the previous session of the SCP must be viewed within the context of utilizing the patent system in a balanced manner for protecting the right holders and for public interest. It was thus timely for the SCP to actively discuss the issue of the patent system and its impact on public health, especially the access to medicines, and for the SCP to decide on the work program suggested by the African Group and the DAG. The African Group thus welcomed the comments from members and observers in document SCP/17/INF/3 which all supported the proposed work program and it thanked the Secretariat for its activities on patents and health reported in document SCP/17/4. The Delegation was looking forward to a constructive discussion on that agenda item. Further, the Delegation thanked the Delegations of Canada and the United Kingdom for revising their proposal on the quality of patents in document SCP/17/8. It noted that the revised paper attempted to clarify some of the issues and concerns raised at the previous session of the SCP, particularly the definition of the concept "quality of patents." The Delegation also noted the proposal by the Delegation of Denmark in document SCP/17/7 and the comments of Member States and observers in document SCP/17/INF/2 on the same. The Delegation reiterated its position that any activity of the Committee including a work program on quality of patents must not lead to harmonization of substantive patent law. The African Group attached great importance to flexibilities provided in the intellectual property system. It was against that background that it had consistently supported the work of the Organization on flexibilities, particularly exceptions and limitations. It thus appreciated that the proposal made by Brazil on exceptions and limitations which the African Group supported was being implemented. The Delegation welcomed the submissions in reply to the questionnaire prepared by the Secretariat, soliciting the views of Member States on their utilization of exceptions and limitations. As agreed at the last session of the Committee, it was looking forward to discussing the possibility of requesting the Secretariat to prepare an analysis of the answers and an additional questionnaire specifically addressing the issue of exclusions. Similarly, the Delegation stated that transfer of technology was an important issue to its Group. In recent years, transfer of technology had become a topical issue in many international fora. It therefore considered that WIPO, by the virtue of it being the main organization responsible for intellectual property in the United Nations' system, should actively lead the discussions on the interface between patents and technology transfer. The Delegation commended the WIPO Chief Economist for organizing the seminar on patents and transfer of technology in the morning. It believed that that was a positive step in the right direction for WIPO to take the lead in the dialogue on technology transfer. The African Group welcomed the amendments made to the preliminary study on technology transfer in document SCP/14/4 Rev.2, which encompassed comments made by developing countries, including comments made by the African Group in relation to practices that impeded technology transfer and dissemination. The Delegation observed that there was a new chapter, Chapter 11, which covered the issue of impediments and incentives to technology transfer. Given the assertion that Chapter 11 was mainly based on theory rather than on practical situations and that paragraph 207 stated "to better understand the practical implications of various possible incentives and impediments, more information on practical experiences from experts directly involved in knowledge acquisition and licenses and case studies might be useful. They may merit a thorough review that goes beyond the level of a preliminary study but could be envisaged future sessions of the Committee", the Delegation was of the opinion that more work still needed to be done in that area. Similarly, 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. Based on the above, in its opinion, the issue of technology transfer should remain on the agenda of the Committee. The Delegation welcomed, with regard to the revised rules of procedure of the Committee in document SCP/17/6, the approval of the implementation of the decision of the General Assembly regarding language coverage in relation to the Committee's documents. In respect to future work, the Delegation was of the view that the SCP should focus on issues of common interest to the membership, particularly for developing and least developed countries. In that regard, the African Group restated 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.

17. The Delegation of Panama, speaking on behalf of the Latin American and Caribbean Group (GRULAC) stated that, concerning exceptions and limitations to patent rights, the work of the SCP showed not only how important it was to find an adequate and balanced patent system, but also how varied the uses of exceptions and limitations were under each national law. The Delegation considered it to be crucial for every Member State to determine the exceptions and limitations which were in line with their own characteristics and which would allow the highest levels of economic development to be achieved. The Delegation observed that the questionnaire approved by the members at the 16th session of the SCP was very valuable and contained much useful information. In its opinion, the exchange of information should, for the time being, be based on case studies on the specific uses of those flexibilities. The Delegation noted that it was crucial for the SCP to consider developing a non-exhaustive list of exceptions and limitations, which could serve as a guideline for WIPO members. Further, the Delegation stressed the importance of patent quality for all Member States, because the proper functioning of a balanced patent system which took into account the interests of all members of society was the basis for the SCP's work. The Delegation considered that it was important to have a specific and concrete definition of the concept of patent quality before moving forward with further work. GRULAC welcomed the debate on patents and health given the importance of that issue for access to lifesaving medicines in developing countries. That debate provided an opportunity to move forward on that issue along with other initiatives within and beyond WIPO. Regarding transfer of technology, the Delegation stated that an analysis of technology transfer should take into account the capacity and other factors within countries which were necessary to absorb the technology. Therefore, in its view, the mere fact of having or not having a patent system was not necessarily related to technology transfer.

18. The Delegation of Poland, speaking on behalf of the European Union and its 27 Member States, reaffirmed its full commitment in continuing support to the work of the SCP. It looked forward to constructive, efficient and fruitful discussions on quality of patents, including opposition systems, exceptions and limitations to patent rights, patents and health, and the confidentiality of communications between clients and their patent advisors. The Delegation welcomed the revised proposal by the Delegations of Canada and the United Kingdom in respect of a work program on the quality of patents and proposal by Denmark entitled “Improving the quality of the search and examination of national patent applications by using foreign search and examination work”, which represented a valuable contribution to the discussion of the SCP under item 6 of the agenda “quality of patents, including opposition systems”. The Delegation considered that further exploration of that issue would be helpful in developing various options, measures and conditions which would contribute to ensuring and improving the issuance of high quality of patents. As regards the exceptions and limitations to patent rights under agenda item 5, the European Union and its 27 Member States acknowledged the importance attached to that issue and welcomed the possibility of continuing discussions on the topic and on possible future steps which might be taken to make use of the information gathered. Referring to the issue of patents and health to be discussed under agenda item 7, the Delegation drew the attention of the SCP to the similar work program carried out in the CDIP, in particular its work program on the flexibilities in the intellectual property system so as to avoid an duplication of efforts. The Delegation was committed to advancing work on the issue of confidentiality of communications between clients and their patent advisors

under agenda item 8, which was of real interest to users of the patent system. The European Union and its 27 Member States were of the view that most of the discussion which had already started in the previous sessions of the SCP had rightly highlighted important issues related to the wide range of relevant questions on the patent system as a whole. The Delegation was convinced that by addressing those issues, the SCP should be aiming at enhancing access to patent information and ensuring a more efficient and user-friendly international patent system. It was hopeful that during the 17th session of the SCP, it would be possible to agree on a balanced future work program based on the non-exhaustive list of issues, which would enable the Committee to achieve its primary objective of working towards international harmonization of substantive patent law.

19. The Delegation of Slovenia, speaking on behalf of the Regional Group of Central European and Baltic States (CEBS), welcomed the submission of proposals from Member States and new working documents prepared by the Secretariat, especially those relating to quality of patents, including opposition systems, exceptions and limitations to patent rights, patents and health and the confidentiality of communications between clients and their patent advisors. The CEBS expressed the belief that the main task of the SCP was to strengthen and improve the quality of the patent system and enhance better access to patent information. At the same time, it considered that the users of the system and their needs should always be the priority of the work. The Delegation stated that, with that in mind, international harmonization of substantive patent law would bring many tangible benefits to the users of the system and other stakeholders who asked for an effective, responsive and user-friendly international patent system. The SCP was addressing many issues that went towards mentioning common goals. In that line, the Delegation noted that the SCP should carefully add new topics on the non-exhaustive list of issues in order to have an ambitious and balanced working plan of the Committee. The Delegation attached great importance to the issue of client-attorney privilege. While thanking the Secretariat for the preparation of the document with the information on cross-border aspects of confidentiality of communications between clients and patent advisors, it regretted that there had not been many Member States sharing their national legislation and experience. Nevertheless, in its view, the document was useful in understanding different solutions aiming at ensuring confidentiality between the two parties as well as towards the outside world.

20. The Delegation of the United States of America, speaking on behalf of Group B, expressed its appreciation for the detailed studies prepared by the Secretariat which provided a valuable contribution to the SCP's work in addressing important questions of the current international patent system. Group B remained committed to the balanced work program of the SCP. It looked forward to engaging in positive discussions on the issues before the 17th session of the SCP, 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 expressed its hope that the work on those topics would lead the SCP to addressing specific issues impacting the international patent system whereby further work could be developed by the SCP. Group B remained firmly committed to advancing work on the work program proposed by the Delegations of Canada and the United Kingdom on quality of patents (document SCP/17/8) and proposed by the Delegation of Denmark (document SCP/17/7). In referring to former proposal, the Delegation observed that the three main components, technical infrastructure development, information exchange on quality of patents and process improvements, were necessary to advance discussions in line with improving the quality of patents. Group B was also keenly interested in continuing with the discussion on the subject of confidentiality of communications between clients and patent advisors. It appreciated the efforts of the Secretariat in preparing document SCP/17/5 and looked forward to discussing the findings contained therein. The Delegation was of the opinion that a return to exchange of information and discussion on technical issues regarding patent law, practice and policies should be the benchmark in measuring progress in the SCP. It hoped that those topics and the varying viewpoints among regional groups would lead to a more efficient and accessible international patent system, and eventually, to substantive patent law

harmonization. In particular, in its opinion, the discussion on the issues should be undertaken in a manner that sought to improve the quality, functioning and effectiveness of the patent system as a tool to deliver economic and social policy objectives.

21. The Delegation of Egypt reiterated the importance it attached to providing documents for future SCP sessions in the Arabic language in accordance with the recommendation of the Program and Budget Committee (PBC) and the General Assembly 2011 decision regarding the WIPO language policy, as contained in the revised rules of procedures outlined in document SCP/17/6. The Delegation supported the statement made by the DAG and the African Group. It noted that the 17th session of the SCP contained important issues which constituted priorities for developing and least developed countries as far as the patent system was concerned. In its opinion, issues such as patents and public health, exceptions and limitations to patent rights, quality of patents and transfer of technology were all at the heart of ensuring that the international patent system was balanced, development-oriented and effectively promoting innovation, creativity, economic and social development in developed and least developed countries. Moreover, the Delegation observed that those issues were prerequisites for allowing WIPO Member States to have the appropriate policy space required to pursue public policy objectives related to health, education and scientific research. The Delegation expressed its hope that discussions to be taken at the 17th session of the SCP would continue to be rational, constructive, fact-based and development-oriented, and guided and informed by the relevant Development Agenda recommendations, especially those related to technical assistance and capacity building, flexibilities and public policy and technology transfer. It stated that the SCP should be moving forward cautiously on a consensus-based manner and avoid as much as possible controversial issues related to harmonization that could only be divisive instead of bringing Members together and able to move ahead.

22. The Delegation of India observed that the agenda of the SCP covered a wide range of subjects such as the international patent system, compilation of responses to the questionnaire on exceptions and limitations to patent rights, quality of patents including opposition systems, patents and health, confidentiality of communications between clients and patent advisors, transfer of technology which could form a good basis for discussion on those issues and further consolidate the viewpoints of Member States. In its view, since compared to other IP rights, patent rights were assumed more significant to, and impacted directly on, technological, industrial and economic growth, innovation and other developmental aspects of the country, the discussions of the SCP were of special interest to all Member States. The Delegation expressed its willingness to participate in the discussions in a meaningful way. Further, the Delegation stated that the revised proposal by the Delegations of Canada/United Kingdom on quality of patents needed to be further assessed in view of the implications on the national patent laws and national interest of the Member States. Particularly, in its opinion, the definition and scope of quality of patents, proposed modalities for checking the quality of patents and capability of countries should be given attention. The Delegation observed that the proposal suggested a very broad definition not only to cover the examination process but also overall functioning of patent offices, including the relationship of the patent office with clients, as well as the judiciary. The Delegation stated that such a broad definition was problematic, and did not focus on the main issue of the application of high threshold level for granting patents. Further, the Delegation considered that the judiciary should be excluded from the work program. With respect to the indirect suggestion in the proposal that a patent office develop a client relation with applicants, the Delegation stated that a patent office, being a public office supposed to work independently in a transparent and accountable manner, should be guided by a statute that reflected public policy concerns. The Delegation thus considered that such relation might spoil the independence of patent offices. With that in mind, the Delegation requested further clarification on the proposed work plan comprising of three main components. The Delegation emphasized that the prior art search was of vital importance in assessing patentability of the claimed subject matter, and the same should be conduced with utmost care to avoid the wrong grant of patents. Given that the developing and least developing countries lacked financial and technical resources, in its opinion, assistance should be provided to strengthen the institutional

capacity and patent search facilities as per needs of developing and least developed countries. The Delegation expressed its belief that, with the upgraded institutional capacity, the patent prosecution, i.e., prior art search, examination and grant refusal of patents could be conducted in an effective manner as per their national laws. The Delegation observed that such assistance could be provided through WIPO by providing access to patent and non-patent databases, for example, by making available the search engines. The Delegation noted that the document regarding opposition systems had provided a good overview of the opposition systems as existing in different countries. The Delegation believed that a robust opposition system was necessary to have a review in the granting procedure. In its view, a patent granted on an invention that had gone through opposition proceedings would be considered as having a higher credibility in terms of fulfilling the patentability and other requirements of patent law. Speaking with respect to client-patent advisor privilege, the Delegation observed that it would be desirable that each country should be allowed to set its own level of privilege and extent of disclosure, depending upon the social and economic circumstances and level of development of each country, since the matter might not form the part of a national patent law, as in the case of India, and also, there was a provision concerning the client--attorney privilege neither in the Paris Convention nor in the TRIPS Agreement. Any confidentiality of the information between a client and his attorney could be protected through a non-disclosure agreement. The Delegation considered that protection of important information through client-attorney privilege would lead to a situation where vital information would be suppressed and kept out of the public access, and therefore, it could be detrimental to public interest, particularly in developing countries. Hence, any sort of norm-setting and harmonization of the client-attorney privilege may not be desirable. The Delegation stated that the deliberations at the Seminar on Transfer of Technology were very helpful to understand the interface between transfer of technology and patent rights. It hoped that such useful seminar on transfer of technology would lead to concrete follow-up action to facilitate transfer of technology as envisaged under the TRIPS Agreement. Similarly, the Delegation observed that the inputs provided by members in the questionnaire on exceptions and limitations to patent rights and their compilation would bring more clarity on the subject and would lead to further follow-up actions, such as analysis of the inputs, compilation of data and enumeration of a reference guide. The Delegation expressed its satisfaction on the progress made by the SCP in bringing out the reasonable documents providing clear picture on the existing situation across countries on the issues before the Committee and it looked forward to a meaningful participation in the Committee’s deliberations.

23. The Delegation of Morocco, speaking on behalf of a group of Arab States, recalled that these countries had been among the first which had requested that the documents of the SCP be translated into all the official languages of the Organization, including in particular the Arabic language. That would enable all countries to take the best possible advantage of the valuable information, which was included in those documents. For that reason, the Delegation expressed its satisfaction with the proposal contained in document SCP/17/6, and assured its support to the proposal.

AGENDA ITEM 4: REPORT ON THE INTERNATIONAL PATENT SYSTEM

24. The discussions were based on documents SCP/17/2 and 2 Add.

25. The Secretariat informed the Committee that Annex II of the Report on the International Patent System would continue to be updated as soon as new input from Member States would be received.

26. The Delegation of Chile stressed the importance of the document and of it being kept up-to-date. The Delegation informed the SCP that it would submit some amendments to the Chilean legislation to be reflected in the document so that updated information could be provided in a future version, either in a subsequent paper version of the document or on the website.

27. The Delegation of Japan informed the Committee that, in Japan, the bill for partial revision of the Patent Act had been approved and enacted on May 31, 2011, and promulgated on June 8, 2011. Since that revision had not entered into force yet, the Delegation noted that it would submit the information after the entry into force of the revised provisions. Nevertheless, the Delegation informed about the changes to be made, specifically related to the expansion of the scope of application of the grace period. More specifically, the Delegation explained that, since the existing provision on grace period did not fully cover diverse forms of publications of R&D results, including inventions broadcasted on TV, under the revised Patent Act, an invention that had become publicly known as a result of an act of the inventor himself or herself could be patented, irrespective of the form of publication. The Delegation remarked that it was useful to have a system where Member States could easily update information on revisions of laws and regulations for easier grasp of the information by others, and supported the continued update of that Report.

AGENDA ITEM 5: EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

28. The discussions were based on documents SCP/14/7, SCP/17/3 and 3 Add.

29. The Delegation of the Russian Federation stated that its preliminary assessment of the answers to the questionnaire and the information provided to the SCP on the Electronic Forum website seemed to bear witness to the comprehensive and multifaceted description of the provisions in legislation and how those were applied. It was of the view that they would require further analysis. In that connection, the Delegation suggested that the Secretariat prepare, for the next session of the SCP, a document with a thorough and detailed analysis of the provisions presented, including examination of the particular features existing in the legislation of Member States and regional patent offices. The Delegation further suggested the devising of essential recommendations on the issues so that they could be further discussed by the SCP. The Delegation drew attention to the following aspects regarding the answers prepared by the Russian Federation which did not form part of any section of the draft questionnaire. It specifically referred to the provisions of the Russian legislation relating to right of subsequent use, and also to obtaining a patent created during employment based on a State or municipal contract. The Delegation stated that systematic compilation of information on exceptions and limitations provided for by national and regional legislation, as contained in the responses to the questionnaire, was useful for, both from the point of view of assessing existing national approaches and also in terms of further enhancement of the various legal, economic and social aspects of the development of States. The Delegation hoped that that analysis would be continued and it was willing to participating in working on the questionnaire. The Delegation remarked that an analysis and collation of the experience of Member States on exceptions and limitations was of interest, both for right holders and for society as a whole, and important in terms of stimulation of the development of science and technology. In its view, the results of such analysis might serve as a good basis for the preparation of proposals to enhance national and regional legislative systems. The Delegation also supported the establishment of a draft questionnaire on exclusions for the 18th session of the SCP.

30. The Delegation of Brazil stated that it was pleased to see the positive evolution on the work conducted in the SCP. The Delegation observed that the interchange of ideas and dialogue on various aspects of the patent system was very useful for developing countries, and could help them to better examine and make improvements to their national standards and legislation according to their specific social and economic realities. It noted that exceptions and limitations to patent rights were relevant to an adequate and balanced patent system, to which Member States had different approaches. The Delegation believed that a flexible policy space was necessary in order to allow Member States to better determine the set of exceptions and limitations which was in line with their capabilities and which allowed the attainment of higher levels of economic development. Taking into account the work developed so far since the 13th session, it considered that it was time for the SCP to adopt the proposal by the Delegation

of Brazil in document SCP/14/7, which would be an important step in the implementation of the Development Agenda. The Delegation observed that, while the questionnaire approved by Member States during the 16th session of the SCP was available and contained useful information, the exchange of information was not exhausted so far. In its view, it was the first part of the first phase of its proposal and therefore, that exchange should now focus on case studies on the concrete use of those flexibilities. With regard to the questionnaire itself, in order to better process the information sent by Member States, the Delegation encouraged the Secretariat to further elaborate on the answers, taking into account the qualitative aspects, such as the nature of the provisions adopted in different countries. After completing that first phase, in its opinion, the SCP would be able to investigate what exceptions or limitations were effective to address development concerns and what were the conditions for their implementation. The Delegation also stressed the importance of evaluating how national capacity affected the use of exceptions and limitations. The Delegation stated that, in the third phase, the Committee should consider the elaboration of an exceptions and limitations manual in a non-exhaustive manner to serve as a reference to WIPO Member States.

31. The Delegation of Norway, noting that it had responded to the questionnaire, pointed out one of the exceptions provided for in the Norwegian Patents Act, the so-called Bolar exemption, which had entered into force on December 18, 2009. The Delegation stated that the wording of that exemption to the rights conferred by a pharmaceutical patent was broad, as that exception included trials and experiments for obtaining a marketing authorization in any country which was party to the WTO agreement, and not only for countries within the European Economic Area (EEA). Since the information about the Bolar exemption in the Norwegian Patents Act had not been included in the Annex of document SCP/17/2, the Delegation requested the Secretariat to update the Annex according to the information found in the response to the questionnaire.

32. The Delegation of Poland, speaking on behalf of the European Union and its 27 Member States, observed that, of the 56 responses to the questionnaire received, 17 were from EU Member States and from one regional patent Office. The responses provided the SCP with a useful approximate outline of what was done throughout the world on the issue of exceptions and limitations and, to some extent, it contributed to the knowledge of the SCP about the state of laws in different Member States. Nevertheless, the information gathered was not sufficient enough for the preparation of a comprehensive study which would be helpful to enable all members to use the results of the questionnaire, as well as for meeting the objective of Development Agenda recommendations 37 and 38. The Delegation therefore suggested that the deadline for submitting the responses to the questionnaire should be extended for a longer period of time. In its view, that would probably encourage more countries to respond and would enable the SCP to gather more valuable information which could serve as a basis for the preparation of the study. The Delegation reiterated the view that neither exclusions from patentability nor exceptions and limitations to patent rights should be discussed to the detriment of other substantive issues of patentability which the SCP had focused upon, such as the definition of prior art, novelty and inventive step. In the case of any exception or limitation to patent rights, the Delegation reiterated that the appropriate balance should be maintained between the interests of the right holders and the general public.

33. The Delegation of Pakistan, referring to document SCP/17/3, stated that exceptions and limitations were one of the very important elements of the international IP system, as they were the ones which brought about the necessary and required balance in the global IP system. In that context, it appreciated the efforts for putting together the questionnaire and all the Member States' efforts in providing responses to it. The Delegation believed that, with regard to the further work that had to be carried out in regard to the questionnaire, the following four actions of follow-up, which were not exhaustive, had to be taken: firstly, the information which had been provided in the responses had to be processed. Secondly, the SCP could focus on specific case studies. Thirdly, there was a need to elaborate on the nature of the provisions. Fourthly, further analysis on the following issues needed to be carried out: (i) national experiences; (ii) national legislation; and (iii) the rationale for the specific limitations and exceptions. The

Delegation believed that those activities could eventually lead up to a non-exhaustive manual providing detailed information on limitations and exceptions on the patent rights.

34. The Delegation of Japan expressed its appreciation for the efforts that the Secretariat had made to consolidate the responses to "Draft Questionnaire on Exceptions and Limitations to Patent Rights". The Delegation considered that the number of Member States and Regional Patent Offices which had submitted their responses were not sufficient yet for conducting an analysis or planning the further work program. Acknowledging the time it took to answer carefully to that detailed questionnaire, the Delegation observed that, following receipt of responses from a majority of Member States, the SCP could initiate further discussions on the future direction of that project.

35. The Delegation of Algeria, speaking on behalf of the DAG stressed that its Group attached a particular importance to the question of flexibilities, and that those flexibilities within exceptions and limitations were particularly important to it. With the flexibility on limitations, for example, the Delegation considered that it could achieve a better balance between those who hold intellectual property rights and the wider society. The Delegation observed that through the flexibility of limitations, Member States could adapt their laws in line with their strategies, so that they corresponded with the development in individual countries. In its view, only through those exceptions and limitations, developing countries could get into a position where they could integrate intellectual property into their overall and broader national economic development strategies. The Delegation considered that such integration could itself guarantee that intellectual property did become a homogeneous element among others making up a national strategy. The Delegation expressed its belief that those were some of the reasons why the proposal which had been made by the Delegation of Brazil in respect of exceptions and limitations to patent rights should be given careful consideration. The Delegation observed that such consideration had been made clear by the statements made on the subject, as well as by the fact that there had been a broad response to the questionnaire sent out on the question of exceptions and limitations to Member States. The Delegation considered that the countries which had responded to the questionnaire represented a wide range of regions of the world, including developed, developing and least developed countries, having different legal regimes and different approaches to those issues. The Delegation stated that the proposal made by the Delegation of Brazil and the responses to the questionnaire sent out by the Secretariat should be analyzed and taken into account in the SCP' s future work. The Delegation was of the opinion that the SCP should try to use the full information received in the attempts to respond to the question about the conditions in which Member States used the exceptions and limitations enshrined in international instruments. The Delegation stated that, in analyzing this data, another question relating to the difficulties that prevented Member States from using the exceptions and limitations, despite the fact that they were available for use in various international instruments, could be addressed. In addition, the Delegation considered that the SCP could also try to find an answer to the question as to how the exceptions and limitations were actually used in practice by the various Member States. In its preliminary statement, the Delegation had also expressed the hope that the SCP would draw up a manual which would list the various exceptions and limitations used by the various Member States, fully understanding that those exceptions and limitations varied from one country to another, depending to a great extent on the level of development of the country concerned.

36. The Delegation of Chile reemphasized the importance that the issue of exceptions and limitations to patent rights had for its country. Turning to the responses received to the questionnaire, the Delegation highlighted that despite the level of detail in the questionnaire, a very high number of responses had been received. Nonetheless, it was important that the questionnaire remained open for response so that other Member States who had not yet had the opportunity to do so could respond to those questions. The Delegation remarked that it was very important, certainly for Chile, to have an idea about the legislation applied by other WIPO Member States and the real situation in other WIPO Member States' patent offices. In its view, that might be helpful in thinking about modifications that the country might make in respect to

those issues to its own legislation in the future. The Delegation stated that the information available needed to be used in such a way as to make it possible to have a better understanding of that subject. For example, as indicated by the Delegation of Brazil, the Secretariat could be requested to carry out case studies, or to do some analysis which would help the SCP to have information in statistical form. The Delegation was of the opinion that, when thoroughly analyzed, the information relating to the state of legislation in other Member States would help the SCP to make progress in the future on that very important issue and, in so doing, take forward the SCP' s agenda.

37. The Delegation of South Africa, speaking on behalf of the African Group, supported the work program submitted by the Delegation of Brazil on exceptions and limitations. The Delegation noted that, although the SCP had not adopted the work program proposed by the Delegation of Brazil, the SCP was implementing *de facto* the first phase of that proposal through the questionnaire. The Delegation noted that given the fact that the compilation in document SCP/17/3 only reflected whether or not a particular country had its national law provisions related to an exception or limitation, it was advisable for the SCP to undertake deep analysis and substantive discussion on national experiences and legislation on the use or non-use and rationale for having such limitations and exceptions, which was consistent with the conclusion of the 16th session of the SCP. The Delegation supported the Secretariat's work on the questionnaire, analyzing whatever information gathered. The Delegation observed that the work program proposed by the Delegation of Brazil had a life span which culminated into a non-exhaustive manual on exceptions and limitations. The Delegation stressed that it was supportive of the intervention made by the Delegation of Brazil, and stated that the African Group would suggest other activities in addition to that work program proposed by the Delegation of Brazil.

38. The Delegation of Spain supported the statement made by the Delegation of Poland on behalf of the European Union and its 27 Member States. While the Delegation expressed its thanks to all those Member States who had responded to the questionnaire approved at the 16th session of the SCP, it regretted the fact that not more responses had been received. It appeared that the SCP had not yet received a sufficient number of replies to draw some conclusions on the basis of the comparative table drawn up by the Secretariat. Perhaps it might be possible to have an extension of, for example, two months during which additional responses from Member States could be received. The Delegation observed that, once that deadline had been reached and the SCP had the sufficient number of additional answers, it would be the task of the Secretariat to prepare a study on the basis of the answers and provide conclusions which would help the SCP to make further headway on its work on that question. The Delegation expressed its unease at the fact that not all the parts of the annexes of document SCP/15/3 had been translated into Spanish, despite the fact that the need for translation was recognized in paragraph 13 of the Chair's Summary of the 15th session of the SCP and was picked up also in 16th session of the SCP by the Delegation of Spain (see point 12 from the report of the 16th session). Therefore, the Delegation expressed its concern about the fact that since the proposal for the modification of the rules of the SCP stated that if a document happened to be exceptionally voluminous, the translation into other working languages from the original would be done only upon request of a Member State, this system might not work properly.

39. The Delegation of the Republic of Korea recalled that about 130 years ago, when the Paris Convention had been adopted, the priority system had been included in the patent system due to a problem with filing applications in foreign countries. In 1970, the Patent Cooperation Treaty (PCT) was agreed upon in Washington, which simplified foreign filings and had evolved in a good direction. The Delegation stated that since the market had become more global and patent owners had become stronger, the balance in the patent system appeared to be not maintained. The Delegation observed that that was why the SCP had been discussing topics, such as technology transfer, limitations and exceptions to patent rights and patents and health. The Delegation stressed the importance of optimal discussions on those topics. The Delegation was of the opinion that, in those discussions, an incentive for innovation should be provided,

which was also required in developing and least-developed countries.

40. The Delegation of Poland, speaking on behalf of the European Union and its 27 Member States, reiterated its position that the deadline for submitting the responses to the questionnaires should be extended for a longer period of time in order to encourage more countries to respond. As the Delegation of Japan, in its view, it was premature to discuss further steps before the completion of the work on the first phase.

41. The Delegation of Switzerland recalled that, at the 16th session of the SCP, it had insisted that a longer period of time should be provided for the Member States so that they had sufficient time to respond to the questionnaire. Since it was not possible for its Delegation to provide a response to the questionnaire in the amount of time available, it endorsed the statements made by the Delegations of Poland, on behalf of the European Union and its 27 Member States, and Japan. The Delegation stated that an extension should be accorded so that the Secretariat would be given a more complete picture of the various systems in operation. The Delegation also noted that there was no point in working on exceptions and limitations unless, in parallel, the Committee looked at positive rights.

42. The Delegation of China expressed its thanks to the Member States who had provided responses to the questionnaire. It observed that the active participation in answering the questionnaire by States and the exchange of information between members were important both for the SCP's work and for furthering knowledge in those matters. The Delegation was of the opinion that the SCP could now embark upon further work at the next stage, proceeding to analyze the information received from Member States, to consider studies carried out by experts and to a comparison of the responses received by Member States. In its view, that would lay down the firm foundations for the building of a guidance document.

43. The Delegation of Germany was pleased to have been able to contribute to the discussions on the issue of exceptions and limitations, which were of core importance, by having filled in the questionnaire through its national patent and trademark office. The Delegation aligned itself with the intervention made by the Delegation of Poland on behalf of the European Union and its 27 Member States. It observed that there was no such thing as a single and decisive aspect of patent law and patent politics, and that, without exceptions and limitations, the patent systems would be as unpractical and anti-innovative as some claimed it to be. In its view, such allegations of the patent system's deficiencies did not take into account the available exceptions and limitations. The Delegation considered that, in its own jurisdiction, exceptions and limitations were part of a functioning and balanced system. In its opinion, it was impossible to assess the impact of the patent system on society as a whole without clearly assessing and examining the mechanisms of exceptions and limitations. The Delegation stressed the importance of seeking more answers to the questionnaire and to examine the issue in the context of other patentability requirements. Without such consideration, in its opinion, the appropriate balance of interests would not be preserved.

44. The Delegation of the United States of America stated that the detailed preliminary studies had provided a valuable contribution to the SCP's work in addressing important questions of the current international patent system. In its view, the compilation of answers to the questionnaire on exceptions and limitations was interesting and a valuable work. The Delegation observed that the questionnaire was lengthy, and that a number of Member States had not yet responded to it. Therefore, the Delegation considered that, as stated by the Delegations of Poland on behalf of the European Union and its 27 Member States and Japan, a reasonable additional time for other Member States should be allowed to respond before proceeding further. With respect to the suggestion by the Delegation of the Russian Federation that the Secretariat be requested to analyze the responses, the Delegation sought further explanation as to what analysis the Secretariat would be asked to undertake. With regard to the suggestion by the Delegation of Pakistan that further work needed to be done, the Delegation believed that the SCP would be better able to determine what, if any, further work needed to be done once additional responses

were received. The Delegation agreed with the statement of the Delegation of Poland on behalf of the European Union and its 27 Member States that any discussion of exceptions should not be carried out to the detriment of substantive issues of patent rights.

45. The Chair noted that, following the discussions held so far, the topic of exceptions and limitations would remain on the SCP's agenda for the foreseeable future. He suggested that the Committee take the whole process one step at a time, deciding only what the next step would be. He observed that one was to extend the deadline for the questionnaire and to strongly encourage additional offices to provide their answers to the questionnaire, and another step was the possibility of some further analysis of the results of the questionnaire that could be undertaken by the Secretariat, on which the Secretariat might need to have more guidance.

46. The Delegation of Pakistan requested clarification as to the timeframe for the extension of the deadline and the type of further analysis by the Secretariat.

47. The Chair remarked that while the two questions were interrelated, a reasonable deadline could be three months so that there would be time to conduct the analysis before the next session.

48. The Delegation of Peru supported the extension of the deadline, since the questionnaire was currently looked at in its capital. In its view, the three-month deadline was an acceptable period, given the quantity of information which the questionnaire had been requesting. It suggested that the SCP leave the scope of the analysis to the Secretariat to decide.

49. The Delegation of Egypt observed that, currently, each Member State needed to go through all the responses to the questionnaire, which might be in different languages. Therefore, the Delegation considered it useful if the information was presented in a new document, compiling the questions and the different responses by Member States, which would render the reading easier. It noted that the compilation could be presented to the next session of the SCP, or even beforehand, and be published on the web site.

50. The Delegation of Brazil stated that, in terms of further analysis, one suggestion would be to have a kind of a mapping of the measures that different Member States put in practice, as different Member States might have the same answer to equivalent problems. Further, the Delegation expressed its interest in also having an assessment of the difficulties encountered in their implementation, since implementing flexibilities could be harder than designing them. The Delegation remarked that it would be very interesting for Member States to have an assessment of what were the actual difficulties encountered in implementing those flexibilities. The Delegation also suggested selecting some cases for studies on some very specific issues, for example, the implementation of the Bolar exception. The Delegation observed that while practical effects of such implementation might differ from one country to another, some countries which did not have a given kind of flexibility might have the advantage of knowing what were the difficulties actually faced by other countries in their implementation.

51. The Chair observed that case studies might need to be submitted by Member States rather than being drawn up by the International Bureau, since Member States had that experience.

52. The Delegation of Ireland stated that, due to resource reasons, it was one of those countries that unfortunately had not managed to submit the questionnaire on time. Therefore, the Delegation welcomed an extension of the deadline so that it could contribute to that important topic. The Delegation observed that, since legal provisions were interpreted by the courts, it would be useful to find out court decisions across all Member States, which could also shed light in terms of the real practical meaning of those provisions.

53. The Chair stated that the deadline could be kept open also for those that had submitted

the questionnaire, if they wished to supplement their questionnaire with additional answers, with court interpretations, with assessment of difficulties or with case studies.

54. The Delegation of Pakistan stated that it would be helpful to have more answers. With regard to the four steps suggested by the Delegation, it clarified that elaboration on the nature of the provisions and the benefits received from, and any hindrances to, the implementation of those provisions were in its mind. The Delegation observed that national experiences would be examined through some form of case studies and sharing of national experiences, which would render the understanding of the issue more realistic.

55. The Delegation of Argentina stated that one idea regarding the potential analysis of the results of the questionnaire could be for the Secretariat to carry out a purely statistical analysis of how widespread each of the categories of exceptions and limitations was. For instance, what percentage of members having responded to the questionnaire used, or had legislative provisions on, exceptions for experimental use or scientific research. The Delegation observed that a statistical analysis could also be carried out within each of the categories, if possible, identifying the common elements which had been described in the responses. The Delegation emphasized the importance of having an idea of the statistical distribution of the exceptions in addition to legal interpretations of limitations and exceptions.

56. The Delegation of South Africa clarified that, in its view, information on the language of the provisions and the policy thinking behind the provisions were missing, since those were two important questions that affected developing countries. The Delegation stated that, although it understood that some of them would be determined by the cases involved, at least a synthesis of the information could be provided as an analysis.

57. The Delegation of Portugal expressed its wish to add a note of caution, since a legal analysis or an analysis over a legal regime that would be done by an international organization over state law was always delicate. Referring to the statistical approach suggested by one Delegation, the Delegation considered that, for example, with regard to the exception for scientific purposes, what would be the scientific purpose under its law could be different in each country. Therefore, in its view, the SCP might end up carrying out a legal analysis with no exact information given. The Delegation stated that while an analysis in factual terms was not problematic, going further than that should be considered carefully.

58. The Representative of AIPPI expressed its support for the study on exceptions and limitations to patent rights. He noted that AIPPI had studied exceptions and limitations in several instances, and had adopted a number of resolutions in that regard, the most recent of which had dealt with the issue of patents and health.

AGENDA ITEM 6: QUALITY OF PATENTS, INCLUDING OPPOSITION SYSTEMS

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

60. The Delegation of the United Kingdom recalled that, at the sixteenth session of the SCP, together with the Delegation of Canada, it had emphasized its wish to avoid being prescriptive in providing an absolute definition of quality of patents. Nevertheless, following the comments of some Member States stating that they could not support further work on the current agenda item without a definition, the Delegation stated that their revised proposal contained in document SCP/17/8 provided a definition of quality of patents, and suggested activities to achieve a high quality of patents. The Delegation explained that, in providing the definition, it deliberately had sought to make it broad so that it would encompass the various understandings Member States might have of the concept within their national frameworks. The Delegation noted that it was already evident by the statements of the Regional Groups that it might not have been successful in providing a definition agreeable by all, and that concerns over the

broad definition had been expressed. In its view, that was indicative of a difficult, if not impossible, nature of the task, given the different nature and role of the patent systems in Member States. The Delegation, however, stated that precisely because Member States had different understandings of quality of patents, the topic was worthy of consideration. The Delegation pointed out that their proposed work plan for the SCP had three main elements: (i) technical infrastructure development; (ii) information access and exchange of quality of patents; and (iii) process improvement. In its view, the Committee could come to a proper understanding and definition of quality through its work on those three elements. As part of the first step on the first element, the Delegation suggested that the Secretariat invite Member States to share their definitions of quality of patents within their national systems in the electronic forum with the view to drawing up a compendium, since a number of Member States had already provided useful definitions. The Delegation further stated that, via the SCP electronic forum, the United Kingdom had shared its experience in encouraging applicants and their representatives to file patent applications that were of high quality. The Delegation encouraged other delegations to do likewise, because, regardless of the type of operation of a national patent system, the higher the quality of patents submitted, the higher the quality of patents granted. The Delegation considered that it still had much to learn from other Member States on how to best help and encourage its applicants and their representatives to file applications with higher quality. The Delegation therefore proposed that the Secretariat invite Member States to share the details of their efforts and experiences in encouraging applicants and their representatives to file applications of higher quality.

61. The Delegation of Canada expressed its appreciation to the Delegation of Denmark for its constructive proposal on improving the quality of the search and examination of national patent applications by using foreign search and examination work. The Delegation was also grateful to other delegations who had offered comments and constructive suggestions on possible work items on quality of patents during the previous session and/or the inter-sessional period. Noting the positive comments received from Member States on the prospects of furthering the Committee's work on quality of patents, the Delegation observed that all Member States who had commented had emphasized the importance of the work in the Committee to the global patent system and had supported further work based on the three foundational pillars identified in document SCP/17/8. As a result, in order to move forward, the Delegation of Canada, together with the Delegation of the United Kingdom, proposed the development by those two delegations of a questionnaire to facilitate the sharing of information among Member States and patent experts from national and regional IP offices. The Delegation noted that, as identified in document SCP/17/8, the Delegations of Canada and the United Kingdom had attempted to provide a definition of patent quality in response to concerns expressed by some delegations. Recognizing that quality of patents encompassed many different components and that it could have different meanings for different patent offices, different countries or for different stakeholders, the Delegation endorsed the view that prescribing to a harmonized, one-size-fits-all definition was not in the best interest of all Member States of the SCP. Therefore, the Delegation recommended that, as part of the proposed information gathering exercise, Member States be asked to provide a definition of quality that was utilized in their respective national or regional patent offices. The Delegation noted that those Member States who appeared most concerned over the lack of a common definition were encouraged to provide input. As recommended in the revised proposal submitted by the Delegations of Canada and the United Kingdom, the Delegation was of the view that a common definition might remain an objective, but it should not be an impediment to commencing tangible work on the topic. With respect to the proposal made by the Delegation of Denmark, the Delegation stated that the Delegation of Denmark had identified a practical and helpful tool in improving the quality of patents granted by national and regional IP offices. As the work item captured under the third pillar, i.e., process improvement, the Delegation considered that the compilation of information on how the patent offices and Member States exploit the work done in foreign jurisdictions and the perceived benefits and challenges was very useful. The Delegation pointed out that the questions included in such a proposed survey should consider both legal mechanisms and bilateral or multilateral arrangements, and should gather information concerning the guidelines

for examiners of national and regional offices on the exploitation of work done by other offices. Building upon the focus of the Delegation of Denmark on process improvement, the Delegation proposed that, in addition to the survey of Member States, future sessions of the SCP provide opportunities for Member States to present their national experiences with improving quality through bilateral or multilateral mechanisms to efficiently exploit the search and examination results from foreign offices.

62. The Delegation of Denmark presented its proposal contained in document SCP/17/7. The Delegation drew the attention of the Committee to the fact that utilization of foreign work would increase quality. The Delegation explained that its proposal was to explore and discuss how a patent office's use of foreign work in its own granting process led to granted patents of higher quality. In other words, how search and examination work performed by a patent office of earlier filing or examination could be utilized for searching and examining later filed patent applications at another patent office and thus enhance the quality. The Delegation noted that the Danish Patent and Trademark Office used foreign work to the extent possible, and that, to its knowledge, a number of other patent offices did the same. The Delegation clarified that its proposal was not seeking or looking for harmonization, introducing any sort of full recognition or export standards of other offices' work, since offices still had full discretion, must comply with their own legislation and had a duty to search, examine and decide on their own motion. It stated that the proposal was intended to ensure the best enlightened foundation to evaluate the patentability criteria, based on the understanding that the more prior art was revealed, the more robust patents were granted. The Delegation observed that utilization of foreign work was neither new nor unexploited, and that a number of programs were already running. For instance, within the European context, under a pilot project, the European Patent Organisation had decided to make it mandatory to furnish national search information to the European Patent Office when filing a European patent application. The Delegation explained that the result of that pilot was that the search findings of the national offices had increased the quality of work on subsequently filed European patent applications. Similarly, the Patent Prosecution Highway (PPH) was another example which had led to higher quality. The Delegation, however, acknowledged that not all were rosy, and there were indeed challenges, for instance, language barriers, lack of access to, or inappropriate, file dossier systems, etc. Nevertheless, the Delegation was of the view that it was a subject the Committee could look further on and proposed investigation of: (i) how national patent offices used foreign work; (ii) what were the benefits of using foreign work; (iii) what were the challenges for offices; and (iv) how could potential obstacles be overcome.

63. The Chair stated that, according to his understanding, the reference to the utilization of foreign work in the proposal by the Delegation of Denmark by no means gave full faith and credit to that foreign work or one office granted a patent because another office granted a patent. Rather, the proposal was about making available, for example, the search results of one office so that an examiner in the second office had more information before him in making an independent judgment on the patentability of the invention. The Chair sought clarification by the Delegation of Denmark.

64. The Delegation of Denmark confirmed the understanding of the Chair.

65. The Delegation of Spain welcomed the revised proposal submitted by the Delegations of Canada and the United Kingdom that had taken into account the comments made by many Member States, including Spain. It noted that the proposed definition was very close to what many delegations had pointed out during the last session of the Committee. The Delegation stated that, although the PCT Working Group had been dedicating to the issues of quality and Chapter 21 of the PCT International Search and Preliminary Examination Guidelines dedicated to quality management, the treatment of the matter in the SCP would be of benefit to all Member States, many of which were not members of the PCT or were participating in the PCT system as a PCT receiving office. The Delegation supported the comments made by the Delegation of Germany, contained in document SCP/17/INF/2, on the importance of the work within the

European Patent Organisation in search of a higher quality of patents. The Delegation expressed its confidence that the work done within the European Patent Network with the development of the European Quality System (EQS) could be useful in addressing the issue of quality in the Committee. Regarding the comment made by the Delegation of Portugal, contained in document SCP/17/INF/2, the Delegation supported the proposal to request the Secretariat to prepare a questionnaire on the issue of quality, which would collect the experiences on the subject from different national offices. Further, the Delegation supported the proposal made by the Delegation of Denmark which suggested that the Committee consider aspects of reuse by national patent offices of the search and examination work already undertaken by other offices. The Delegation noted that, from the recent experience it had had within the PPH program under which Spain had agreements with Canada, Finland, Japan, Mexico, Portugal, the Republic of Korea, the Russian Federation and the United States of America, the main problem was the language difference, especially when languages were too distant from the mother tongue of the examiners. In its view, machine translation currently available did not provide the quality that was desirable. Therefore, the Delegation expressed its belief that the language issue was the main impediment to proper reuse of search and examination results of other offices. The Delegation reiterated its proposal contained in document SCP/17/INF/2 as follows: (i) the work plan outlined in document SCP/16/5 (Proposal by Canada and the United Kingdom) stated the element "process improvement" as one of the three components. That component was an opportunity for the Committee to continue its study of substantive patent law; (ii) there was broad agreement among patent professionals that the most contentious and difficult element in relation to the assessment of the patentability requirements was the assessment of inventive step; (iii) the important part of Member States had repeatedly opposed to the harmonization of patent laws in the Committee. However, the definition of inventive step requirement was very similar in most legislation. Therefore, there appeared to be an urgent need for harmonization of national and regional patent laws in that regard; (iv) given the complexity presented by the assessment of inventive step, as proposed by the Delegations of Canada and the United Kingdom, Member States would benefit from a series of studies coordinated by the Secretariat in collaboration with Member States, which would aim at a better understanding of the issues; (v) to begin with, a study might be conducted on the main elements relating to the definition of inventive step, for example, examining the definitions of the state of the art and a person skilled in the art in various laws and how internal guidelines used by examiners referred to those elements; (vi) the first study might be followed by a comparative study on the different methods of evaluating the inventive step in Member States, which would take a practical orientation with abundant examples. It would consider cases where the results of the assessment of inventive step diverged among Member States; and (vii) these studies would contribute to an improved understanding of the requirement of inventive step and its assessment, which would result in granting the exclusive rights on inventions that warrant it.

66. The Delegation of Portugal stated that the issue of quality was very important for its country. It noted that, in 2006, the Portuguese office had implemented a quality management system which was ISO 9001certified. The Delegation strongly supported the proposal made by the Delegations of Canada and the United Kingdom as well as the proposal made by the Delegation of Denmark. Referring to its comments contained in document SCP/17/INF/2, the Delegation considered that the creation of an international forum where all offices could share information about the quality of their patents in their system could be helpful to improve the quality of patents in each national office and to share best practices. Further, the Delegation expressed its strong support for the proposal which suggested the collection of views and experience from users relating to quality of patent office processes and operations, which would be shared with the Committee. In that regard, the Delegation suggested the elaboration of a common questionnaire, the result of which could be compiled in a quality report prepared by WIPO and shared among the offices.

67. The Secretariat clarified that the work that was being done in the PCT Working Group related to the quality of documents produced in the international phase of the PCT system, most importantly, the international search reports. Therefore, although somewhat similar at a very

high level, it noted that the context, practical effects and policy considerations that may impact on the discussions within the SCP were quite different from those within the PCT Working Group.

68. The Delegation of Poland, speaking on behalf of the European Union and its 27 Member States, stated that it shared the view of the Delegations of Canada and the United Kingdom that the quality of patents should be understood in a broad sense as the quality of all the work that national and regional patent offices and judicial systems undertook in satisfying their legal, social and economic requirements. In its view, the quality of patent applications as well as the examination and enforcement procedures were of paramount importance to ensure that the whole system functioned in a way that it served the purposes for which it was designed. The Delegation reiterated its support for the work plan proposed by the Delegations of Canada and the United Kingdom consisting of three main components. The Delegation also expressed its support for the proposal made by the Delegation of Denmark concerning improving the quality of the search and examination of national patent applications by using foreign search and examination work. The Delegation considered that both proposals were fully complementary and within the mandate and the core expertise of the SCP, and took into account a number of recommendations of the Development Agenda, in particular, recommendations 10, 11, 19 and 29. In addition, the Delegation noted that several Member States of the European Union, including Denmark, Finland, Germany, Portugal and Spain, had already contributed to the discussions on quality with comments and additional proposals compiled in document SCP/17/INF/2, thus showing their commitments to making progress on the issue. The Delegation drew the attention of the Committee to the fact that within the European Patent Network, the European Quality System, consisting of the European Quality Management System and the Product Quality Standard, had been introduced. In its view, information about the work done under that System could be helpful for the discussions within the Committee. The Delegation stated that the adequate application of patentability criteria, such as novelty, inventive step and industrial applicability, represented another important aspect of the issue of quality of patents. In its opinion, without adequate application of the patentability criteria, it was not possible to ensure that patent protection was only granted for inventions which were truly innovative and enriched the state of the art. Therefore, the Delegation suggested that the Committee establish a work program elaborating options, measures and conditions, both legal and practical, that would be required to ensure, and where necessary, improve the issuance of high quality patents. In that regard, the Delegation observed that the proposals by the Delegations of Canada and the United Kingdom as well as by the Delegation of Denmark should be considered as the steps in the right direction.

69. The Delegation of Norway expressed its support for the future work along the lines described in the revised proposal made by the Delegations of Canada and the United Kingdom. The Delegation stated its understanding that one of the main objectives of the initiative proposed by the Delegations of Canada and the United Kingdom was to develop the discussions on quality without touching on national patent policies and objectives of each national and regional patent system, but to focus on the contribution of patent offices to procedures and practices where all Member States could benefit from the sharing of experience, improvements and suggestions. The Delegation noted that the revised proposal attempted to provide a definition of quality of patents taking into account the discussions that had been held at the previous session of the SCP and concerns raised by some delegations. In its view, since the issue of quality had many facets, the components of the proposed work plan on quality were practical, administrative in nature and technical, and ensured the continued full autonomy of various public policy concerns. Therefore, the Delegation expressed the opinion that there was no need for an exhaustive definition of quality for the purposes of a work plan proposed by the Delegations of Canada and the United Kingdom. With respect to the proposal made by the Delegation of Denmark, the Delegation expressed its belief that the issue of how search and examination took place and how patent offices made use of foreign search and examination work was at the core of striving for high quality patents. The Delegation explained that the patent office in Norway was mandated to grant patents when the national legal requirements,

which were set to secure the grant of the exclusive rights on only true and novel inventions and the society's interest in retaining a public domain, were met. The Delegation considered it essential that search and examination of patent applications were of high quality and in accordance with the Norwegian patent law. It observed that, when practicable, examiners of the Norwegian patent office always used work already done by other offices in the areas of search and examination, and that the Norwegian patent regulations stipulated that the patent office could request applicants to provide copies of foreign patent office's search and examination results. The Delegation further noted that the Norwegian patent office had also recently concluded PPH agreements with the Japan Patent Office (JPO) and the United States Patent and Trademark Office (USPTO). The Delegation observed that there were challenges to making full use of foreign search in examination work, and that increased access to search results via a file dossier system was a practical solution. In that regard, the Delegation informed the Committee that the Norwegian patent office was preparing a searchable, full-text publication on its website. The Delegation also considered that receiving information on the concrete search methodologies used by foreign examiners might be useful for increase examiners' confidence in work done by other offices. The Delegation highlighted that, in connection with yearly courses on industrial property rights for participants from developing countries, the Norwegian patent office always received very good feedback on the sessions involving practical prior art searches and guidance on methods for conducting the searches. In conclusion, the Delegation looked forward to the SCP proceeding on each of the proposed components of quality discussions, and supported the suggestion that Member States be invited to share information on how they defined quality. It also supported the proposals by the Delegations of Portugal and Spain for the preparation of studies. With respect to the document on opposition systems, the Delegation expressed its belief that efficient opposition systems and systems that allowed interested third parties to submit observations were helpful mechanisms to secure the quality of patents. The Delegation was of the view that the systems for administrative review after the opposition period might also be significant in that regard. It explained that, in Norway, any person could submit observations to the patent office regarding a pending application. In that case, the patent office was obliged to consider whether the observation had an impact on the patentability. In addition, according to the Regulations under the Norwegian Patent Act, any person could file a protest against a pending application. The Norwegian Patent Act also provided for a post-grant opposition system, under which any person could oppose a patent within nine months from the publication of the grant. If the opposition was based on the argument that the granting of the patent should have been refused on the basis that commercial exploitation of the invention would be contrary to *ordre public* or morality, the opposition period was three years. A decision by the patent office regarding an opposition could be appealed. After the opposition period, the patentee could file a request to the patent office for limitation of the patent by amending the claim. The Delegation informed the Committee that, in 2008, administrative reviews of granted patents after the opposition period, which was similar to the Danish system, had been introduced in order to offer a less costly, simplified and quicker alternative to court proceedings for those who wanted to attack patents after the expiry of the opposition period. According to the Norwegian system, any person could file a request for review of a granted patent to the patent office, which could be based on a claim that the patentability criteria had not been met. In conclusion, the Delegation supported continued work on opposition systems in the future sessions of the SCP.

70. The Delegation of South Africa, speaking on behalf of the African Group, stated that, with respect to the proposal made by the Delegations of Canada and the United Kingdom, while appreciating their efforts in defining quality of patents, the definition provided was still too broad. The Delegation noted that the broad definition confirmed the view of the African Group that the quality of patents referred to the ability of an office to apply the domestic law effectively to achieve its legal, social and economic goals which would include the strengthening of the national capacity for protection of domestic inventions. In its view, another way of clarifying the concept could be by way of defining what quality was and what it was not. Noting that there was general agreement that the concept varied from one country to another and that it depended on national laws, the Delegation considered that it was necessary to understand in

general terms what quality of patents was and was not. The Delegation, therefore, welcomed the statement made by the Delegation of Canada, inviting Member States to submit to the Committee their understanding of what the concept might entail. It was of the opinion that, once there was clarity on the concept, it would be easier to discuss the components of the proposed work program. Further the Delegation noted that it understood the proposal by the Delegations of Canada and the United Kingdom within the context of Development Agenda recommendations 10 and 11 related to the development of infrastructure in IP institutions, which were of importance to developing countries. The Delegation considered that focusing on enhancing institutional and human capacity of the developing countries' patent offices could be beneficial in the strengthening of the patent system, including the granting of quality patents based on national laws of Member States. Since a majority of offices in developing countries were not examining offices, the Delegation found it difficult to envisage how the proposal by the Delegations of Canada and the United Kingdom could be "inclusive of a broad range of interests of Member States at different levels of development, as well as interests of users of the patent system and society more generally", as stated in paragraph 21 of document SCP/17/8. With respect to the proposal by the Delegation of Denmark, the Delegation noted that it sought to complement the third component of the proposal by the Delegations of Canada and the United Kingdom on process improvement, and was aimed at advocating for the use of foreign search and examination work performed by other patent offices on the understanding that that would lead to granting of quality patents. In its view, the "process improvement" should clearly be defined and be clarified whether it referred to procedural or substantive aspect of patent grant, since the comments submitted by some Member States in document SCP/17/INF/2 referred to process improvement as substantive law issues. The Delegation stated that the African Group found comfort in the proposal by the Delegation of Denmark which did not aim at harmonizing patent law, as explicitly stated in paragraphs 7 and 21 of document SCP/17/7. In its view, paragraph 21 resonated with the view of the African Group that countries should be provided a policy space to determine their patent laws in accordance with their national development needs. The Delegation stated that, in principle, it was in agreement with the proposal by the Delegation of Denmark that the granted patents must be robust and of high quality. However, the Delegation considered that there might be a contradiction in the proposal, i.e., if the objective of process improvement was to grant high quality patents, why had the example regarding successful use of foreign search and examination work led to an increase of the patent granting rate? In its view, if the proposal was about granting high quality patents, there should not be a significant increase in the patent granting rate. The Delegation, therefore, was under the impression that the proposal was linked to resolving backlogs, which was discarded in paragraph 7. In a nutshell, the Delegation was of the opinion that the questions posed by the Delegation of Denmark for the consideration of the Committee must be first contextualized, as it was not clear what constituted process improvement. In conclusion, the Delegation emphasized the following points: (i) the main objective of any work on quality of patents should ensure the effective application of the criteria of patentability, that is, novelty, inventive step and industrial applicability, as well as sufficiency of disclosure, so as to prevent frivolous patents. For that matter, the focus should be on strengthening technical assistance and capacity building activities for IP offices in developing countries; (ii) any work on technical infrastructure development should involve new and additional resources to the WIPO budget on technical assistance and should not diminish resources allocated to implement the Development Agenda recommendations; (iii) most importantly, any work on quality of patents should not involve any form of harmonization of substantive patent law. The Delegation reaffirmed its readiness to continue working with the proponents so as to ensure further development, with the view to having the proposals more clarified and focused in order to achieve the interest of developing countries and forcefully implement the Development Agenda recommendations.

71. The Delegation of Algeria, speaking on behalf of the DAG, noted that the revised proposal submitted by the Delegations of Canada and the United Kingdom was not very different from the original version of the proposal, although it acknowledged the effort to give a definition of the concept of quality of patents. The Delegation further noted that the proposal made by the Delegation of Denmark highlighted certain difficulties being encountered when seeking an

improvement of the quality of patents, for example, accessibility to foreign search and examination results, language and linguistic difficulties, problems with uncertainty and competence of patent offices, etc. The Delegation however observed that any of those proposals did not provide a clear definition of quality of patents. The Delegation stated that, without a clear definition of the term, it was difficult to decide upon a work program and activities relating to quality. The Delegation considered that quality of patents referred to the capacity of offices to apply national patent legislation effectively, and that the patentability criteria was something that could be defined and implemented differently in accordance with different national legislation. Therefore, the Delegation was of the opinion that there was a direct link between quality of patents and development, the level of which differed from one country to another. In its view, quality of patents could not be improved by adopting the practices followed by some other offices or by harmonizing patent law. Rather, the Delegation considered that building capacity within a national patent office, reviewing different patent legislations and their operation and ensuring the proper implementation of national legislation in each domestic situation were needed. The Delegation further observed that the references to technical development, technical infrastructure and IT systems in the proposals only confirmed the divide that currently existed in terms of the available resources. The Delegation stated that, if developing countries got caught up in a mechanism whereby they were encouraged to depend on other offices due to the lack of their resources, such situation would have an adverse effect on the development of their own domestic IP system. With respect to the references to the Development Agenda recommendations in the proposals, the Delegation was of the view that recommendations 19 and 29 were irrelevant. In conclusion, the Delegation stressed that in order to make headway with those proposals, it was essential to first define quality of patents so that the Committee would know the direction it would be taking.

72. The Delegation of the Russian Federation recalled that it had supported the proposal by the Delegations of Canada and the United Kingdom at the previous session of the SCP. The Delegation stressed the importance of having a definition of quality of patents in terms of how the Committee would study the issue and how it would craft recommendations to improve the whole patent granting system. For that reason, in order to determine the work program for the SCP on quality of patents and to study that issue, the Delegation considered it appropriate to first decide what the concept of “quality of patents” included and what a “quality patent” should be. The Delegation noted that the Committee should first focus on the issue of “information exchange on quality of patents”, the examination of which was essential for defining the concept of “quality of patents”, and then follow the approaches as proposed by the Delegations of Canada and the United Kingdom in document SCP/17/8. In its view, once the Committee defined the components of that concept and also the factors affecting quality of patents, it would be able to move on and focus on examining the other components. The Delegation therefore supported the development of a questionnaire on quality of patents, as suggested by the Delegations of Canada and the United Kingdom. Further, the Delegation reiterated that quality of patents was affected by a multiplicity of factors, for instance, quality of conduct of prior art search and examination, information and methodological support for examiners, provision of access to different kinds of prior art resources, and the use of advanced technologies when undertaking patent prosecution. In that regard, the Delegation supported the proposal made by the Delegation of Denmark, and stressed the importance of collecting and analyzing data and information from foreign patent offices and studying the results of their search and examination. The Delegation stated that ROSPATENT used the search and examination results prepared by foreign patent offices, both under the conventional patent granting process as well as under the PPH and the PCT. The Delegation explained that patent examiners of ROSPATENT had, (i) free access to the search and examination results prepared by a number of foreign patent offices in relation to a priority application, on the basis of which a conventional application had been filed with ROSPATENT, and (ii) access to the search results provided by the EPO, as well as patent offices of Germany, Japan, the Republic of Korea and the United States of America, on the applications considered by their offices and PCT applications. They also had free access to databases in all of the aforementioned patent offices via the Internet, and had special access to internal databases of the Japan Patent Office and the Korean Intellectual Property Office.

Those databases could be accessed only by patent examiners. In view of such successful cooperation with other offices, the Delegation noted that it had not encountered any problem with respect to access to the outcome of search and examination conducted in certain patent offices. Further, the Delegation pointed out that the PPH was a successful project which enhanced the quality of national search by using the results of a foreign search, thereby leading to the grant of higher quality patents. The Delegation further noted that ROSPATENT had entered into bilateral PPH agreements with Finland, Japan, Spain, the Republic of Korea and the United States of America which provided for the mutual consideration of substantive examination results on the same patent applications filed with the offices of those countries. In other words, within the PPH, the Office of Second Filing used the search and examination results of the Office of First Filing. The main advantages, in the view of the Delegation, were: (i) the enhancement of the quality of search and examination, since examiners in the Office of Second Filing were able to use all of the additional information from the Office of First Filing; and (ii) a reduction in examination period, since examiners could reduce the number of activities, including the time for prior art search and correspondence with the applicant. The Delegation noted that ROSPATENT had been able to cut the time taken for search by one and half times, in accordance with the PPH Program as part of an agreement with the Japan Patent Office. The Delegation further stated that ROSPATENT had concluded bilateral agreements on the PCT-PPH Program with the patent offices of Finland, Spain and the United States of America. It noted that the production, within the PPH and PCT-PPH Programs, of uniform requirements and procedures, applied by each patent office, would increase the effectiveness of patent protection, and also reduce the workload of examiners, since the work would be shared. The Delegation informed that detailed information on the issues raised in paragraph 28 of document SCP/17/7 was available to the Secretariat in writing from the Delegation. On documents SCP/17/9 and SCP/17/9 Add, the Delegation noted that the Russian legislation did not provide the possibility of an administrative appeal against the grant of a patent by third parties. However, the Russian legislation did not limit the right of any person to provide prior art documents known to him, which might be used in the patent examination process. Such prior art might be provided by any third party at any stage of the examination process until the grant of the patent. Where an examiner found that a piece of prior art was relevant for the invention claimed, such prior art was included in the search report. Thereby, the applicant would be informed on the prior art through the search report or communication of results of the examination of patentability. Until such a final decision was taken, the applicant had the right to put forward her/his arguments regarding that source of prior art and the examiner's conclusion. An applicant was then entitled to amend the claims, taking into account the prior art and the preliminary examination of patentability. Where a relevant prior art had been identified by a third party, he/she had the right to use that prior art for challenging the patent post-grant. In accordance with the Russian legislation, any person had the right to request the conduct of a prior art search of the patent application of another person upon payment of a fee. The procedure for conducting such a prior art search was regulated by the office rules. A search report was then sent to the person concerned after the publication of an application. The results of such a search report were taken into account when examining the patentability of a claimed invention. In addition, the Russian legislation provided for a deferred examination of applications, in which case an appropriate request was required. Where an application contained a report on a search conducted at the request of the person concerned, the level of the fee for conducting an examination on the application was reduced by fifty per cent. Thus, the Delegation stated that the absence of a direct provision in the Russian legislation for an opposition at the application and examination stage did not limit the right of any person to oppose to the grant of a patent by means of submitting prior art documents which destroyed novelty or inventive step, or by prior art identified during the search carried out upon request of that person. According to the Russian legislation on the procedure for challenging the validity of patents, any person could oppose to the grant of a patent if it had been granted in violation of requirements under the law. The Delegation therefore pointed out that the procedure laid down in documents SCP/17/9 and SCP/17/9 Add. was similar to the administrative procedure for challenging the validity of a patent under the Russian legislation. In particular, any person could

oppose to the grant of a patent until expiry of the patent's term of validity. For exhaustive information on the provisions of the Russian opposition system, the Delegation referred to document SCP/15/6.

73. The Chair noted that, with respect to the definition of quality of patents, while he agreed that it was very important to have a discussion of the definition, he was interested in hearing from delegations about their opinions on the scope of the work program of the SCP on quality, since the Committee would never be able to discuss all aspects of patent quality, given the limited time and resources.

74. The Delegation of Malaysia expressed its belief that a high quality of patents was of utmost importance to the patent system of all national offices, since granted patents of high quality would ensure the best interest of all parties, especially the owners and the public, and would also ensure that no expensive proceedings needed to take place after the grant of patents. The Delegation was of the opinion that the high quality of patents depended also on the high quality of the applications received. Therefore, the Delegation stated that it had been making efforts to improve the drafting skills of patent drafters in Malaysia through continuous training. The Delegation further stated that the Malaysian Patent Office used search and examination reports of other IP offices in order to enhance the quality of patents granted in Malaysia. Further, the Delegation informed the Committee that it also had a system called modified examination to expedite examination with due consideration of the Malaysian Patent Act and Regulations, which made use of granted patents of IP offices of Australia, Japan, the Republic of Korea, the United Kingdom and the United States of America and the EPO. In conclusion, the Delegation welcomed the proposal made by the Delegations of Canada and the United Kingdom.

75. The Delegation of Japan stressed the importance of considering, from a practical perspective, various elements which were related to determining the quality of patents, in particular granting procedures including patent examination and opposition procedures. The Delegation supported discussions on the basis of the proposal made by the Delegations of Canada and the United Kingdom, since the three pillars of that proposal were important factors to achieve a high quality patents. Although some delegations had expressed that the definition of quality had to be clarified first, the Delegation was of the view that, as stated in the proposal by the Delegations of Canada and the United Kingdom, the quality of patents would mean the quality of various elements contained in the whole patent system, and not only specific elements related to quality had to be enhanced. Therefore, the Delegation expressed its hope for continued discussions instead of discussing the definition itself. From the perspective of redundant work, the Delegation observed that some delegations had expressed concern in respect of that proposal. The Delegation pointed out that no study on patent quality during the national phase had been conducted so far, and therefore, in its view, there was no duplication of work between the PCT Working Group and the SCP. The Delegation observed that the issue of quality often appeared in different decisions between the administrative authority and judicial body, between lower and higher courts, or among different jurisdictions, which often emerged in decisions concerning common patent requirements, such as novelty and inventive step. Therefore, the Delegation considered that it would be significant to find the above-mentioned commonalities of patent requirements among countries, and to find out why such differences in decisions would occur. To that end, the Delegation was of the opinion that it would also be beneficial to conduct a specific analysis of the patentability requirements, for instance, conducting a comparative study on the method of evaluation of inventive step/non-obviousness and discussing the results, and considering how to enhance patent quality based on such results, the outcome of which could be the basis for the discussion on "process improvement." The Delegation, therefore, aligned itself with the views expressed by the Delegation of Spain. The Delegation further noted that, in advancing discussions on the issue, it was meaningful to analyze and compare "quality of patents" in the granting procedure from a practical perspective. Therefore, the Delegation considered that it was beneficial to exchange information on the method of quality management. As the basis for such discussions, the Delegation introduced

the quality management system of the Japan Patent Office: in order to improve the quality of patent examination work, several examiners consulted with each other and shared know-how on search strategies. In addition, the Directors of each examination unit checked the search and examination work. Based on those activities, the Japan Patent Office strived to ensure the provision of uniform examination practices. Activities for measuring and analysing quality by the quality management unit included internal reviews by third parties in the patent office of individual cases. Activities also included collection and analyses of user satisfaction surveys and related statistical information. The internal reviews were carried out by a committee of 13 members that consisted of three Directors from each of the four Patent Examination Department. The committee's analysis was presented to the meeting of the Deputy Commissioner and the Director-Generals, and the section concerned should take that analysis into consideration in forming plans to improve processes related to quality. Those results and measures were provided to the examination units. With regard to the PPH, the Delegation noted that it was also one of the members who had been dealing with the PPH from the beginning.

76. The Delegation of the United States of America, speaking on behalf of Group B, stated that it was interested in getting a better understanding of how Member States defined quality which could entail looking at criteria and evaluating the quality, without necessarily trying to develop a common definition.

77. The Delegation of the United States of America, speaking in its national capacity, stated that it would circulate its proposal on quality of patents. The Delegation welcomed the opportunity to study and discuss the topic, because granting high quality patents was fundamental to having a well-functioning patent system that promoted innovation, economic growth and employment. The Delegation stated that low quality patents were wasteful and drained resources by, for example, inhibiting others from marketing certain products that would otherwise be brought to market and by resulting in unnecessary litigation costs. The Delegation informed the Committee about the recently passed America Invents Act (AIA), which reflected historic change in the patent law of the United States of America, and brought about the most far-reaching and important revision of the patent law in many years. It noted that several provisions of the Act were directly related to increasing patent quality by creating more certain and viable property rights in the innovation marketplace and by providing greater legal certainty. The Delegation explained that some of the relevant provisions included adopting a first-inventor-to-file standard, which transitioned the United States of America to the first-inventor-to-file patent system from the first-to-invent system, while maintaining a one year grace period for disclosure, eliminating the interference proceeding and establishing instead the derivation proceedings. The Act also had an in-house process for challenging patents that was a faster and significantly cheaper alternative to costly and protracted litigation. The system replaced the optional *inter partes* re-examination with *inter partes* review to be conducted by the Patent Trial and Appeal Board on the basis of patents or printed publications. It also established post-grant review before the Patent Trial and Appeal Board to review the validity of issued patents within nine months from grant on any patentability issue except best mode. Rather than having a pre-grant opposition system which delayed examination, the Act allowed for greater use of third party submissions to ensure that examiners had the best prior art available before them. Further, the Act allowed third parties to submit printed publications of potential relevance to examination within six months from the publication of the application accompanied by a fee and a concise description of the asserted relevance of the documents. The Delegation considered that, regarding the topic of quality of patents, it was generally settled that high quality patents were the desired outcome of the patenting process. However, in its view, defining what was a high-quality patent was much more ambiguous concept, which was open to different interpretations in different national IP systems. The Delegation was of the opinion that defining what was a high quality patent was difficult and was often counter-intuitive. The Delegation observed that different users of the system or users of different national systems would define quality differently in view of their historical, cultural, geographical, technological and other points of view, and even with respect to observers of similar backgrounds, the assessment of quality could be difficult. The Delegation noted that some

parameters that had been considered as a measure of quality included the monetary value of patents, the ability of a patent to survive scrutinizing litigation or other quality parameters applied by national offices. However, in its opinion, all of those possible parameters presented difficulties and were likely not valid for every situation and for every country. In view of the challenges of defining high quality patents, the Delegation suggested that attempts be made to determine the various elements that different national offices consider important to a high quality patent and to a patent system that generated high quality patents. The Delegation thus proposed a work program in which offices of Member States were invited to reflect upon and to share the high level goals that they considered crucial to a patent system that produced high quality patents. Those goals would necessarily vary from country to country and would be affected, among other factors, by national industrial policies, by nationally determined balance between the rights of inventors and those of others and by the premium placed on legal certainty and clarity in their respective national systems. Those high level goals represented the office-specific targets against which the quality of national patents and patent examination was measured. The Delegation expressed its belief that sharing and discussing those goals would be useful in shaping a discussion of what was meant by a high quality patent and what qualities must be possessed by a national patenting infrastructure that generated high quality patents. The Delegation also proposed a second part of the work program which involved an analysis of how national offices assessed the quality of granted patents and determined how well the goals set by the offices were met. It explained that that aspect of the proposal was directed to the operations and procedures employed in the various national offices to ensure that quality patents were granted. Accordingly, the Delegation invited national offices to share the specific metrics they used in evaluating granted patents and the work of their examiners and a description of the national quality assurance mechanisms. The Delegation considered that the information on the specific quality metrics used by national offices would be useful in discussions aiming at improving the patents granted by all the offices. The Delegation suggested compilation of a list of best practices regarding patent quality, and noted that the offices would be free to adopt some of the metrics or best practices in their own operation, if they so wished. The Delegation provided the Committee with a description of the quality assurance metrics that were used at the USPTO as follows: the USPTO had formulated a composite quality metric which greatly expanded previous procedures for measurement of examination quality. The composite quality metric was designed to reveal the presence of quality issues arising during examination and to aid in the identification of their sources so that the problems might be remedied by training and so that the presence of outstanding quality procedures might be identified and encouraged. The quality metric was composed of seven total factors that took into account stakeholders' comments, including three factors that had been drawn from the previous USPTO measurement metrics and four new factors. Those factors included: (i) the quality of the action setting forth the final disposition of the application; (ii) the quality of the actions taken during the course of the examination; (iii) the perceived quality of the patent process as measured through external quality surveys of applicants and practitioners; (iv) the quality of the examiner's initial search; (v) the degree to which the first action on the merits followed best examination practices; (vi) the degree to which global USPTO data was indicative of compact, robust prosecution; and (vii) the degree to which patent prosecution quality was reflected in the perceptions of the examination corps as measured by internal quality surveys. To summarize, since the Delegation believed that the exchange of information on quality assurance mechanisms used by the various national offices was of great importance, it proposed two activities for consideration, i.e., (i) to conduct a survey of the offices of Member States inviting them to reflect upon and to share the high level goals that they considered crucial to a patenting system producing high quality patents. Those high level goals represented specific targets against which the quality of national patents was measured; and (ii) a questionnaire to be filled by the national offices in which they would describe the specific metrics that they used in evaluating granted patents in the work of the examiners measured against the office specific targets that were described above. Finally, the Delegation expressed its support for the proposal made by the Delegation of Denmark on the quality of patents and for gathering information from Member States on the use of foreign search and examination work, since it could lead to developing best practices that the offices of

Member States could discuss, study and adopt, if they so wished. In its view, such initiatives whereby a national office utilized the work done by another office to carry out search and examination of applications more efficiently could have a significant effect on the quality of granted patents. The Delegation explained that, for example, in its country, the PPH was the USPTO's most advance work sharing program which allowed applicants to request prioritization of the Paris Route applications when claims had been allowed in one of its bilateral partners. Under the PPH program, the Second Office could utilize, if it so wished, the search and examination results of a First Office, thereby avoiding duplication of work and expediting the examination process, while at the same time improving quality of the search conducted by the office and of the resulting examination. According to the Delegation, as of August 2011, there had been 5,481 PPH and 1,870 PCT/PPH requests filed with the USPTO, and its reviews had shown that the quality of patents granted under the PPH programs had been generally higher than for non-PPH patent applications. The Delegation expressed its willingness to share information and experiences on improving quality by using foreign work with other Member States, and to learn best practices that might be optionally adopted by offices.

78. The Delegation of Argentina stated that any work to be undertaken should bear in mind that Article 27.1 of the TRIPS Agreement stipulated that patents protected inventions that were new, involved an inventive step and could be applied in industry. By not defining what was meant by “inventions” or not defining the three requirements for patentability in the TRIPS Agreement, the Delegation observed that there was room for maneuver as to each Party being able to apply that Article according to its needs and its level of development. As a general concept, the Delegation expressed its belief that Member States could benefit from the flexibilities in the TRIPS Agreement with respect to the scope of the patentability requirements. The Delegation stated that the definition of the patentability criteria in accordance with national priorities was a basic tool that countries had for the promotion of new and inventive inventions. In its view, the adoption of high examination standards was crucial in a well-balanced intellectual property system, since it avoided the grant of patents that were too broad or did not involve an inventive step, which naturally had a negative impact on innovation processes.

79. The Delegation of Poland, speaking on behalf of the European Union and its 27 Member States, reiterated that opposition systems were important tools for ensuring the proper functioning of patent systems as it could contribute to improving patent quality and increasing the creditability of granted patents. To fulfill those functions, the Delegation considered that the opposition procedure had to provide a rapid, easy and cost effective mechanism for third parties to challenge the grant of a patent. While the PCT Working Group, at its fourth session, had supported the introduction of the third party observation system under the PCT as a pilot with the starting date for the service in early 2012, in relation to opposition mechanisms, the Delegation reiterated its preference to preserving the freedom of all WIPO Member States in deciding whether or not to introduce them into their national legislation. Since opposition systems could play a positive role in the proper functioning of patent systems and improving the quality of granted patents, the Delegation suggested the retention of the topic of opposition systems in the work program of the Committee. The Delegation expressed its interest in further exploring other procedures also mentioned in document SCP/17/9 but were not included in it, such as invalidation or revocation procedures and procedures related to the limitation of granted patents by the patentee. The Delegation therefore suggested that the Secretariat conduct another study dealing with those other procedures which also enabled the intervention of third parties in the patent granting procedure and thus contributed to improving the quality of granted patents.

80. The Delegation of Poland, speaking in its national capacity, stated that, in relation to the proposal made by the Delegation of Denmark, the possibility of having access to search and examination reports made by other national patent offices would undoubtedly contribute to increased quality of national search and examination reports, and thus would improve the chances for obtaining strong patents. The Delegation noted examples of the initiatives which could be undertaken to that effect as follows: (i) a list of web page addresses where prior art

search reports were made available could be established; (ii) the use of uniform rules for the preparation of search reports should be promoted; (iii) the preparation of the so-called preliminary written opinions should also be recommended; and (iv) with the view to eliminating language barriers, it would be recommended to ensure machine translations into English of the abstracts and preliminary opinions. The Delegation explained that a cooperation program of the EPO and the European Commission with national offices on machine translation as well as a cooperation project among national offices to create a joint platform of national patent registries, which would ensure quick access to legal status information of each country, were underway. The Delegation expressed its support for the action proposed in paragraph 6 of document SCP/17/7 (proposal by the Delegation of Denmark) which could complement the work plan for the SCP proposed by the Delegations of Canada and the United Kingdom. The Delegation informed the Committee that the Polish Patent Office had established a quality management system which was ISO 9001 certified, and which provided applicants and the public with the certainty that the Polish patent process was transparent and that patent products were uniform and met the goals set out by the Polish Patent Office.

81. The Delegation of Chile acknowledged the value of discussing a work plan on the quality of patents, since having high quality patents was essential for the correct functioning of the patent system. However, the Delegation expressed its belief that the discussion should be developed in a balanced way in view of the patentability requirements under the TRIPS Agreement and should by no means affect or limit the capacity of national offices to carry out their own search and examination or limit the application of the substantive patent law of each country. The Delegation therefore welcomed the statement made by the Delegation of Denmark, clarifying that its proposal was not intended to affect the independent activity of each office when examining patent applications, but to provide more information for a better examination of patent applications. With respect to the revised proposal made by the Delegations of Canada and the United Kingdom, the Delegation considered that the components regarding the development of technological infrastructure and exchange of information were particularly important for ensuring patent quality. In that context, the Delegation highlighted the great usefulness of initiatives in those areas for developing countries, for example, the PROSUR project in which Chile and other South American countries had been participating. The Delegation explained that the PROSUR project intended to use technological solutions proposed by WIPO to share patent information. In its view, the development of technical infrastructure in industrial property offices was an essential requirement for access to information that would ensure patent quality. Therefore, the Delegation considered it appropriate to highlight the importance of WIPO continuing to develop greater resources to implement IT solutions both for internal use in offices, such as the iPAS system, or between offices such as the WIPO CASE system. In that regard, the Delegation requested the Delegations of Canada and the United Kingdom to clarify the way in which their proposal dealt with the technical infrastructure development and the exchange of information on patents, and to provide more information on the way in which the proposal dealt with mutual access to databases for analyzing the state of the art as well as the way in which the problems of differences in languages and forms of applications were dealt with.

82. The Delegation of France aligned itself with the statement made by the Delegation of Poland on behalf of the European Union and its 27 Member States. Further, the Delegation supported the three-stage work program proposed by the Delegations of Canada and the United Kingdom. Regarding the first stage, i.e., infrastructure development, the Delegation considered that it was important to work on search tools and materials available in each office. On the second stage, i.e., exchange of information on the quality of patents, as stated by the Delegations of Portugal and Spain, the Delegation was of the view that it might be useful if the Committee could be informed about the work done by the European Patent Network on quality of patents. The Delegation also supported the proposal made by the Delegation of Portugal that a questionnaire be sent out to national offices in order to gather information on the processing of patents in national offices. In addition, the Delegation supported the collection of information on the way in which offices encouraged applicants to submit applications of better

quality, as suggested by the Delegations of Canada, Spain and the United Kingdom. Concerning the third step, process improvement, the Delegation was of the opinion that it should include issues regarding the application of patentability requirements in relation to the improvement of quality of patents and improvement of the quality of search. In its view, that would involve analyzing prior art and deciding whether or not an invention is new or non-obvious. As suggested by the Delegation of Spain, the Delegation also considered that a number of studies analyzing the inventive step requirement, for example, the way in which prior art and "a person skilled in the art" were assessed by offices, were needed.

83. The Delegation of Brazil informed that the Brazilian patent office (INPI) was one of the International Searching and Preliminary Examining Authorities under the PCT and shared information on patents. It stated that when discussing the issue of quality of patents, views of all parts involved and implications to the society as a whole should be taken into account. The Delegation also noted that it was important to preserve the necessary policy space in different Member States. Referring to the discussions held during the 16th session, the Delegation considered that the subject was paramount for all members, since the proper functioning of a balanced patent system which took into account the interests of society as a whole was the basis of the work of the Committee. The Delegation expressed its appreciation for the references to the WIPO Development Agenda recommendations in the proposals, as they showed that the Development Agenda was being mainstreamed in the diverse areas of activities in the Organization. As its preliminary comment on the proposals, the Delegation stated that more clarification on the definition of quality of patents was needed. It observed that document SCP/17/INF/2 compiled a range of different interpretations by the members: some members understood it with a focus on processes, while some others focused on work sharing. In its view, those interpretations were far apart regarding the premises and possible conclusions as well as possible ways of implementing a work program. Generally, in its view, the issue of quality of patents could be divided into two broad categories, one related to process, the other related to substantive issues. The Delegation therefore expressed the opinion that it was important for the Committee to know exactly what kind of definition could be adopted by the SCP. The Delegation shared the views of the DAG on patent quality, and expressed its preference to the work centered on operational aspects, databases and access to information on search and examination, infrastructure and capacity building.

84. The Delegation of Germany stated that defining quality of patents before entering into a debate on further steps might not be the wisest way to proceed in the Committee. It noted that, although seeking a definition in such a complex debate might be natural, the Committee found itself in a situation that the definition was very hard to find. Referring to its comment compiled in document SCP/17/INF/2, the Delegation explained its understanding of the criteria of quality that followed the lifetime of a patent, i.e., from the application through the examination procedure into the phase of litigation of the patent, bearing in mind that quality of patents was an issue too complex to bring down to a single definition. In its view, such an approach might also be confirmed by the views expressed by some delegations that patent quality interlinked and depended on the situation in each country. Regarding the proposal made by the Delegation of Denmark, the Delegation welcomed that proposal, and noted that using foreign work results must not lead to dependency between different offices. The Delegation, however, was of the view that, from a practical point of view, the risk of dependency was rather small, since using foreign work results did not mean using the results of the examination in total. In its opinion, an examiner was put into a situation to have a hint on how to continue his own work and where to put his efforts, and therefore, that kind of cooperation did not take away work from national examiners.

85. The Delegation of China considered that raising quality and service of patent offices was very important for all countries. The Delegation expressed its belief that the SCP could carry out in-depth and comprehensive research and study on the issue so that all countries could exchange views and increase capacity in that regard. The Delegation suggested that the SCP first collect information from all countries, and then work out a questionnaire to provide a basis

for future work. With regard to the proposal made by the Delegation of Denmark, the Delegation stated that using search and examination results prepared by other offices would be beneficial for improving the quality of patents. It noted that the law in China requested that applicants should provide information on their corresponding applications filed with foreign offices, and expressed its willingness to share its views, experience and practices in that regard.

86. The Delegation of Switzerland stated that opposition systems and other similar mechanisms had an important role to play in guaranteeing the quality and credibility of patents, and provided a rapid, easy and inexpensive method for opposing a patent, thereby enhancing patent quality. In continuing to work on that topic at the next session of the SCP, the Delegation endorsed the proposal made by the Delegation of Poland on behalf of the European Union and its 27 Member States, and stated that the Committee should look in greater depth at the various mechanisms that were referred to in document SCP/17/9, including the re-examination system.

87. The Delegation of the Republic of Korea stated that quality of patents was one of the most important issues in a patent regime. It found the criteria suggested by the Delegation of Germany in document SCP/17/INF/2 interesting. The Delegation noted that the Korean Intellectual Property Office had been focusing on the enhancement of patent quality from the Office's perspective by improving its examiners' prior art search technique, analysis of search results and communication between examiners and applicants. To enhance quality of the legal provisions, its country was amending the Korean Patent Act to be written in easy legal terms so that it would be understandable by all parties concerned. Further, the Delegation observed that the PPH allowed intellectual property offices to benefit from the work previously done by other offices, thereby reducing workload and improving patent quality. The Delegation noted that it planned to expand the number of PPH partner countries from nine to ten, and PCT/PPH partner countries from one to two, next year. In its view, further discussions on that issue would help each Member State understand the term "quality of patents" and improve quality of patents.

88. The Delegation of Pakistan expressed its appreciation for the revised proposal submitted by the Delegations of Canada and the United Kingdom and the linkage made between the proposal and the Development Agenda recommendations. Further, the Delegation welcomed the proposal made by the Delegation of Denmark and the effort to move towards the understanding of usable foreign search and examination works. The Delegation expressed its belief that those were very important concepts which needed to be looked at later at some stage. The Delegation considered that discussions related to quality of patents had to keep two important issues in perspective: (i) all parts of society were involved in that matter; and (ii) the necessary policy space for national policies should be left. Referring to paragraphs 10, 11 and 12 of document SCP/17/8 and the discussion held on the definition of quality of patents, the Delegation observed different perspectives and various elements that could be incorporated into the concept of quality of patents. In order to better understand the concept before working towards finalizing the work program on the issue, the Delegation suggested compilation of those elements that Member States considered as parts of the concept of quality of patents.

89. The Delegation of Zambia associated itself with the statement made by the Delegation of South Africa on behalf of the African Group. The Delegation sought clarification from the Delegations of Canada and the United Kingdom regarding the added value of their proposal for the work of the Committee in relation to the work being undertaken by the PCT so that it was clear that the work in the SCP was truly complementary. The Delegation further requested the Delegations of Canada and the United Kingdom to provide additional information on the envisaged work relating to improvement in quality of patents where technical infrastructure development was a key to attaining that objective. The Delegation raised the question as to how the work of the Committee could contribute to the creation of a framework of enhancing the Development Agenda goals, in particular, recommendation 10 relating to the capacity building for patent offices and recommendation 11 on technical assistance. The Delegation also sought clarification as to what was meant by "giving guide to interested and willing Member States" if the work envisaged was to ensure that both developed and developing countries benefited from

improving the quality of patents. In addition, the Delegation requested more information about the questionnaire proposed by some delegations with a view to clarify the meaning of quality of patents in various jurisdictions, in particular, the usefulness of such a questionnaire and the kinds of information sought through the questionnaire.

90. The Delegation of Singapore stated that it continued to be supportive of the revised proposal submitted by the Delegations of Canada and the United Kingdom. While the Delegation considered that the definition of quality of patents was needed in order to provide the foundation for discussions, it appreciated the difficulty in developing a comprehensive definition that was acceptable to all Member States. The Delegation was of the opinion that the broad definition provided by the Delegations of Canada and the United Kingdom was a good starting point, and was indicative of the wide ranging nature of the issue. The Delegation supported the suggestion to keep the definition open for further comments and suggestions. In its view, a substantial amount of work could be envisaged under that broad definition. In order to focus on the commencement of work, the Delegation suggested that work be initiated under the following sub-definition: the processing of patent applications and the issuance of patent grants in compliance and consistent with each jurisdiction's legislation and obligations. The Delegation stressed that the objective of that sub-definition, which would be covered under the umbrella of the broad definition put forward by the Delegations of Canada and the United Kingdom, was to ensure, as far as possible, that patent applications were processed and patents were issued in accordance with a Member State's own substantive patent law without any need to harmonize substantive patent laws. The Delegation also supported further work under the three main components in the proposal by the Delegations of Canada and the United Kingdom. Further, the Delegation observed that the statement made by the Delegation of Algeria on behalf of the DAG was consistent with its view expressed during the previous session of the SCP. In its view, either as a separate fourth component or as an underlying element of each component, training programs needed to be given due consideration and developed accordingly. In addition, the Delegation expressed its support for the proposal made by the Delegation of Denmark. It considered that the sharing of search and examination documents for examiners' consideration while respecting differences in national patent laws and interpretation was an important work element, and would help examiners conduct a good examination. The Delegation stated that since Singapore had experience in the use of foreign search and examination reports as well as contracting out examination work to other patent offices, it looked forward to sharing its experience in that regard. The Delegation further noted that its country had concluded PPH agreements with certain offices and was also part of the ASEAN Patent Examination Cooperation Initiative (ASPEC). It explained that, under ASPEC, ASEAN Member States who had different levels of experience and who had, or might not have, their own examiners had developed a framework under which search and examination reports in one Member State could be referenced in another Member State to assist in the examination process, and expressed its willingness to share its experience and perspectives on those initiatives, in particular, benefits to a small patent office.

91. The Delegation of Mexico stated that the use of work done by other offices might affect the quality of granted patents, provided that it was seen as an additional tool in guiding the work of examiners in their search and examination work. In its view, such use should not lead to harmful dependence, and the patentability criteria applied in each patent office had to be considered. The Delegation noted that it had concluded PPH agreements with Japan, Spain and the United States of America, and offered its results of substantive examination and search to the Central American offices, so as to provide information that was useful and which could be used as a guide by those offices in their search and examination work. The Delegation also associated itself with the question raised by the Delegation of Chile on the various aspects of the work plan proposed by the Delegations of Canada and the United Kingdom.

92. The Delegation of Spain stated that, with respect to the opposition systems, the Delegation suggested that the study be extended to subjects such as the lodging of appeals against the grant of a patent before national patent offices and the limitation of granted patents,

the latter being of particular interest to its country in view of the possible introduction of such mechanism in the national legislation in the future.

93. The Delegation of India considered that the revised proposal submitted by the Delegations of Canada and the United Kingdom needed further assessment for its implications on national patent laws and national interest of the Member States. With respect to the broad definition of quality of patents suggested by that proposal, the Delegation stated that it was not desirable to include the judiciary in the work program of the SCP. In its view, the broad definition did not focus on the main issue of the application of high threshold level for granting patents (i.e., patentability criteria) to ensure that patents were only granted to truly inventive products and processes. The Delegation therefore observed that the proposed criteria of quality of patents and work program was impractical and could not be applied globally. In its view, quality of patents was a complicated process, as it gave relative understanding depending upon the applicable national patent law. Moreover, a patent that was granted in one country did not necessarily need to proceed for grant in another country, as it might fail to comply with the provisions of the patent law of that country. Therefore, the Delegation was of the opinion that it might not be correct to conclude that an authority which decided to grant a patent on a particular invention was correct and another authority which decided otherwise was wrong, or *vice versa*. For example, the Delegation explained that, under Section 3 of the Indian Patent Act, a mere new use of a known substance, business methods, computer programs *per se*, methods for treatment of human beings and animals, a new form of a known substance, a new derivative of a known drug molecule not showing any enhancement in the known efficacy in respect of properties, were not allowable. During the examination stage, some of the said inventions might be drafted by the applicant as a “process” in order to obtain a patent, and examiners had to remain cautious not to be influenced by such attempts. The Delegation, however, pointed out that, in other countries, those types of claims might be allowed, and therefore, in its opinion, criteria of the quality of patents and the work program as proposed could not be applied uniformly to all cases either within the same patent office or among different patent offices. The Delegation further observed that, in the context of the PCT, sometimes, different conclusions were made in international reports or written opinions prepared by the same international authority on the same invention during the International search and international preliminary examination phases. Noting that the PCT written opinions were non-binding, the Delegation was of the view that it would not be appropriate to harmonize the quality of patents at the international level. Referring to the suggestion in the proposal that patent offices should develop a client-relationship with applicants, the Delegation observed that patent offices were public offices, which were supposed to work independently in a transparent and accountable manner and were guided only by the Statute reflecting public policy concerns so that they did not base their decisions or functioning on the extraneous opinions. Therefore, in its view, such relationship might spoil the independence of a patent office. With respect to the proposed work plan for the SCP on the technical infrastructure development, in particular, the description found in paragraph 15 of document SCP/17/8, the Delegation stated that, while it was indeed important to have good technological infrastructure to enhance the capability of patent offices to access information for the purpose of examining patents, it was equally (and often more) important that patent offices applied the information as per their domestic laws. Further, in its view, it was not just a matter of developing technological infrastructure but also a matter of being able to access patent databases. The Delegation considered that developing countries often had poor access to databases, which were often costly and, thus, had to rely on freely available search systems that were meant for the general public. In addition, in upgrading technological infrastructure, the Delegation observed that the issue of sustainability of such infrastructure in terms of costs, maintenance and expertise were primary issues that needed to be considered. The Delegation requested further clarification on the concrete activities under the proposal with regard to technical infrastructure development, as no details were provided. Further, the Delegation stated that, prior to embarking on mandating the building of infrastructure development, it was important to obtain some basic understanding of the baseline with regard to infrastructure that already existed in countries as well as challenges faced by countries in that regard. With respect to the proposed work plan for the SCP on the information

access and exchange on quality of patents, in particular, the description found in paragraph 16 of document SCP/17/8, the Delegation observed that that component of the proposal was intended to improve administrative processes and operations to please users of the patent system (i.e., applicants) and to make it more right-holder friendly, presumably by a speedier granting of patents, simpler requirements for patent applicants etc. In its view, such an approach was problematic, as the function of the patent office was not to serve the users of the patent system alone but to ensure that patent applications were processed and examined as per requirements under the national law which was designed to meet national objectives and to benefit the society as a whole. The Delegation observed that most of the patent holders originated from developed countries, and as such, collecting views and experience from the users relating to quality of patent office processes and operations and sharing them with the Committee for further consideration, in effect, would simply revealed how right holders assessed the quality of work of national patent offices, giving them undue control in that regard. The Delegation was of the view that such use of opinions from users might be unrealistic, ill-informed, biased or intended to put pressure on a patent office. It noted that, since, presumably, it would also reveal complaints about the speed of patent granting, complex procedures etc., such an information sharing exercise was likely to provide an opportunity to press for more standards with regard to patent processing and examination. The Delegation considered that there was no need to have any formal arrangements for the purpose of access to, and exchange of, information as stated in the proposal, but that such information should be made available in the public domain by each office so that the interested parties, including patent offices of other countries, could access it and could also be shared with WIPO and under bilateral and multilateral agreements. With respect to the component of process improvement in the proposal, the Delegation stated that the issues related to procedures and parameters of grant and relevant processes beyond grant, for example opposition procedures, were best dealt with under the national laws which were subject to change and flexibilities provided under international agreements. The Delegation observed that many countries had amended their laws from time to time to suit the national and public interest. For example, India had amended the Patents Act 1970 in 1999, 2003 and 2005 to be in compliance with the TRIPS Agreement and also to streamline the pre-grant and post-grant patent procedures. The Delegation further noted that all Member States had upgraded their patent laws complying with the TRIPS Agreement, the work of one country was freely available to other countries through e-access, ISA/IPEA reports were available during the national phase, global patent databases were available to conduct effective prior art search, patent examiners were having a fair amount of training about the applicable national laws and there were stringent legal mechanisms available in each country for monitoring granting patents and refusing patent applications. In view of the above, in its view, there appeared to be no need to issue directive suggestions to other countries on process improvement through the mechanism as provided in the proposal. In conclusion, the Delegation summarized its observations and recommendations as follows: (i) quality of patents might vary from one office to another. Therefore, it remained country specific and needed to be dealt with by the respective national patent laws; (ii) there appeared to be no further need to have additional monitoring mechanism on the quality of patents, on the work of national patent systems and on decisions taken by the respective patent office by way of implementing the proposed criteria of quality of patents and work program in all countries, as provided in the proposal made by the Delegations of Canada and the United Kingdom; (iii) such additional mechanism might simply amount to undue interference and prejudice the decisions of the national patent offices, and the proposed work would be rather a premature and hasty step; (iv) Member States might be wary of the initiatives in the proposal that appeared to aim at encouraging a country's patent office to substantially rely on, or to simply endorse, the work of other countries in the examination of patent applications; (v) Member States might also be wary of those initiatives that appeared to be extra user-friendly and allowing users' influence and pressure in assessing the quality and the overall functioning of respective office. Those initiatives might lead patent offices focusing on speedy patent grants or simplifying patent granting processes in order to enable right holders to obtain quick patent grants; (vi) prior art search was of vital importance in assessing patentability of the claimed subject matter and the same should be conduced with utmost care to avoid wrong grant of patents. Given that

developing and least developed countries lacked financial and technical resources, assistance should be provided to improve the institutional capacity of national patent offices and to strengthen search facilities in accordance with the needs of developing and least developed countries. Examination, grant and post-grant processing could then be conducted in an effective manner in accordance with the applicable national laws. Such assistance could be provided through WIPO mechanism by, for example, providing access to patent and non-patent databases or making the search engines available; (vii) it might be a good idea to conduct a study by WIPO on the current state of affairs as regards the technological infrastructure of patent offices for accessing information required for examination of patent applications. The survey should also look at the cost of accessing information for patent examination purposes. The study should also contain problems faced by patent offices, especially developing country patent offices, with respect to technology infrastructure, prior art search and accessing patent information.

94. The Delegation of Nepal stated that although its country had initiated the process of granting patent rights almost 55 years back with the enactment of the Patent, Design and Trademark Act, its country could not materialize it in the real sense for its economic development. The Delegation noted that a new industrial policy had provided the establishment of a separate independent intellectual property office to manage patents and quality of patents. Further, in line with the new industrial policy, the Delegation stated that its country would review the patents law. The Delegation expressed its belief that the 17th session of the SCP would be useful and beneficial to contribute to its national effort in reviewing institutional and legal frameworks. Regarding the revised proposal by the Delegations of United Kingdom and Canada on quality of patents, the Delegation expressed its wish to seek further clarification on, and simplification of, the definition of the term “quality of patents”. The Delegation, however, supported the revised proposal, in particular, regarding the three main components in the proposal. The Delegation was of the view that the lack of technical infrastructure was a major problem to carry out the patent related activities, in particular, for least developed countries (LDCs) such as Nepal. The Delegation suggested focusing on enhancing the capacity building of required human resource to handle patent-related issues efficiently. In addition, the Delegation considered that another problem for LDCs was the lack of access to patent information and quality of patents. Even if patents and quality of patents were very important elements for the economic development of the country, in its view, its country was still in the phase of raising public awareness of patent rights and quality of patents. The Delegation expressed its belief that technical infrastructure development, access to patent information and process improvement were the prerequisites for the quality of patents. Regarding the proposal by the Delegation of Denmark, the Delegation considered that using search and examination results prepared by other offices was important in maintaining a higher level of quality of patents. However, the Delegation stressed the need to keep in mind the affordability and sustainability of such use for the LDCs.

95. The Representative of the EPO expressed its support for the statement made by the Delegation of Poland on behalf of the European Union and its 27 Member States, and the Delegation of the United States of America on behalf of Group B. The Representative echoed the views of those Delegations by stating that quality of patents was a significant parameter of any patent system, and as such, a priority of strategic nature for the EPO and the prerequisite for utilization of available work. In his view, a pragmatic approach to the options for enhancing quality by means of cooperation among patent offices held great potential for the materialization of benefits for all stakeholders, particularly users and patent offices alike. The Representative reiterated his readiness to share with the Committee the valuable experience obtained within his Organisation with the establishment of the European Quality Management System and the development and use of a matrix. The Representative explained that the primary objective of the European Quality Management System as an element of the European Patent Network was to support the national patent offices of the Contracting States of the European Patent Convention (EPC) as well as the European Patent Office to continuously improve the quality of the products and services during the entire duration of the patent granting procedure and

thereafter. Further, the Representative made reference to the work ongoing both within the Trilateral as well as IP5 Cooperation, addressing significant quality-related issues and aligning the quality standards of the offices involved to the extent practicable.

96. The Representative of KEI stated that WIPO should consider: (i) gathering information on the costs of litigation to challenge the validity of patents; (ii) creating a database to share information on the cases where litigation had resulted in the invalidation of patents; and (iii) a system whereby the presumption of patent or patent claim validity would change if a claim were to be found to be invalid as a consequence of litigation in another country.

97. The Representative of AIPLA expressed his appreciation to the Delegations of Canada and the United Kingdom as well as the Delegation of Denmark for bringing quality into focus, especially for users, industry and the public. The Representative stated that, in general, he supported the combination of both substantive and procedural factors in consideration of quality. However, the Representative considered that the definition of quality as phrased to focus on offices might not provide the most relevant guidance for all those having the shared responsibility for the vitality and integrity of the patent system, including users, inventors, practitioners, the offices and the public at large. In his view, there should be greater emphasis on quality in connection with the filing and prosecution of patent applications, which included the quality of a patent application as filed, including its form and content, as well as the quality of the examiner's search and examination and the applicant's responses. Further, the Representative suggested that any consideration of the quality be extended beyond the application prosecution process itself and include post-issuance activities, including appeals and the quality of post-issuance proceedings such as oppositions and re-examination, thus the inquiry would more appropriately concern quality of patents and patent applications. The Representative considered that the process for achieving a quality patent right is: (i) iterative with activity prior to filing, during prosecution and after issue; (ii) cooperative; and (iii) adversarial at times. Therefore, in his view, the quality of a patent right extended beyond validity and included concepts of predictability and legal stability. The Representative stated that putting a focus on actions in an office might be too narrow, as it appeared to concern only procedural and transactional aspects without considering infrastructure, training, work sharing and cultural factors that had a direct impact on quality during prosecution. In his view, quality would be enhanced when there was an appropriate combination of both substantive and procedural quality that involved the office, applicants and the public. The Representative was of the view that the achievement of quality as an absolute matter might be elusive, especially in view of existing limitations on the patent search and examination process due to differences among the offices in law, language and procedure, inadequacies of infrastructure and human factors, and given the dynamic and independent process of innovation in any given technology that took place concurrently around the world. The Representative noted that while the quality of the patenting process and the resultant quality of the patent right at any given point in time might be achieved only as a relative matter, it should be a primary task during the examination process to ensure that the description and enablement requirements for an application were fully met and that the claims were clear, concise and effective in defining over the available prior art. As to the prior art, the Representative stated that the achievement of absolute quality for the patent right should be the goal that drove investment, training and procedural initiatives for the patenting process. In conclusion, the Representative stressed that those efforts towards quality were the ones to be studied, measured and consistently modified on the basis of the feedback.

98. The Representative of ICC referred to its Policy Statement regarding cooperation between patent offices and prior art searching of patent applications, dated June 28, 2010, which was available on the ICC website.

99. The Representative of AIPPI expressed his support for the revised proposal on the quality of patents submitted by the Delegations of Canada and the United Kingdom. The Representative noted that quality of patents was a very important topic not only from the offices' point of view but also from the applicants' and the general public's points of view. The

Representative supported quality management programs described, for example, by the Delegation of Denmark, since the primary focus of the process improvement component was on search and examination processes in patent offices. The Representative also supported work-sharing between offices as an efficient means to improve quality of examination, while also contributing to reducing backlog of examination. In that regard, the Representative supported the position paper recently submitted by FICPI. The Representative considered that the ability of mutually exploiting search and examination results could be improved if patentability requirements were made more uniform. The Representative informed the Committee that, a couple of weeks earlier, AIPPI had for the first time adopted the resolution on the inventive step requirement in its Annual Meeting in Hyderabad, India. Further, the Representative noted that AIPPI had recently adopted other resolutions which were also relevant to patent quality and opposition systems.

100. The Representative of IPO noted that his organization was a part of the Trilateral Industry Group representing the industry of the United States of America, together with AIPLA. The Representative informed the Committee that the Trilateral Industry Group had submitted a paper to the Trilateral Offices on patent quality about a year ago, and highlighted a few points from that paper. First, the Trilateral Industry Group paper noted that a quality patent or a quality patent right was a patent that satisfied all of the legal patentability requirements. Patentability requirements included, for example, novelty, inventive step or non-obviousness and description requirements. Claims of a quality patent would be found valid, if subsequently reviewed by a patent office or a court. While patent quality was often determined separately for each patent, when a patent was granted with one or more claims that failed to satisfy one or more of the patentability requirements and they were found to be invalid, that patent could be said to have low quality. The paper therefore suggested ways to improve quality and to increase the likelihood that the all patented claims would be valid. The Representative considered that the number of low quality patents would be reduced if applicants improved the quality of their applications and filed patent applications which had fully satisfied the applicable patentability requirements. Therefore, the Trilateral Industry Group was of the view that patent quality was including the quality of patent applications, the quality of search and the quality of examination. In its view, the quality of patents, which must be distinguished from the monetary value of the patents, also included the concepts of predictability and legal stability of the patent right. The Representative explained that well-defined metrics would provide an essential resource for gauging the quality at various stages of the patenting process. In the opinion of the Trilateral Industry, patent quality was a shared responsibility from the time an invention was created, moved into the patent granting process up to the enforcement process, during which inventors/applicants and their patent attorneys and many other parties, including patent offices, courts and third parties, were involved. The Representative stated that the paper also provided recommendations for each of the actors in the process. With respect to applicants, it was noted that the applicants should thoroughly analyze the prior art at their disposal, prior to filing patent applications, and should draft patent applications as far as possible in a standard format, preferably in line with the PCT and the common application format recently proposed by the Trilateral Group. The applicant should clearly state what the invention was and what made it a patentable invention. The Representative considered that, since a patent application was a complex legal document, the services of a qualified and experienced patent attorney were essential. Regarding patent offices, the paper recommended that patent offices should ensure independent search and examination and not depend solely on the applicant's search or analysis. The patent offices should share results with other offices in real time and, to the greatest extent possible, avoid duplication of effort. Further, the paper suggested that patent offices provide incentives for quality work by examiners. In terms of courts, the paper recommended that courts should render clear and explicit decisions in patent cases. Finally, for the public, the paper suggested that a company cooperate with patent offices on training programs for examiners and for newer, complex technologies, and that training courses be taught by scientists and engineers. The paper also recommended that members of the public should submit prior art analysis during the permitted time periods before or after grant, and that companies should consider donating databases of non-patent prior art publications such as

scientific and technical journals. It was also recommended that patent offices should improve the examination procedure by widely collecting prior art information from the public, such as peer-to-patent programs offered by certain patent offices.

101. The Representative of FICPI looked forward to taking part in the discussions on the issue of patent quality which was a very important matter for all stakeholders. The Representative expressed his support for work sharing between offices as a manner to improve quality of examination while also contributing to reduce backlog in examination. The Representative considered that the proposal made by the Delegation of Denmark (document SCP/17/7) was a good starting point for such sharing of search and examination results. The Representative, however, stated that the ability of the mutually exploiting search and examination results was more convenient between offices that had similar patentability requirements. While still supporting discussions about substantive patent law to be resumed in WIPO at the appropriate time, The Representative acknowledged the importance of preserving flexibilities under the TRIPS Agreement, and also the autonomy of each office to examine and grant patents which were valid in the respective territory. The Representative informed the Committee about its submission available on the SCP website. Specifically, the Representative noted that FICPI had submitted its comments about possible advantages of further work on substantive patent law from a development perspective, and suggested adding particular provisions to a future treaty that would reaffirm basic principles of the TRIPS Agreement and the Paris Convention. With respect to the issues of opposition systems, referring to a FICPI resolution adopted in 2005, the Representative stated that FICPI recognized the importance of an opposition system in ensuring patent quality. The Representative considered that opposition proceedings should be neither unreasonably complex nor prolonged. In his view, an opposition system should be provided in the following manner: (i) a time limit for filing and substantiating an opposition should be sufficiently long so that an opponent could fully prepare his case; (ii) the extent to which the right was opposed should be fully presented together with all available supporting evidence and arguments before expiry of any such a time limit; and (iii) a time schedule for completion of proceedings should be established - such schedule being as short as reasonably possible, taking into account the number of opponents, the difficulty of the matter and the amount of evidence and argument, whilst allowing for the possibility of a settlement of discussions.

102. The Representative of IPIC noted that improving the quality of granted patents was a common goal for all, and that all members of the Committee had been making considerable efforts to improve the patent examination process in order to improve the quality of granted patents, including international treaties, bilateral and trilateral agreements and amendments to national patent laws and regulations. The Representative stated that since a patent specification had been typically prepared for a given jurisdiction and later submitted to other patent offices, such specifications were not drafted in isolation: i.e., although the patent laws of many jurisdictions shared a number of common requirements for patentability, when preparing a given specification, a patent attorney must take into consideration, for example, the sufficiency of disclosure requirement under the Canadian law, the enablement and best-mode requirement under the law of the United States of America and Section 3(d) and (k) requirements under the Indian law. Where an application failed to meet national requirements, such application would be subject to refusal in that jurisdiction with few options available for corrective actions by the applicant. In his opinion, the proposals made by the Delegations of Canada and the United Kingdom as well as by the Delegation of Denmark would serve to assist national offices in conducting their respective independent reviews. The Representative considered that the proposals provided a road map for how national offices might cooperate to share work products and facilitate the respective and independent examination of patent applications. As a frequent user of the PPH, the Representative affirmed that while the PPH had greatly assisted examiners in their work, the application of national law by such examiners had not been hampered in any way. In his view, the PPH was one example of how work sharing amongst national offices had advanced the goals of both applicants and patent offices. The Representative was of the

opinion that the proposals outlined by the Delegations of Canada, the United Kingdom and Denmark built upon the cooperative principles of programs such as the PPH, and provided a strong foundation on which future work could be based.

AGENDA ITEM 7: PATENTS AND HEALTH

103. The discussions were based on documents SCP/16/7, SCP/16/7 Corr., SCP/17/INF/3 and SCP/17/4 and 11.

104. The Delegation of South Africa, speaking on behalf of the African Group, pointed out that the granting and exercise of patent rights should be consistent with the basic goals and entrants of the public, particularly the promotion and protection of public health. The Delegation reiterated that at the 15th session of the Committee, the African Group had made a proposal that the Committee should undertake preliminary work on the topic "patents and health". The issue of patents and its impact on public health had been the subject of discussions in other fora, notably the WHO and the WTO. Among the activities aimed at addressing the interface between IP and public health, the WHO had adopted the Global Strategy and Plan of Action on Public Health, Innovation and IP (GSPOA) in 2008. Similarly, in 2003, the WTO had agreed on provisions relating to paragraph 6 of the 2001 Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration), in order to allow poorer countries to import cheaper medicines under compulsory licenses if those countries were unable to manufacture the medicines themselves. The Delegation noted that the discussion on patents and health was still ongoing at the WHO and the WTO, and progress had been made to a certain extent. Prompted by developments in other intergovernmental fora and in order to take WIPO to a lead on the activities on patents and health, the Delegation recalled that the African Group and the DAG had presented a joint proposal on patents and health at the 16th session of the SCP. The Delegation reiterated the three elements of that proposal, namely, (i) the elaboration of studies to be commissioned by the Secretariat following consultations of Member States of the SCP from renowned independent experts; (ii) information exchange among Member States and from leading experts in the field; and (iii) the provision of technical assistance in relevant areas to Member States, particularly developing countries and LDCs, as well as building upon work undertaken under (i) and (ii). In essence, the proposal sought to enhance the capacities of Member States, particularly developing countries and LDCs, to make full use of the flexibilities contained in the international systems to promote policies towards public health. The Delegation was pleased that the proposal had been well received by most Member States and observers. However, some Member States had stated that the Committee should concentrate "on the added value WIPO brought and could bring on health from the point of view of the technical expertise and that the Committee should not attempt to import discussions held in other fora". The Delegation further stressed that the issue of health was cross-cutting. At the WHO, health was discussed within the context of people's well-being. At the WTO, health was discussed within the context of trade and IP because of the TRIPS Agreement. The Delegation noted that all of those organizations had structured the intergovernmental discussions on health, while WIPO had not done so far. In its opinion, it was ironic that WIPO, known as the UN specialized agency for IP, had never addressed health at an intergovernmental level. The Delegation observed that, on the other hand, WIPO had been actively engaged in discussions on the same subject at the WHO, having resulted in the adoption of the GSPOA, which clearly indicated the role WIPO should play. The Delegation noted that health was one of the main priorities of the international development goals, including the UN Millennium Development Goals (MDGs). Hence, the Delegation emphasized the need for WIPO to take the lead on that issue. On the submissions made by Member States and observers contained in document SCP/17/INF/3, the Delegation thanked the Delegations of Costa Rica, Indonesia, Kyrgyzstan and Mexico, and also the Representative of TWN for their contribution. The Delegation welcomed those comments and suggestions, for instance, the idea presented by the Delegation of Kyrgyzstan of eliminating the patent term extension for pharmaceutical patents from its patent law. The Delegation observed that the norm regarding prolongation of the patent term for five

years was interesting and could form part of the studies that had been already proposed by the joint proposal. In the Delegation's understanding, the rationale for that proposal was to explore ways of limiting patent monopolies. Moreover, the Delegation noted that KEI and TWN had made interesting suggestions on additional elements to the work program, including the creation of a database to facilitate promptness of information pertaining to pre- and post-grant opposition to patents on pharmaceutical products filed in WIPO Member States. At the 16th session of the Committee, a number of observers had commented on the implementation of the first and second elements of the work program. Some Member States had indicated an interest in sharing their national experience on the issuance of compulsory licenses, including the challenges encountered in that process. The Delegation paid tribute to the support of the joint proposal by many members of the Committee. It was, therefore, opportune for the Committee to discuss the work program with a view of identifying the activities that would be undertaken by both Member States and observers. The Delegation noted the information contained in document SCP/17/4 on activities of WIPO in the area of patents and health. The Delegation quoted paragraph 8 of that document which provided a solid argument for the work program proposed by the African Group and the DAG: "Many activities relating to patents undertaken by WIPO were not specifically addressing the health area. Nevertheless, they may be relevant to the issues relating to patents and public health, since the general objectives of the patent system, i.e., the promotion of technological innovation and the transfer and dissemination of technology, were of fundamental importance for improving public health". The Delegation urged to ensure that the patent system worked as intended and as enumerated in the above-mentioned paragraph. The Delegation acknowledged the responsibility of the Global Challenges Division for advancing most issues pertaining to public health activities within WIPO, and supported the collaboration with WHO and WTO. The Delegation noted that none of those activities of that Division were considered in an intergovernmental body within WIPO, and as a result, many Member States had come to know about the activities of WIPO in the area of patents and health at the 16th session of the Committee and through document SCP/17/4. The Delegation highlighted that the proposed work program would properly structure and further strengthen the activities of WIPO in the area of patents and health. Notwithstanding the activities carried out in other WIPO bodies, such as the CDIP, the SCP was the appropriate forum to discuss the interface of patents and health from a substantive patent law perspective. The Delegation recalled that WIPO was cooperating with the WHO and the WTO and, to that extent, had to implement and keep to the letter and spirit of Articles 7 and 8 of the TRIPS Agreement, which outlined the importance of public health in relation to IP. Therefore, in its opinion, it was timely for the SCP to actively engage in the issue of patents and its impact on public health, especially, on access to medicine, in order to facilitate finding solutions to the problems by agreeing on the work program.

105. The Delegation of the United States of America, speaking on behalf of Group B, took note of document SCP/16/7. The Delegation stated that the proposal by the African Group and the DAG focused on the perceived flaws in the patent system relating to access to medicines, without acknowledging that a strong patent system promoted innovation. In its view, without that incentive, there would be a significant reduction in available medicines. The Delegation noted that 96% of the medicines on the WHO's Essential Medicine List (EML) were not protected by patents: either the patents had expired, or no patents were originally obtained on those medicines. The Delegation considered that medicines on the EML, which were no longer protected by patents, had been originally developed in large part due to the protection afforded to the developers by the patent system. In its opinion, that fact highlighted the large volume of important medicines that had been developed under IP protection and subsequently became available in generic form upon expiration of the relevant patents. The Delegation observed that although most medicines on the EML were not protected by patents, their availability in many markets was limited, which was particularly true in developing countries and LDCs. Therefore, the delegation was of the opinion that other factors, external to patent protection, were at play in limiting availability of those medicines. As such, instead of continuing to place blame on the patent system for contributing to the lack of access to medicines, in its view, the focus should shift to studying the more relevant factors hindering access in the appropriate fora. Therefore,

the Delegation stated that Group B could not support the adoption of document SCP/16/7 in its current form. Moreover, it considered that the SCP should focus on its core mandate and avoid duplication of work carried out in other committees.

106. The Delegation of Algeria, speaking on behalf of the DAG, pointed out that the proposal found in document SCP/16/7 substantively discussed the issue of patents and public health and showed a work program that would assist countries to adopt their patent laws and make full use of the patent flexibilities, in accordance with public health needs and in compliance with international obligations. In addition to the statement made by the Delegation of South Africa on behalf of the African Group, the Delegation referred to the role of WIPO in addressing patents and health. In its opinion, the proposal on patents and health was timely and an important step forward in initiating discussions on patents and public health within WIPO. The Delegation observed that WIPO's work on patent and public health followed the path of what had already been an engagement of the international community. The Delegation recalled that the WHO GSPOA adopted in 2008 stated: "International IP agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries. International IP agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries. However, developing countries may face obstacles in the use of these flexibilities". Thus, there was a need to address that problem and to remove that status faced by developing countries by making full use of the public health-related flexibilities. The Delegation indicated that the Agreement between WIPO and WTO and the Agreement between the United Nation and WIPO, as well as the TRIPS Agreement suggested that WIPO have the mandate and duty to analyze, reflect and provide guidance on issues pertaining to patents and public health. Indeed, the WIPO-WTO Agreement established the basis for WIPO to providing legal technical assistance and technical cooperation to WTO members and non-members of the TRIPS Agreement. Thus, the Delegation considered that WIPO's mandate on IP issues extended not only to issues that affected the rights holders, but also to flexibilities that formed part of the system including the use of such flexibilities in specific sectors. The Delegation also recalled that Article 8 of the TRIPS Agreement recognized that IP protection could have adverse impact. The Declaration on the TRIPS Agreement and Public Health had also expressed concern about IP protection and its effect on prices. The Delegation was of the opinion that while discussing patent protection as such, WIPO should also address the adverse impact of patent protection. In its view, such discussions were important not only to protect public health, but also to ensure that IP-related creativity was not hindered. Recommendation 14 of the WIPO Development Agenda stated that within the framework of the Agreement between WIPO and WTO, WIPO should make available advice to developing countries and LDCs on the implementation and operation of the right, obligation, understanding and use of flexibilities contained in the TRIPS Agreement. The Delegation reflected therefore on the achievability of the work plan contained in the proposal on patents and health. The Delegation observed that the comments submitted by members on the proposal compiled in document SCP/17/INF/3 witnessed the importance given to that issue and the desire of mainly developing countries to see that issue successfully addressed. The Delegation seized the opportunity to thank all Member States and observers which had made a contribution to that issue. Referring to document SCP/17/4 providing a description of WIPO-related activities on patents and public health, the delegation stated that the proposed work plan would not duplicate but complement the current WIPO activities and contribute to their effective implementation. At that moment, WIPO undertook a number of activities related to technical assistance on its own and with other international organizations. The Delegation explained that the proposed work plan would help to give direction to the work of WIPO on that issue. Regarding the first element contained in the proposal in document SCP/16/7, i.e., the elaboration of studies to be commissioned by the WIPO Secretariat to independent experts selected in consultation with the SCP members, the Delegation proposed that the studies included information on the use of compulsory licenses, the use of exhaustion to allow parallel trade in medicine and the assessment of the benefits of disclosure of International Non-Proprietary Names (INNs) in the abstract or title of patent applications. The Delegation further requested a cost-benefit analysis of the admissibility of Markush claims. As regards the second element, i.e., information exchange, the Delegation

observed that that element would contribute to exercise flexibility and show the difficulty faced by mainly developing countries. The Delegation noted that the Group could agree with the observed need to ensure that the experts were fully informed about the challenges and constraints faced in using the flexibilities. It further noted that the idea of the contribution of the civil society in providing experts and the exchange of information among Member States and leading experts in the field could also be considered. The activity proposed under the second element included inviting the UN Special Rapporteur on the Right to Health to present his report to the SCP and sharing of national experience in the SCP on the use of patent flexibilities for promoting public health objectives. The Delegation considered WIPO as an ideal forum for such discussion on national experiences as that would lead at the end to provide guidance to the design of technical assistance. Other activities suggested by the Delegation were to hold a technical workshop on state practice involving the licensing of medical technology, including the application of the TRIPS Agreement, and to develop databases on patent status in Member States of relevant diagnostic tools and medicines. Regarding the third element, the Delegation proposed to provide technical assistance to Member States, in particular, developed countries and LDCs. The Delegation explained that the third element was proposed so as to develop targeted technical assistance programs flowing from the outcome of the studies and information exchange.

107. The Delegation of Poland, speaking on behalf of the European Union and its 27 Member States, noted that document SCP/17/4 which provided the SCP with comprehensive and valuable information on the wide range of activities undertaken by WIPO in the area of patents and health, was essential for enabling the Committee to discuss and decide on possible future work on patents and health. The Delegation fully understood the concerns of developing countries and LDCs, as well as the challenges of constraints they faced in handling public health problems. The Delegation favored any initiative which might assist those countries to overcome the difficulties faced by their own policy choices. In that respect, the activities under the work program proposed by the African Group and some other members in document SCP/16/7 might help those countries adapt their patent regimes and make full use of their patent flexibilities. However, in its view, it should be carefully considered whether the SCP was the appropriate forum for those activities and whether the substantial work in the area of public health should be left to other WIPO Committees or other international organizations which had been already carrying out work in that area. Within the framework of the CDIP, a work program was ongoing on flexibilities in the IP system, which discussed patent-related flexibilities and the strategy for WIPO's technical assistance in the area of flexibilities. So far, two documents describing patent-related flexibilities in the multilateral legal framework and their legislative implementation at the national and regional level (documents CDIP/5/4 Rev. and CDIP/7/3) had been submitted to the CDIP. Those documents presented the implementation and use of flexibilities in national and regional laws and regulations, including flexibilities, relating to compulsory licenses, government use, exhaustion of rights, research exemption, regulatory review exemption, transitional period and the patentability of substances existing in nature among others. When comparing the two work programs, the Delegation was 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 other Delegations could be easily addressed and undertaken within the framework of the future work program on flexibilities of the CDIP so that the SCP could avoid unnecessary duplication of work. After having carefully examined document SCP/17/4, describing WIPO’s activities on patents and health, the Delegation had noticed that, among the activities undertaken so far by WIPO, some were already implemented, to a certain extent, in the second element of the proposed work program concerning information exchange. For example, by providing information on the patent status of medicines in WIPO Member States and by developing a web-based patent data retrieval environment, access was provided to patent information related to essential health technologies on a jurisdiction-by-jurisdiction basis. The Delegation stated that any further work in respect to the work program on patents and public health should be carefully examined, taking into account the work program on flexibilities and patent information carried out within the framework of the CDIP. In that respect, the Delegation was of the opinion that it would be desirable to

avoid the situation where WIPO Committees duplicated work done elsewhere, entailing additional financial obligations for their organization. Furthermore, it stressed the importance of close collaboration with other international organizations, in particular with WHO, WTO and UNCTAD.

108. The Delegation of Brazil stated that public health policies were a top priority in governmental programs of its country. It noted that universal access to health care was a right guaranteed by the Brazilian Constitution, and internationally, Brazil had supported initiatives and negotiating processes that upheld and promoted models of universal health care. The Delegation observed that providing access to essential medicines at affordable prices was a common goal of both developed and developing countries, and a necessary step to achieve the MDGs. The Delegation informed the Committee that Brazil had hosted in Rio de Janeiro the World Conference on Social Determinants of Health, co-sponsored by the WHO and the Brazilian Government, in October 2011, which had been the biggest international meeting on health ever held outside of Geneva. Representatives from over 120 countries had attended the meeting, of which 70 had been Ministers of Health. The Conference had been a landmark in the fight against inequality in health within societies and among countries. The "Rio Political Declaration on Social Determinants of Health", which had been adopted at that event, recognized that health was a shared responsibility and required the engagement of all sectors of government, of all segments of society and of all members of the international community. Among other initiatives, the Declaration pledged to "promote access to affordable, safe, efficacious and quality medicines, including through the full implementation of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property". As a UN Specialized Agency, the Delegation considered that WIPO had an important role to play in the field of public health. In its view, the relationship between the patent system and health offered a clear picture of the trade-off inherent to the IP system, showing the importance of finding a balance between the incentives required to foster innovation and the need to provide access to medicines at affordable prices to all. In other words, the system had to generate enough incentives for the industry to invest in new drugs, but at the same time those new drugs should not be so expensive as to prevent those from having access to them, who actually needed them. The Delegation considered that the work in that field could focus, among other topics, on corporative practices and patent strategies having consequences to access to medicines, such as evergreening, pay-for-delay agreements and patent thickets, among others. The Final Report of the European Commission Pharmaceutical Sector Inquiry published in 2009 provided a detailed description of such anti-competitive practices. One of the consequences was that, in certain cases, the entrance of generic drugs in the market had delayed. The Delegation expressed the opinion that a good example of the work that could be developed by WIPO in the area of public health was the recently announced WIPO Re:Search initiative, which sought to bolster the production of pharmaceuticals for diseases in developing countries for a concerted effort involving different stakeholders. The Delegation informed that the Oswaldo Cruz Foundation (Fiocruz) of Brazil would participate in the consortium, which was also supported by the Drugs for Neglected Diseases Initiative (DNDi). The Delegation stated that the joint proposal was of great importance to advance the work of the SCP in a balanced and structured manner. Noting that the proposal addressed, among other issues, how to make full use of the flexibilities embodied in international IP systems and especially in the TRIPS Agreement, in order to promote public health policies, the Delegation observed that the complexities and difficulties involved in the use of the flexibilities should not be underestimated. The Delegation reiterated its willingness to contribute constructively to the debates on patents and health in the year of the 10th Anniversary of the Doha Declaration as there was still much to be done.

109. The Delegation of Norway supported the statement made by the Delegation of the United States of America on behalf of Group B. With respect to the joint proposal by the African Group and the DAG, the Delegation provided some additional comments, fully supporting and respecting the freedom of every country, and particularly developing countries and LDCs, to choose an appropriate level of protection within the multilateral legal framework. The Delegation noted that the use of that freedom fully applied to the flexibilities in the patent system,

which should be assisted by the activities of WIPO and other international organizations. Therefore, the Delegation shared the concerns and intentions behind the proposal of the African Group and the DAG. The Delegation was of the opinion that, since it was essential to avoid duplication of work, it was necessary to closely examine to what extent the various elements of the joint proposal had already been taken care of by work conducted or under way in the SCP, or other fora within WIPO or other international organizations. The Delegation noted that, for example, document SCP/17/2 contained important collection of information with regard to patent studies mentioned in paragraph 8 (b) of the proposal, and that important work on patent flexibilities had been conducted in the CDIP. The Delegation also believed that the implementation of the GSPOA adopted in 2008 was of particular importance in that regard as it addressed the issue in a comprehensive manner with a very specific work plan. In addition, the Delegation noted that, as reflected in document SCP/17/4, WIPO was one of those organizations that collaborated with the WHO in delivering the various action points under the GSPOA.

110. The Delegation of South Africa commended the African Group and the DAG for the good work done on the joint proposal on patents and health, and fully supported that proposal. In its view, the implementation of that proposal would bring a significant contribution to the struggle for health issues in that region. The Delegation noted that, in order to address the health issues, the South African Government had introduced the Medicines and Related Substances Control Amendment Act, as means to facilitate, amongst other things, access to affordable medicines for all. The Delegation explained that the Act provided for parallel importation of medicines, although the domestic patent legislation only provided for national exhaustion of rights, and included the enabling provisions for parallel importation of medicines as stated in South Africa's response to the questionnaire on exceptions and limitations to patent rights.

111. The Delegation of the Republic of Korea reminded the Committee that it should focus on the framework of the patent system. Noting that, eventually, the patent system existed to enhance human welfare, the Delegation highlighted the converging contributions of the patent system. The Delegation noted that since tremendous investment was needed specifically in the pharmaceutical field, the patent system had the function of encouraging inventors to invent new life saving medicines. The Delegation, however, was of the view that the most important role of the patent system was to promote innovation and development of technology the result of which could be enjoyed by all human beings. The Delegation proposed that the Committee address the practical and tangible conditions under which flexibilities could function properly.

112. The Delegation of Argentina stated that the proposal by the African Group and the DAG, which aimed at assisting members of WIPO in adjusting and adapting their patent systems in order to be able to make use of the flexibilities which were available to them in the international patent system, was very interesting, well thought out, well structured, and was relevant to WIPO and the SCP. The Delegation observed that the work should take into account the interests of all members. In that regard, it expressed its gratitude for the observations and comments included in document SCP/17/INF/3, and referred to the comments submitted by the Representative of ALIFAR which had been posted on the SCP electronic forum.

113. The Delegation of Chile stated that understanding and discussing the link between the patent system and public health was extremely relevant, and that the discussion should take place in all international fora, where such a discussion was appropriate within the purview and the remit of the organizations concerned. The Delegation observed that the issue of access to medical products and to medicines was a multi-facetted issue. Those aspects had been discussed in various international fora. The Delegation, however, considered it difficult to understand that the aspects relating to patents and their link to public health had not been analyzed within the SCP. As had been previously pointed out, WIPO was working through the Global Challenges Division with other agencies and organizations within the UN system, such as WHO. Therefore, in its view, it was appropriate and fitting that, within the SCP, Member States should be given the opportunity to hold a discussion on those issues in a balanced way

and to make progress in understanding that issue. That meant, looking at the issue from a technical point of view, including issues such as the costs and the benefits stemming from the patent system related to access to medicines and medical products, the development of new medicines and the final analysis on the protection of public health. The Delegation acknowledged that the problem of access to medicines was one which was going beyond the patent system as such, and therefore, some aspects of the discussion were outside the remit of the SCP. The Delegation was of the opinion that the Committee should concentrate on not excluding itself from the discussion on those aspects, which fell within its competence. The Delegation observed that the proposal of the African Group and DAG included some very interesting aspects of the problem, for example, the carrying out of studies and the exchange of information. In its view, those elements could be a first step forward in exploring the link between patents and public health within the purview of the SCP.

114. The Delegation of Egypt noted that the case for an SCP work program on patents and public health had been eloquently made by the statements made by the Delegations of South Africa on behalf of the African Group and of Algeria on behalf of the DAG. The Delegation thanked WIPO Member States who had expressed their support and enthusiasm for that joint proposal, especially the Delegations of Costa Rica, Indonesia, Pakistan and Mexico, as well as organizations and civil society groups such as KEI and TWN, which had also made very useful and specific proposals to be addressed as part of the suggested work program. The Delegation highlighted recent developments at the international level which, in its view, clearly affirmed and emphasized the important dynamic relationship between the international patent system, public health, medicines and vaccines at affordable prices and transfer of medical technologies. The Delegation considered that if the Committee did not establish a correct relationship, there was a risk of losing precious human lives. It stated that WIPO could not afford that and should not deprive itself from taking the lead in that debate. The recently published UNAIDS report "Doha+10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from the past, opportunities for the future" stated that only 47 per cent of people eligible for treatment currently were receiving antiretroviral therapy, and thus the reiteration of commitments to achieve universal access in the June 2011 UN Political Declaration on HIV/AIDS would require the continued use and possible expansion of TRIPS flexibilities. Action would also be needed to tackle a range of emerging challenges. The UNAIDS report further stated that the sustainability of the generic production of HIV treatment and other new antiretroviral medications, in countries, such as India, which were major generic antiretroviral suppliers, also needed to be carefully monitored. Further, the Delegation noted that the UN High-level Meeting on Non-communicable Diseases had produced important outcomes and documents. In its opinion, those all affirmed that WIPO should coordinate efforts with WHO, UNAIDS and WTO, trying to make intellectual property part of the solution and not part of the problem for access to medicines. The recent WIPO study presented to the WHO negotiations on WHO Pandemic Influenza Preparedness had shown that patent rights existed in some elements of technologies and products which were needed in order to be able to effectively respond to global pandemics and provide medicines and vaccines to save human lives. In that regard, the Delegation observed that WIPO had played a role in the field of public health, and WIPO could indeed continue to do so. The Delegation observed that the document prepared by the Secretariat on WIPO activities on patents and public health affirmed several points. In its view, WIPO had a mandate to work with international organizations, NGOs, civil society, academia and the private sector to address global policy issues including public health. However, the Delegation noted with concern that the external review on WIPO's technical assistance had found out that there was little cooperation between WIPO and WHO, UNCTAD, UNAIDS and WTO and that no systemic efforts were being taken by WIPO to enhance the cooperation with those organizations, including technical assistance on IP and public health. The Delegation hoped that those findings were reversed in the coming period and the proposed work program for the SCP could assist in that regard. In its opinion, the document prepared by the Secretariat revealed that the proposed work program did not duplicate or overlaid with current WIPO's work on patents and public health, and the suggested elements for the work program could, indeed, complement and augment WIPO's activities. The Delegation was of the view that those activities transcended

the boundaries of the CDIP touching on patents and public health including seminars, conferences, technical and legal assistance, cooperation of WIPO and WHO, initiatives such as WIPO Re:Search. Further, the Delegation considered that the document prepared by the Secretariat revealed that there was a strong linkage between international patent systems and public health, including high quality of patents, sufficient disclosure of inventions in patent applications, implementing patent exceptions and limitations, improved infrastructure for accessing patent information and legal status information necessary for technology transfer, including information on who owned which health-related technology in which countries and for how long, as well as the capacity of patent examiners. The Delegation expressed the view that all those elements were captured by the proposed work program. Looking closely at the work program, the Delegation stated that several elements in document SCP/16/7 could be easily harvested, especially the framework study to examine the challenges and constraints faced by Member States in making full use of the public health related flexibilities and inviting the UN Special Rapporteur on the Right to Health to the 18th session of the SCP to address the multi-facetted aspects between IP and access to medicine. In its opinion, those simple measures would have no constraints or require resources and extensive activities. The Delegation called upon its partners to embrace the proposed work program in order that WIPO could take the lead on IP and health. The Delegation expressed its hope for the balanced focus on harnessing innovation for public policy objectives as well as on the WIPO Development Agenda recommendations that should be mainstreamed in all WIPO activities and programs.

115. The Delegation of China remarked that document SCP/17/4 provided a sound basis for moving forward to further promote work on patents and public health policies. The Delegation supported the joint proposal by the African Group and the DAG, and considered that it was feasible and practicable. The Delegation highlighted the importance of the studies that would examine the difficulties and challenges faced by developing countries LDCs in the use of patents for public health. The Delegation expressed the view that the suggestion for information exchange among Member States as being particularly useful and beneficial for developing countries and LDCs in order to tackle the public health problems faced. The Delegation believed that WIPO was the forum where the development of the patent system was discussed and an important platform for discussing and promoting international cooperation on patents. Therefore, in its opinion, further work had to be done in that area.

116. The Delegation of the Holy See pointed out that, despite enormous progress in the treatment of diseases, developing countries often remained excluded from the benefits of modern science. People in LDCs were facing shorter life expectation and economic decline. The Delegation noted that half of the world's population had been without access to life saving and other essential medicine in 1975. While the proportion had decreased to about one-third of the world's population, the absolute number remained to be two billion people according to the WHO. Expanding access to medicine for infectious disease, maternal and child health and communicable disease would save more than 10.5 million lives a year by 2015. The Delegation stated that access to medicine, recognized as a fundamental right in international customary law, as well as in treaty law, had emerged as a major public health issue, especially considering patents and the price of medicines. Article 25 of the Universal Declaration of Human Rights included the rights to medical care within the right to enjoy an adequate standard of living. Ten years before, the WTO Conference in Doha had adopted the Doha Declaration on TRIPS and Public Health as a response to public concern. That Declaration affirmed that the TRIPS Agreement should be interpreted by WTO members in a supportive manner in order to protect public health and, in particular, to promote access to medicines. Notwithstanding the political and legal success for developing country members to the WTO, the Delegation was of the view that the Doha Declaration had not addressed the significant obstacles that the TRIPS Agreement created to access to medicine. While the Delegation recognized that the Doha Declaration was a milestone, in its opinion, the extent of use of compulsory licenses had been limited. As indicated in the external review of WIPO’s technical assistance in the area of cooperation for development, the Delegation considered that there was a lack of sufficient information regarding the range of flexibilities. In its view, while the importance of flexibilities

was noted, practical and proactive advice on how to use such opportunities were limited. The Delegation expressed the opinion that experts of technical assistance often failed to distinguish compulsory licenses granted under part II of the TRIPS Agreement concerning patent rights and licenses and granted under part III for arrangement for infringement of those rights, notwithstanding all the efforts that had been undertaken for the implementation of the Development Agenda. The Delegation observed that, under the project ‚WIPO Re:Search, the international community had not yet succeeded to provide credible access to medicine and that indicated the need for further creative reflection on action in that regard. The Delegation therefore endorsed the proposed framework study by independent experts, which had been requested by the African Group and the DAG to examine the challenges faced by developing countries and LDCs and to make full and effective use of public health related flexibilities. The Delegation stated that the social mortgage on propriety affected also IP and knowledge, and that the law of profit alone could not be applied to what was essential for the fight against hunger, disease and poverty. In its view, whenever there was a conflict between property rights, on one side, and fundamental human rights of a common group, on the other side, property rights should be balanced by an appropriate authority. As Pope Benedict XVI had stated, the Delegation urged that treatment should be extended to every human being as an essential element of the search for the greatest possible human development with a strong belief that those perspectives were based on the dignity of the human person and on the fundamental rights and duties connected with human development.

117. The Delegation of the Russian Federation referred to the joint proposal of the African Group and the DAG and the proposed work program to be developed on the issue of patents and health. It noted that a number of difficulties and challenges had been encountered by developing countries concerning the issue of patents and public health. With reference to the issue of protecting public health, the Delegation was of the view that specific difficulties had been encountered with respect to access to appropriate medicines and drugs. Referring to the three components of the proposal, the Delegation expressed its belief that the work on the first two elements of the proposal had already begun, since a questionnaire on exceptions and limitations had already been prepared in relation to the issues within the proposed work program. The Delegation considered that comments from a number of member States and NGOs contained in document SCP/17/INF/3 were very useful for the better understanding of the problems that had been encountered. The Delegation noted a number of questions raised, particularly, the question of various methods for treatment and diagnosis being encompassed in the remit of that study. It observed that there were a number of restrictions or problems that had been encountered in ensuring appropriate technical decisions to be taken in the area of public health policy and ensuring that appropriate rights could be guaranteed in the area of public health. The Delegation explained that, in the Civil Code of the Russian Federation, there were provisions which ensured that conducting scientific studies for research and for certain products and methods related to a given invention, and experimentation carried out on certain methods for treatment or on certain drugs, did not constitute an infringement of patent rights. Where emergencies, such as natural disasters or other kinds of problems, arose, it may be necessary to use the patented product in a way it would otherwise not be permitted, in which case, the patent holder was given an appropriate compensation, as in compliance with the Paris Convention. The Delegation further noted that, in the Russian Federation, the legislation included provisions stating that it was possible to grant compulsory licenses in cases where there had be no or insufficient use of a given invention. However, the provisions within the Russian Civil Code established various conditions, which had to be applied to the use of certain inventions in the interest of national security, when that was required and when appropriate. Therefore, analyzing legislation and practices, for instance on exhaustion of rights, in certain circumstances and, in particular, on imported pharmaceuticals, it had to be noted that, in accordance with the relevant provisions of the TRIPS Agreement, members of the WTO had the right to regulate particular issues in accordance with national requirements when there was a need for particular medicines or drugs to be provided in their country. The Delegation explained that the Russian Federation had a system of parallel importation, making it possible to regulate those issues in a way that made medicines from national producers guaranteeing their rights

and medicines produced abroad available. In its view, that mechanism made it possible to expand access to needed medicines by ensuring the use of imported medicines legally. While the terms of exhaustion of rights varied in different countries, the Delegation considered that the Russian Federation had a regime that operated within the Eurasian context and made it beneficial to allow access to medicines. The Delegation noted that that mechanism had allowed its country to produce active ingredients in certain drugs and medicines, in accordance with the standards of the WHO. With respect to the proposed study relating to the INNs, the Delegation considered that a reference to INNs in patents or patent applications could make it easier to monitor patenting activities of corresponding medicines. The Delegation, however, observed that it took some time for a product that corresponded to the INN to be patented and to go through the whole procedure. In its view, a patent office might take a long time for checking the INNs, and consequently, the whole process for the granting of patents might took longer than otherwise. While the Delegation recognizing the importance of disclosing the corresponding INNs, it was of the opinion that the disclosure of such INNs should be a simple recommendation, rather than an absolute requirement. The Delegation stressed the importance of reducing the duration of the procedure. In the case of new biological substances, which, for instance, were described in a patent application, the Delegation observed that it could take a long time to check all of the requirements to obtain a market approval due to a very detailed analysis that had to be undertaken. Therefore, it was necessary to have the broadest possible protection for inventions as market authorization took a long time and was very costly. Hence, in its opinion, the access to patented medicines for the general public would be restricted, simply because of the expenses of the whole procedure. It was recognized in the Russian Federation that that could have an adverse effect on public health and its promotion. Therefore, the Delegation ensured that it did not restrict the possibility of access being made available to inventions in the area of chemistry and related areas, simply in order to prevent that that was happening. The authorities in the Russian Federation worked very closely together in seeking to ensure that access to chemical products and chemical inventions could be dealt within a different system. It ensured that inventions of new drugs enjoyed a broad patent protection on the basis of the Markush Claim. However, that meant to have an integrated approach to cover the whole picture. In its opinion, it was necessary to look at studies undertaken under the first element of the proposed work program. On the second element of the proposed work program, the Delegation considered it appropriate to reflect on having a database in that area, available to all Member States on diagnostic methods and on drugs available. However, in its view, the establishment of such a database would be very expensive and required a lot of resources and funding. On the third element of the proposed work program, the Delegation was of the opinion that a specific program for technical assistance would depend on the results of the first two elements. The Delegation urged the necessity of developing targeted programs, which could be developed under the auspices of the Secretariat and in agreement with Member States. The Delegation expressed its willingness to participate in that discussion on the exact scope of the study. In relation to document SCP/17/4, the Delegation emphasized the importance for its country of working with the WIPO Academy, in particular, a Summer School in St. Petersburg, which focused on contemporary issues relating to patent law, including patentability of medicines and medical technology. The Delegation considered that academics were playing an important role in the issue of public health and IPRs, and the Summer School provided an excellent opportunity for experts to get together and exchange information in the area of public health.

118. The Delegation of Switzerland noted that, according to its view, the proposal by the African Group and the DAG suggested that IP protection had an adverse impact on the availability of medicines, and thus health. With that underlying assumption, according to its understanding, the proposal implied that the protection of IPRs, and patents in particular, were an obstacle to access to medicines. The Delegation, however, stated that it did not share such view. In the opinion of the Delegation, the contrary was true and the patent system was a key incentive for pharmaceutical companies to invest in R&D of new medicines and vaccines. The delegation considered that, by granting patent holders the exclusive right to commercially market their inventions for a limited time, the patent system allowed the right holders to recoup investments made in the development of the drug by making a profit which could be reinvested

into further innovation, thereby creating incentives for research and development (R&D), which was particularly costly in the field of pharmaceuticals. The Delegation was convinced that IPRs played a key role in innovation for public health and in long term access to new and more effective medicines. It stated that, essentially, everyone was affected by health concerns and everyone wanted to have access to the best possible medicines, and therefore, in the Delegation's view, the positions among Member States were not that different. The Delegation observed that while the patent system was essentially to stimulate R&D of new and more effective medicines in the long term, it was by its very nature a monopolistic instrument in the short run. In its opinion, the proposal by the African Group and DAG placed more emphasis on the short run. While regretting the problems, the Delegation preferred looking at the issues more from a systemic and long term perspective. The Delegation considered that a patent system was put into questions in the short run, for instance, by using the existing flexibilities systematically, a fundamental incentive system in the long term would be destroyed, which might lead to a shortage in R&D for more effective and new drugs that were needed to battle future health challenges. Since the issue of patents and health was an ongoing topic of discussions in other forums, in particular the WHO, the Delegation expressed its concern about duplicating efforts in the SCP. The Delegation also expressed its uneasiness with the underlying assumptions in the proposal, since an economically viable market combined with the incentive of patent protection provided a steady flow of innovation. Concerning the issue of neglected diseases, in its view, insufficient market incentives were the decisive factor, why low innovation concerning insufficient access to relevant medicines occurred. The Delegation therefore stated that weakening, or even lifting, patent protection by extending the flexibilities would not remedy such insufficient situation, but rather aggravate it. The Delegation further observed that continuing innovation was also needed to face current and future health challenges and diseases. In its view, patents were part of the solution to the access problem. The Delegation, therefore, felt that the underlying assumptions in the present proposal were misleading and, in its view, incorrect. The Delegation noted that patents did not entitle to charge automatically a certain price, as in many countries, prices for certain pharmaceuticals which were still under patent protection were administered and, for example, included in a public health reimbursement scheme. The Delegation explained that important market conditions further contributed to the availability or lack of access to medicine, such as government procurement conditions, customs tariffs, supply chains and efficiency of producers. Due to its long tern perspective, the Delegation expressed its disagreement with the view expressed in the proposal, implying that compulsory licenses would increase access to medicine. The Delegation believed that acute health problems could not be best solved by attacking the fundamentals of the long term incentive system which attracted enough investment into R&D in coming up with medicines against new diseases. While compulsory licenses were one of the tools at hand to counter a possible shortage of medicine, in its opinion, it ought to be the exception, otherwise the entire incentive system would be undermined. Whilst, in principle, the decision to grant a compulsory license was a legitimate and legal response to a series of health threats, the Delegation was convinced that voluntary licenses provided the best means to grant expeditious access to important medicines through increasing production capacity and output. The Delegation further explained that another advantage of voluntary licenses was that the new manufacturer could rely upon the assistance of the original manufacturer, who could guarantee, through its transfer of know-how, high quality and safe products. In its opinion, a systematic use of TRIPS flexibilities, such as resorting to compulsory licenses, would undermine the international IP system and thus erode the economic incentive for the private sector to invest into R&D for the development of new and more effective medicine. If no innovative medicines were being researched and developed, there was nothing on which a compulsory license could be granted in a serious public health situation or that could be copied by generics manufacturer after the expiration of patent protection. Therefore, the Delegation was of the view that in the long term, the overall access to medicine would be diminished and thus it would be detrimental to a country's ability to respect the right to health. For that reason, the Delegation did not see that the Committee could launch work on the issue of patents and health based on the proposal in document SCP/16/7. Moreover, the Delegation considered the CDIP to be the more appropriate WIPO forum to deal with that issue. In it opinion, studies could be launched in the

CDIP and the Committee could discuss further, if additional steps were needed. The Delegation stated that, if work should be launched in WIPO concerning patents and health, the long term perspective, which was essential to have a broader and balanced picture of the situation, should be taken into account.

119. The Delegation of Japan supported the statement made by the Delegation of the United States of America on behalf of Group B. The Delegation observed that the proposal made by the African Group and the DAG did not refer to the aspect where the patent system contributed to the enhancement of health. Thus, in its view, such a proposal was lacking an appropriate balance. While admitting the necessity and importance of approaching health issues, the Delegation noted that, in general, studies on compulsory licenses or exhaustion of rights had been already conducted under the agenda item of exceptions and limitations to patent rights. Furthermore, referring to document SCP/17/4, the Delegation was of the view that many technical assistance activities had been already carried out by WIPO. In addition, noting that other international organizations, such as WTO and WHO, not only had taken up the issues, but had been collaborating with WIPO, the Delegation expressed its concern about duplication of work. The Delegation considered that patent rights had not been the main cause of global health problems and were not hindering appropriate access to medicine. Rather, in its view, delay in building environmental hygiene, insufficient quality management of medicine and improper management of systems, which were factors outside the patent system, had also a great impact on the health issue. Considering that those other factors, rather than the patent system, currently had greater impact on global health issues, and that the international development aspects were significantly related to public health, the Delegation invited the Committee to reflect upon the appropriate forum for discussing those issues. Since there were many diseases for which no effective treatment existed, the need for new medicines was great, whether in developing countries or developed countries. The Delegation noted that since developing a new medicine was complicated and hard work, requiring a large amount of time and cost, giving a certain incentive to inventors was a reasonable measure to obtain an effective medicine which had not existed yet. In that regard, the Delegation stated that the patent system itself could serve as such measure.

120. The Delegation of Spain supported the statement made by the Delegation of Poland, speaking on behalf of the European Union and its 27 Member States. Referring to its comments that had been submitted, the Delegation stated that, regarding the study on compulsory licenses, the SCP had to avoid duplication of efforts with the work that had already been carried out on exceptions and limitations in the SCP on the basis of the Brazilian proposal. The Delegation noted that, for example, the questionnaire had already included questions on that issue. Furthermore, the Delegation expressed its concern about the possible risk of duplication with the work carried out by the CDIP, particularly, those activities described in documents CDIP/5/4 and CDIP/7/3. Moreover, the Delegation pointed out that, at the last session of the CDIP, the future work program on flexibilities in the IP system had been presented, which included: (i) technical assistance provided at the request of Member States; (ii) the holding of various seminars on those issues; and (iii) a database precisely dedicated to those flexibilities, and articles on the WIPO web page on experiences with flexibilities. In its view, it should be avoided to have duplication with that work program. The Delegation then turned to the evaluation of the benefits of compulsory disclosure of INNs in the abstract or in the title of patents. The Delegation pointed out that such disclosure was impossible for those applications covering new products, since, by definition, the INN of such new product could not be known in the WHO and one would not have been able to include that generic name, which was subsequently established years later when the administration of marketing the pharmaceutical was granted. The Delegation considered that if those INNs could be included in the databases later, it would be useful to identify the generic medical product which was the subject of a given patent. The Delegation expressed its satisfaction for the substantive patent law aspects of the proposal. The Delegation supported a study on the various types of claims which used formula similar to the Markush claim. The Delegation observed that such a practice had already posed difficulties for patent offices, such as classifying a patent application in

accordance with the International Patent Classification (IPC) due to a large number of examples included in the claim and searching prior art in order to determine the novelty and inventive step. While patent offices had made attempts to deal with those difficulties by the concept of unity of invention, the Delegation noted that in order not to slow down or restrict research in the pharmaceutical area, and in particular, due to its particularities, those patent applications had been accepted, and generated great complications and difficulties. The Delegation observed that the specific nature of pharmaceutical innovation was one of the reasons why that situation had occurred, i.e., often a very long time period passed between the start of the research and the marketing of the final product – sometimes it took about 12 years or more – and the principle of the first-to-file under the patent system. In its view, given that situation, innovative pharmaceutical companies had to take a decision as to when patent protection should be applied. If those companies did not apply for patents relatively quickly, they faced the risk that third parties would file before them. However, in such an early phase, they were confronted with a great uncertainty of future products that could be placed on the market. Furthermore, in its view, that was an issue that innovative companies also suffered from when they carried out prior art search, and patent holders could get discouraged where third parties filed patent applications, for example, on certain substances which were included within the generic claim. In addition, the Delegation considered that there were also problems of enforcing patent rights in courts, where others could claim that certain details of a product had already been disclosed in thousands of different technical literatures or where a patent holder must demonstrate adequacy of the description. The Delegation therefore suggested that the Secretariat, together with the Member States, carry out an impartial and objective study on the practices of each member States with respect to such claims. In its view, such activity would improve the way such claims in patent applications were handled by patent offices.

121. The Delegation of Zimbabwe aligned itself with the statements made by the Delegations of South Africa on behalf of the African Group and Algeria on behalf of the DAG. The Delegation noted that various delegations, especially from developed countries, had consistently reminded the Committee that WIPO should only address issues to which it added value and where it had expertise. In the Delegation's view, it was practically impossible to discuss medicines or health issues without discussing the issue of patents. In its view, for a long time, there had been distortions over the issue, either deliberately or unintentionally. While the Delegation did not question the rights of patent holders, it considered that there was a need to balance those rights with the public interest, such as global public health. The public interest in the context of patents and public health was more centered on the issue of access and affordability of medicines to the developing countries' population. That raised the question as to how to get medicines under patent protection or how could innovation be achieved other than through patents. The Delegation stated that, in an attempt to provide answers to those questions, the African Group and the DAG submitted a joint proposal. It observed that WIPO, as the leading organization dealing with IP, was heavily involved in the deliberations and adoption of the WHO GSPOA in 2008. According to the Delegation, the GSPOA was a product of interagency cooperation amongst the different UN specialized agencies and other entities which also provided clarity on the role to be played by each entity within their respective mandates and area of competence. Therefore, the Delegation was of the view that the Committee should embrace the relevant provisions of the GSPOA to enhance its work on patents and health. In its opinion, the work program proposed by the African Group and the DAG should be considered as the first step forward. The Delegation acknowledged the need to avoid unnecessary duplication with work done in other committees and other fora. In its view, the fact that the SCP was called the "Standing Committee on the Law of Patents" should give the Committee its confidence to discuss the subject of "patents and health", and the Committee should deal with the issue of the interface between patents and health. According to the GSPOA, WIPO played a role with reference to the following elements: (i) prioritizing R&D needs; (ii) promoting research in development; (iii) building and improving innovative capacity; (iv) transfer of technology; and (v) application and management of IP to contribute to innovation and promote public health. The strategy clearly indicated that WIPO would collaborate with other UN specialized agencies and international organizations in advancing those issues. As

such, the Delegation did not see where any duplication would take place. The WHO through the GSPOA had no mandate to direct WIPO. Directing was the precept of WIPO Member States through the SCP. Otherwise, in its opinion, the GSPOA would remain beautifully delegated to the archives. The Delegations expressed its wish to receive information from WIPO about its clear work plan that implemented the GSPOA, for instance, by implementing the following action areas: (i) improving innovative capacity in accordance with the needs of developing countries; (ii) developing successful health innovation models in developing innovative capacity; (iii) incentive schemes for health related innovation; (iv) award schemes for health innovation; and (v) transfer of technology and the production of health products in developing countries amongst others. The Delegation fully agreed with the Delegation of Egypt that Member States needed to give WIPO a mandate to follow up and implement outcomes emanating from other UN bodies. The Delegation also stressed the importance of understanding how WIPO had linked such outcomes within the context of existing programs, including the WIPO Development Agenda. The Delegation concluded by thanking the Delegation of the United States of America that drew the attention of the SCP to the availability of patents for essential drugs under the Medicines Patent Pool, most of which still had to be proven. However, the Delegation reminded that patented medicines were not easily available for the latest generation of medicines. For example, everyone knew that many viruses, including malaria and tuberculosis, had tended to adapt to and resist the cure by drugs. By the development of a newer generation of drugs, it would be misleading to state that all essential drugs for such diseases were available in the public domain. The Delegation encouraged viewing that issue in a holistic manner within the context of the supply chain and distribution of medicines, which essentially included R&D.

122. The Delegation of the United States of America supported the intervention made by the Delegations of Switzerland and Japan, particularly with respect to the positive effects of the patent system on medicines and on obtaining medicines. It affirmed that, as reflected in the 2001 Doha Declaration, the United States of America had strongly respected the countries' rights to protect public health and, in particular, to promote the availability of medicines for its people. The proposal on patents and health was an important and timely topic. However, the Delegation affirmed the importance of IP rights in promoting public health, and it did not believe that the use of flexibilities allowed under the TRIPS Agreement was sufficient to promote public health. With respect to the specific elements of the proposal, the Delegation thanked the Delegation of South Africa for their paper in document SCP/16/7 and welcomed a discussion on the relationship between patents and public health, as part of the wide ranging investigation into the facts that influenced the availability of safe, efficient and effective medicines. The Delegation insisted that the discussion needed to be balanced and had to address both the positive and the negative effects, that practicing of flexibilities had on public health, including on the development of new medicines, the distribution of medicines, and on the transfer of health care technology to developing countries. In its opinion, the proposed studies had also to include the other factors, which were not related to patents but which impacted on the availability of medicines, such as the lack of infrastructure and expertise. The Delegation was of the opinion that the effectiveness of those non-patent factors had to be evaluated and quantified, in order to evaluate the potential impact of patents, if any, on the availability of medicines. The Delegation considered that a more productive approach could be to look at best practices and practical solutions to overcome all barriers and that could lead to a better availability of medicines. Regarding the second element of the proposal, the information exchange, the Delegation supported having experience sharing sessions, as long as they were open to all and were balanced. In its view, the discussion should address patent rights as incentives to R&D and to technology transfer, and how non-patent related issues affected public health and the availability of medicines, which should be carried out within existing budgetary constraints. In addition, the Delegation stated that the experience sharing sessions should be open to representatives from the pharmaceutical industry who could discuss the multiple various initiatives they were undertaking to promote the availability of medicines. Furthermore, in its opinion, the discussions should also consider non-patent issues that affected the availability of medicines and might focus on the impact of the efficient infrastructure, the impact of trade

barriers, such as discriminatory and non-transparent regulatory regimes, on the problems regarding the availability of medicines, the impact of falsified and substandard medicines in public health and, in particular, on the availability of genuine life saving medicine. The Delegation supported in principle the proposed database on the status of patent. However, patents had a limited effect on the availability of medicines. Therefore, in its opinion, the utility of such database might be limited, as far as improving access to health care. In addition, the Delegation noted that it was difficult to generate a database that addressed every possible step of a change of status of a patent, for example, due to litigation, licensing and other factors. The Delegation was concerned about the high cost to the Member States and/or to WIPO of generating and maintaining such a database. With respect to having a presentation by the UN Special Rapporteur on the Right to Health, the Delegation was reluctant to include that presentation in the SCP program because the Rapporteur was not a patent expert. However, if the presentation were to take place, the Delegation insisted that it should be balanced and should include the beneficial effects of patents on the development of new medicines and on the availability of medicines. Regarding the third element of the proposal, technical assistance, the Delegation could not support the third element of the present proposal, since the SCP was not mandated to carry out that type of technical assistance. The Delegation did not support expanding the work program of the SCP outside its mandate and, in particular, to encroach or duplicate the work already taking place in the WTO and the WHO. In its view, the present proposed program was not within WIPO's mandate as it asked the SCP to provide its opinion on the legality of specific flexibilities, and that function was within the purview of the WTO. The Delegation considered that WIPO's technical assistance was demand driven, and that a one-size-fits-all approach of full flexibilities was not appropriate. It was of the opinion that flexibilities were only effective when carefully tailored to a situation existing in a specific country. The Delegation reiterated that that issue should be discussed as part of a wide ranging investigation into factors that influenced the availability of safe and effective medicines. In that spirit, the Delegation expressed its willingness to contribute to that discussion by submitting a proposal, and introduced some of the aspects of its proposal. The Delegation observed that some of the public health issues faced in developing countries and LDCs included neglected diseases, the spread of tuberculosis, malaria, HIV/AIDS and the availability of medicines to treat those and other ailments. However, in its view, none of those issues could be solved by patent rights flexibilities alone, and, in particular, could not be solved by the wholesale use of compulsory licensing. To the contrary, the lack of effective patent protection was one factor which prevented the appropriate medicines from reaching the neediest patients in developing countries and LDCs. The Delegation emphasized 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 lead manufacturers to keep already developed medicines out of those markets. Furthermore, the Delegation considered that, in addition to the detailed disclosure which was found, for example, in a patent, know-how and specialized skills were often required for successful deployment of technology, such as manufacturing of medicines. In its opinion, since using compulsory licenses or non-voluntary mechanisms would not gain cooperation of the patent owner, the recipient of the compulsory license might not easily be able to successfully manufacture the medicine. The Delegation therefore concluded that weakened patent protection for innovative medicines was not a productive approach for health care, because many factors other than patents affected more directly the availability of medicines. The Delegation observed that, although approximately 96 per cent of medicines on WHO's List of Essential Medicines were not protected by patents, their availability in many markets was limited, particularly in developing countries and LDCs. Therefore, in its opinion, other factors external to patent protection were at play in limiting the availability of those medicines. The Delegation stressed the importance of a complete assessment of the topic of patents and health by also considering those other factors affecting the availability of medicines which were outside of the patent system. In its view, such assessment was a necessary step which would help to properly quantify the impact of patents, if any, on the availability of medicines. The Delegation considered that, by studying the availability and reasons for the lack of availability of unpatented medicines, it was possible to estimate the potential effect, if any, of the patent system on the availability of medicines and to determine what factors, which were not

related to patents, impeded that availability. Instead of exploiting patent flexibilities that undermined incentives, i.e., the incentive to innovate, the Delegation enumerated the following examples which illustrated some programs that were more effective in promoting the development of medicines and their dissemination in developing countries and LDCs: patent pools, such as the Medicines Patent Pool, tiered pricing, novel voluntary licensing and funding schemes, such as, for example, the research consortium at WIPO, namely "WIPO Re:Search", Global Funding, advanced market commitments and various other programs. The Delegation supported efforts to curb trading of falsified and other substandard medicines. Those medicines were not approved under a regulatory system as being safe and effective and were dangerous in treating patients' diseases and might, in fact, make patients sicker. The proliferation of falsified and other substandard medicines interfered with the distribution of genuine medicines, both patented and generic, because the patients were very often fooled into taking the fake medicine. The proposed work program should, therefore, address to what extent the presence in the market of falsified medicines hindered the availability of genuine medicines, both generic and patented. To contribute to that important discussion, the Delegation proposed the following elements of a work program for consideration by the Member States of the SCP: (i) Inviting the WHO to make a presentation to the SCP on the availability of generic medicines in developing countries and LDCs, on the non-patent barriers to the availability of safe and effective medicines and on the effect of falsified medicines on the availability of proper medicines, both generic and patented. That presentation would help to put in context the potential effects of patents as compared to the effects of other factors on the availability of medicines; (ii) Conducting a comprehensive study on the positive impact of patent systems in providing life saving medicines to developing countries and LDCs. That study would evaluate the role of patent protection in providing incentives for R&D leading to innovative medicines and in fostering the technology transfer necessary to make generic and patented medicines available in those countries; and (iii) Conducting a comprehensive study to examine the availability of life saving medicines that were not protected by patents and the reasons for the lack of availability of such medicines. Determining which factors that were unrelated to patents affected the manufacture and availability of medicines would help to distill the effect, if any, of patents on the availability of medicines. An important element to be reviewed in that study was the effect of falsified medicines which circumvented any regulatory and enforcement regime that had been set up to ensure the safety of those medicines. The Delegation observed that the availability of safe and effective medicines was a multi-facetted problem which impinged on many areas of law, national policy, physical infrastructure, social, educational and economic factors, to name only a few. In its view, informed analysis, on how the patent system might or might not affect the availability of medicines, was only possible with an understanding of those additional factors that affected the problem. The Delegation clarified that the SCP would not be expected to take action on those non-patent issues, which were not within its mandate. However, in its opinion, the Committee would benefit from understanding where its action fit within the broader range of factors influencing access to medicines.

123. The Delegation of India supported the proposal submitted by the Delegation of South Africa. The Delegation noted some serious considerations given at WIPO platforms to resolve that important issue. In the CDIP, the Delegation had also supported the proposal which had been elaborated in document SCP/16/9. The Delegation stated its appreciation of WIPO's important work done in the area of health. The Delegation suggested further strengthening that area within WIPO's activities. The Delegation hoped that future work in the area of IP and health in WIPO would contribute to increase the quality of such work. The Delegation reiterated that patents should be used to hedge those issues in LDCs. It noted that, along with like-minded countries, India was one of the main contributors for the Doha Declaration. The Indian Patent Law had been amended in 2005, linking many provisions to public health. The Delegation explained that one of the major objectives was, as stated in Section 8 of that Act, that the patents, which were granted in India, did not to impede the public health and that those were granted to make available medicines at affordable prices and did not curtail the development of patented products. Section 3(d) of that Act allowed stopping the "evergreening" of patents, i.e., patents in histories, rather than new medical treatments with new properties or

new uses of a known substance. The Delegation noted that the granted patents were subject to some restrictions, and that an analysis was needed even if the patent was valid. Furthermore, it explained that exclusive licenses could be given to manufacturers in India which preferred to export the licensed medicine to certain countries in accordance with Section 92(a). The Delegation expressed its hope that the proposal submitted by the Delegation of South Africa would find its way through.

124. The Secretariat provided an update of the key activities carried out either by WIPO or in collaboration with the WHO, the WTO and other partners, particularly, by the Global Challenges Division. Regarding the WHO-WIPO-WTO trilateral collaboration, it noted that, over time, the joint participation of those three organizations in a number of activities had led to organize a series of seminars, conferences and symposia. That working relationship was supported by the WIPO Development Agenda recommendation 40, i.e., "to intensity its cooperation on IP related issues with UN agencies", and had matured into an informal but practical trilateral corporation. Among the highlights were a workshop on patent searches and freedom to operate, which took place in February 2011, and had introduced participants to the basic concepts of how patent searches and freedom to operate worked together. It had led to a number of inquiries from participants and others to WIPO about further information in that area. A joint technical symposium had been organized, also with WHO and WTO, and had addressed a growing importance of patent information for public health with respect to freedom to operate strategies, procurement of medicines, technology transfer and setting research priorities and strategies. In that context, enhanced trilateral cooperation of WIPO, WHO and WTO had been increasingly engaged in providing inputs into their respective activities. As an illustration, the WIPO-WTO Colloquium for Teachers of Intellectual Property which took place in June and July 2011 or the WTO Workshop on Intellectual Property and Public Health, organized and engineered by the WTO Secretariat, in collaboration with WHO and WIPO from October 10 to 13, 2011. Also, WHO, WIPO and WTO were consulted by the Global Health Programme of the Graduate Institute of International and Development Studies for the organization of the Fifth High Level Symposium on Global Health Diplomacy, "Ten Years After the Doha Declaration: the Future Agenda at the Interface between Public Health, Innovation and Trade - an Outlook on the Next Ten Years". That event had taken place on November 23, 2011 at the WTO. The meeting had been held by the Graduate Institute under the auspices of Madame Ruth Dreifuss, former Chairperson of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), and with the participation of the three Directors Generals of WHO, WTO and WIPO and other prominent speakers from governments, academia, the private sector, international organizations and non-governmental organizations. Furthermore, the most work-intensive collaboration between the three agencies was the Trilateral Study on Promoting Access and Medical Innovation: Intersections between Public Health, Intellectual Property and Trade by the three Secretariats, which was building on the expertise of the three agencies. The full study was to be expected to be finalized in early 2012, and an outline was available and had been distributed at the Doha +10 Conference. Another program consisted of the Access to Research for Development and Innovation (ARDI) program. As of October 13, 2011, ARDI had become a full member of the "Research for Life". Research for Life was a Public-Private Partnership (PPP) between WIPO, WHO, the Food and Agriculture Organizational (FAO), the United Nations Environmental Programme (UNEP), the International Association of Scientific, Technical & Medical Publishers (STM), Cornell University, Yale University and several technical partners, including Microsoft. The goal of that partnership was to enable free or low cost access in developing countries or LDCs to research, data and publications, with ARDI providing a particular focus on applied sciences and technology. The third area consists of what was considered the flagship project of WIPO, "WIPO Re:Search". On October 26, 2011, WIPO launched WIPO Re:Search, sharing innovation in the fight against neglected tropical diseases, malaria and tuberculosis. Through WIPO Re:Search, a range of public and private sector institutions came together to make available very valuable IP assets to a very broad and wide research community across the world, and developing countries alike, in order to enhance existing research into neglected tropical diseases, such as malaria and tuberculosis, and in order to encourage new research to take off. The WHO was supporting that initiative by

providing technical advice to WIPO. It was a direct response of WIPO to the CDIP and the WIPO Development Agenda, which also constituted one of the rationales for that project. WIPO Re:Search was founded on the belief that IP, knowledge and materials could be used creatively to stimulate more investments and to enhance existing investments in the development of health solutions primarily for developing countries. The mechanism worked entirely on a voluntary basis of all participating parties and provided users with new tools, new information, new data and new licenses that they would not otherwise easily be able to obtain. As such, WIPO Re:Search had no impact on the legal instrument or the legal establishment of the patent regime but rather provided a very creative way to leverage valuable IP in new ways that had not been done before. It allowed public and private sectors alike, across the world, to share and use compounds, compound libraries in the case of those libraries containing millions of compounds, unpublished scientific results, regulatory dossiers and data, screening technologies, platform technologies, know-how licenses, and also patent licenses. And those were provided to qualified researchers and research institutions anywhere in the world royalty-free for the research, development and manufacture of drugs, vaccines or diagnostics for neglected tropical diseases, malaria or tuberculosis, and the willingness to sell those products in LDCs royalty-free and the willingness to negotiate access for all other developing countries under agreed terms. More information could be found at http://www.wipo.int/research/en/. WIPO was also exploring, in partnership with its sister organizations, a collaborative and web-based data retrieval environment that allowed transparent access to the patent status of a range of medicines in selected developing countries where such data was available. It was aimed at improving access to pertinent patent data and patent information of existing products that were already on the market. As such, that initiative complimented WIPO Re:Search. WIPO Re:Search was, on one end, the encouragement of research into new products in order to make products available, and, at the other end, the new initiative would encourage a better understanding of the patent situation of existing medicines in order to facilitate accessing those medicines.

125. The Representative of the WHO gave an update of the activities of his organization in relation to global health and IP. Lack of access to medical products remained one of the most serious global health problems. Despite the achievements in past decades, nearly 30,000 children were dying every day from diseases that could easily be prevented if those children had access to a basic range of essential medicines. However, in 27 developing countries for which precise data had been obtained, the average availability of essential medicines in the public sector was only about 34 or 35 per cent. In the past, governments, philanthropic organizations, pharmaceutical companies, NGOs as well as WIPO had undertaken many initiatives and had increased their efforts to address lack of access to medicines. But more were needed to be done. There were a number of key determinants for access to medicines, namely the rational selection and use of medicines, sustainable financing, reliable health and supply systems and affordability of medicines. IP rights were but one of the determinants for affordability of medicines to the extent that they were protected by IP. WHO's activities in the area of public health and IP focused on technical cooperation which included transfer of technology, capacity building and training and also direct technical assistance to Member States. The overall objective of those activities was to support the application and management of IP in a manner that maximized health-related innovation, especially to meet the needs of developing countries and promote access to those medicines for all. As had already been pointed out by the Secretariat and highlighted by a number of delegations, the GSPOA, on the initiative of the WHO, the three organizations, WHO, WIPO and WTO, had strengthened their efforts to effectively coordinate work in the field of public health and IP to make better use of available resources and to enable a more effective program delivery in the field of all three organizations. Within the scope of that trilateral cooperation, the three organizations had started a number of joint activities, which included a series of joint technical symposia to enhance the dialogue between the organizations and to provide a platform for exchanging information and experiences that had been highlighted by the Secretariat. Currently, the three organizations were preparing a joint Study on Promoting Access and Medical Innovation: Intersections between Public Health, IP and Trade. That study was a follow up to an earlier study published in 2002 that had been done by the WHO and WTO Secretariats, which had covered all

WTO agreements and public health. The ongoing study would cover the whole range of issues at the intersection of access to medicines and IP, which would include issues around procurement, regulatory requirements, the impact of tariffs, markups, voluntary license agreements and tiered pricing. The study was expected to be available for the 18th session of the SCP. Together with the United Nations Development Program (UNDP) and UNAIDS, WHO had published a policy brief on the flexibilities in the TRIPS Agreement to provide access to HIV/AIDS treatment. That paper had reviewed how countries could use and have used the flexibility of the TRIPS Agreement to increase HIV/AIDS treatment. In order to provide Ministries of Health in the Eastern Mediterranean region with analysis of public health implications of IP provisions, including those in Free Trade Agreements (FTAs), the WHO Regional Office for the Eastern Mediterranean region had published a Policy Guide on Public Health Related TRIPS-Plus provisions in Bilateral Trade Agreements, which was available on the WHO web site. Following the negotiations on the Pandemic Influenza Framework, WIPO and WHO were currently developing a global patent landscape on patenting trends in the field of vaccines, which would provide an overview of what was being patented in terms such disease, targets and approaches, who was doing the patenting, where patents were filed and how patent policies changed over time. That was a very good example for an activity that could neither been carried out by WHO nor by WIPO on its own, because the patent and the public health expertise was necessary, in order to map all the patent activity in the field of vaccines. The patent landscape report was expected to be published soon on the WIPO web site. The Representative pointed out that WHO had also some concrete activities in the field of transfer of technology. It facilitated transfer of influenza vaccine production technology to eleven developing country vaccine manufacturers in order to provide those manufacturers with life attenuated vaccine technology, which was a specific vaccine production technology. WHO had negotiated and acquired a non-exclusive license to that technology and the right to sublicense that technology which had been granted to three developing country vaccine manufacturers to enable them to start production using that technology. In vaccine production, the use of less antigen per dose of vaccine enabled an increase in the umber of doses to be produced and to overcome know-how barriers. WHO had facilitated the technology transfer hub of the University of Lausanne, and it was using information in the patent adjutant to develop technologies where the patents were filed or granted, and using the information disclosed in the patents to develop technologies, where the patents were neither filed nor granted. And that technology had so far been transferred to one developing country, and WHO was currently working on the transfer to another developing country. As part of the trilateral collaboration with WTO and WIPO in capacity training building activities, for the first time ever, WHO had taught a module on public health and IP in the framework of the Master's degree on IP in the Africa University in Zimbabwe. That showed how effective collaboration could be because that program allowed a two-day or three-day teaching on public health and IP by one expert in an already existing environment instead of setting up parallel structures that would involve investing a lot of resources. The program was joining forces with WIPO and the African University bringing the experts from the relevant organizations together. WHO had also provided substantial support to the organization of the WHO-WTO Workshop on Public health that took place in Geneva in 2011. That workshop had addressed the respective TRIPS Agreement provisions and flexibilities that were of relevance to public health, as well as, issues ranging from procurement to regulatory questions and prizes of immediate prices of medicines that were usually covered by experts joining from the WHO Secretariat. Together with its regional office in Copenhagen, it collaborated with WIPO in the organization of a regional workshop for Central Eastern European and Central Asian countries on IP that took place in Vienna earlier in 2011. WHO also continued to provide, upon request and in collaboration with other relevant international organizations, technical and policy support to Member States to favor the application and management of IP in a manner that maximized health related information and provided access to medicines for all. With regard to further details of the activities carried out by WHO, the Representative invited delegations to visit the WHO web site or to take note of the WHO report on the technical and financial cooperation activities that had been submitted to the WTO TRIPS Council in October 2011 (document IP/C/W/559/Add.1).

126. The Representative of the WTO expressed its appreciation for an excellent opportunity to briefly present WTO's activities in that field. In the situation ten years after the Doha Declaration, numerous events had been happening to harvest the experience gained in improving access and promoting medical innovation in the context of the Doha Declaration. Those events, in particular, had confirmed the wide-spread agreement that the situation had evolved in a significantly positive way since 2001, among others: (i) because the Doha Declaration had reached greater clarity and certainty about the link of relative TRIPS provisions with public health, which implied, in particular, about the link the verification of patent-related flexibilities; (ii) because the Doha Declaration had shaped the framework for multilateral cooperation on IP and public health, which had led to increased policy coherence, collaboration and dialogue at all levels; and (iii) because it had supported countries in the implementation and use of TRIPS flexibilities as necessary. As the Director General of WTO had mentioned at the High Level Symposium organized by the Graduate Institute of International and Development Studies in Geneva, one had moved from the question of compatibility between IP protection and public health objectives to the question of consistency between the two at all levels: (i) The current debate in the SCP was supported by much greater awareness. Nowadays, there was a much better understanding of the TRIPS provisions and their built-in flexibilities, but also recognition that those needed to be part of a wide action required at national and international level, as already expressed in the Doha Declaration; (ii) There was much better problem identification and a clearer picture of gaps in the global public health framework, as well as public health problems which required further substantive R&D. In response, there was a solid policy debate about innovative mechanisms for R&D financing. (iii) Data: One had a better coverage and accessibility of data. Examples included the pricing of medicines but also patent information. Those data certainly could provide the solid basis for informed decision making and cooperation. (iv) Cooperation: Those had significantly improved all levels and had policy coherence cooperation with dialogue with the international system so that it could give an effective response to challenges which were posed for public health. In particular, the trilateral cooperation was well-established, built on an effective partnership that recognized each organization's complimentary expertise and roles. The Representative summarized a few key observations of the trilateral study: (i) the dynamic interplay between trade and competition, for example, procurement policies, quality regulation and IP rights. The impact of those issues on access and innovation was clearly one of the key observations in that study; (ii) the growing impact of trade agreements outside the established fora, not only in the area of IPRs but also other areas such as competition and procurement rules; (iii) the emergence of broader and multi-disciplinary policy perspectives, including the human rights perspective. As regards the access, two key observations were made by the Representative: (i) the Doha Declaration had facilitated judicious use of TRIPS flexibilities, and countries had taken diverse choices of implementing those flexibilities; and (ii) key importance of having effective procurement strategies, competition strategies as well as lowering tariffs, which the Director General of the WTO had supported in the context of harvesting low hanging fruits in times of financial difficulties, had been mentioned in the context of access. The study looked in detail into the innovation dimension. Because of the particular interest to the SCP, the Representative highlighted that the key finding in that policy debates had actually broadened from a narrow consideration of how patents supported innovation to the examination of key drivers of innovation and effectiveness of various incentive models, as well as, improved data on patents. There was a shift in the landscape. One important capacity-building activity, carried out on an annual basis and which was effectively held for the seventh time in October 2011 with close collaboration with WHO and WIPO for the first time, was the WTO Workshop on Intellectual Property and Public Health. That was a specialized program for developing country government officials, which focused on capacity building so that those countries could understand and, therefore, create and use flexibilities for the pharmaceutical sector. To that end, the Workshop had familiarized participants with the key concepts of the TRIPS Agreement and other IP instruments and how those provisions, including the Paragraph 6 System, could be implemented in a national law. The Workshop had also covered a range of activities outside the traditional IP areas such as pricing, procurement, policies, safety, efficacy and quality of medicines, technology transfer etc. Furthermore, the WTO Annual Report of the TRIPS Council

(document IP/C/W/55) provided a report on the WTO's technical assistance activities, including information on public health-related activities. One specific new element on the WTO web site was a dedicated web page dealing with health-related matters. Since October 2011, a set of modern notifications for the use of the Paragraph 6 System were available, so as to facilitate the task of Members who wish to use the system in the future. The Representative reported on the work of the TRIPS Council, which was the main body dealing with IP rights. With regards to patents, particularly worth mentioning was the annual review of the functioning of the Paragraph 6 System. That agenda item embodied a discussion on whether the system was providing an effective and expeditious solution to public health problems. The question was whether its role was changing in the future as full product patent protection would fall into place in the pharmaceutical sector, and whether the WTO should have an open-ended workshop to gather information from all stakeholders. Interestingly, in that context, at least one member had suggested that, given that the use of compulsory licenses turned out to be difficult, one focus instead on voluntary licenses and examine the question as to whether WTO should elaborate a model agreement, which could then be used by developing countries in their negotiations with pharmaceutical companies. Beyond that narrow focus of the annual review of the Paragraph 6 System, the interesting development since 2010 brought it into much broader discussions on the elements which impacted existing access to medicines. In particular, the WTO had the opportunity to discuss alternatives to the use of the Paragraph 6 System. That was similar to the trilateral cooperation, which had moved beyond the traditional just IP right focus, into procurement, quality and other aspects.

127. The Chair posed a question to the Representative of the WHO about the respective roles that could be played by WIPO and WTO under the GSPOA and the status of its implementation.

128. The Representative of the WHO noted that the GSPOA had been adopted in 2008 with respect to the main parts of the plan of action and some remaining open questions had been solved in May 2009. The GSPOA was a medium-term plan lasting from 2008 to 2015, which consisted of eight elements, regrouping 108 specific actions to be implemented by the WHO Secretariat, its Member States and a wide range of other stakeholders. Those 108 specific actions were addressed to a wide range of players. They all had to take up the responsibility for implementing those specific actions. The Representative did not have the exact number of the recommendations that were directed to the WHO Secretariat, but elaborated on the actions on which the WHO was focusing on with regard to its activities. There were a number of actions that were addressed to the three organizations: WIPO, WTO and WHO and other organizations. Those were the actions WHO was focusing in its trilateral collaboration. Then there was a huge amount of actions that were addressed to Member States and to governments. It was up to governments to take action to implement those activities. The Representative informed the SCP that the WHO had developed an assessment tool to be pilot tested in a number of countries. That tool would then give a gap analysis to identify specific needs for technical assistance and possible development of national implementation plans. Further, national case studies would be developed in collaboration with some Member States who had already taken actions at the national level. In the context of the issue of financing of research in the area of neglected diseases, a Consultative Expert Working Group on the Financing and Coordination for R&D had been set up to examine proposals for new and innovative sources of financing to stimulate R&D related to the diseases that disproportionately affected developing countries. That Group of experts was going to submit its report to the upcoming World Health Assembly (WHA) in May 2012 and would be available ahead of WHA. Other activities had been carried out by WHO’s regional offices.

129. The Secretariat enumerated a number of activities undertaken by WIPO in relation to the GSPOA. In September 2010, WIPO, upon request of UNITAID, organized a workshop on Medicines Patent Pool licenses. There was a reference in the GSPOA on pooling of IP. The specific topic of that workshop was to work with UNITAID, and the emerging patent pool foundation (Medicines Patent Pool Foundation) prior to its formation of licensing strategies both on the out-licensing to generic manufacturers in order to achieve the objectives that had been

set, and on the in-licensing from innovative companies, in order to constitute the clearinghouse functions or the patent pool. That was a very welcome and very constructive, as well as proactive, activity that served as an initiative very well and squarely fell within the mandate of WIPO and the calls under the GSPOA. WIPO Re:Search, as mentioned earlier, was also specifically related to the GSPOA and to the WIPO Development Agenda. The Secretariat referred to WIPO Development Agenda recommendations 19, 25, 26 and 30, which were related to technology transfer, to promoting the use and access of knowledge for developing countries, particularly for LDCs, encouraging Member States, especially the developing countries, to urge their research and scientific institutions to enhance cooperation and exchange with R&D institutions. Specifically on the GSPOA, it related to element 1, which was about the prioritization of R&D needs to neglected diseases. It also included element 2 of the strategy, promoting research and development and finally, element 3, building and improving innovative capacity. The Secretariat had visited the Fiocruz Foundation in Brazil, which was a member of WIPO Re:Search. The Representative reported on their contributions to enhance existing research on other organizations, but also existing research that was going on and development of products within Fiocruz, in particular, on IP know-how, platform technologies and compounds, which it wished to access from companies and from public sector organizations in other parts of the world. That was a very tangible expression of those recommendations that were made at the policy level and for WIPO Re:Search, in collaboration with many other stakeholders.

130. The Representative of the WTO stated that financial cooperation was the main response to the raise of action points in the GSPOA and, in that sense, cooperation with WHO and WIPO was particularly fruitful. More specifically, WTO had an ongoing monitoring system for technology transfer in the TRIPS Council. Its scope was much broader than the area covered by the GSPOA, but certainly useful for discussions on the transfer of technology and the obligations under the TRIPS Agreement by developed country Members. Most of WTO's activities focused on the implementation of the flexibilities in the TRIPS Agreement and an element that was particularly mentioned in the GSPOA, the so-called Paragraph 6 System. Those capacity-building activities focused on analytical data, but also on options which were available under the TRIPS Agreement so that countries got a better understanding and could take the most appropriate decision for their domestic purposes.

131. The Delegation of Zimbabwe welcomed the collaborative work of the three organizations, which had clarified and demystified the whole issue of the need to avoid duplication and overlapping activities, thereby eliminating the fears that had been expressed by some delegations. The Delegation observed that the mandate or the guiding principle between the three organizations were the GSPOA, which had been negotiated in the context of the WHO. WHO was implementing the actions contained in the GSPOA within its mandate, as a result of WHO Member States having been involved during the negotiation in that outcome. With respect to the activities undertaken by WIPO, as contained in document SCP/17/4, the Delegation urged to link those activities with the implementation of the GSPOA so long as they were directed towards WIPO. Referring to the WIPO Academy's Masters Program at the African University, hosted by Zimbabwe, the Delegation stated that only a limited academic group, which might not necessarily be policymakers and represent civil society, discussed the broad issues of public health. While appreciating the Program, the Delegation was of the view that the participation in that program should be expanded beyond academics in order to ensure a broader outreach. Furthermore, the Delegation stated that the mandate of commissioning a trilateral study was not clear. Since those three entities were Member States' driven, the Delegation expressed its appreciation for getting more information about the processes of commissioning a study.

132. The Secretariat referred to the Program and Budget for the 2010-2011 biennium that had been approved by Member States, including the Global Challenges Program in Program 18. That provided guidance from the Member States and the point of reference for those activities, as established in detail by the Program and Budget Committee (PBC). During 2011, the Global Challenges Program had had a number of discussions with the PBC, updating them on activities

that were all anchored in and explained in Program 18. In that context, the work program of Program 18 for 2012 and 2013 had been established, and the Secretariat stood ready to provide Member States any updates and information. For example, prior to launching WIPO Re:Search, Member States had been invited to an informal briefing session attended by a number of delegations and were briefed specifically on WIPO Re:Search and its operation. The Secretariat had received some constructive and positive comments from Member States at that informal briefing. Therefore, Member States were consulted, formally within the PBC and informally at various levels, including consultations by the Director General with the Ambassadors.

133. The Representative of the WHO informed that its Program was reporting to WHO's Governing Bodies on the implementation of the GSPOA. The Program reported to the Executive Board of WHO, as well as to the WHA, on the activities undertaken to implement the GSPOA, including on the activities undertaken in the framework of the trilateral cooperation. With regards to the Master's Program of the African University, the Representative, who had contributed to that Program, informed that 30 participants from 16 African countries had attended with very diverse backgrounds, for instance, a fashion designer from Ghana, several staff from national IP offices, several staff from the Ministry of Justice in different countries, as well as people from private practice and from NGOs.

134. The Representative of the WTO pointed out that guidance to the WTO Secretariat did not only come from the GSPOA but also from the Doha Declaration. The Representative noted that the preparation of the trilateral study had been mentioned in the report of WTO activities to the TRIPS Council in the context of its annual review. Information on that study had also been made public on a dedicated web page on the trilateral cooperation, as early as of late summer of 2011 and that was well known. The Representative clarified that the three organizations had not commissioned a study, but were working themselves on the study, which was an extension of the day-to-day work, as comprehensive capacity building activities. He noted that, in order to reap the benefits of the respective areas of expertise of the three organizations regarding the overall framework on access and innovation, the study was consolidating and updating practical experiences and empirical data. He explained that the objective of the study was supporting and objectively informing policy discussions, and there were no recommendations provided in that study, which could go beyond the mandate of those organizations.

135. The Delegation of Cameroon asked for elaboration on the synergies between the agendas of the three organizations in terms of the 2015 deadline for achieving the Millennium Development Goals (MDGS), since, among those goals, many concerned health, particularly HIV/AIDS and so-called neglected diseases such as tuberculosis and malaria. Noting that the results and impact of the activities undertaken were dependent on the resources, strategies and timetable, the Delegation requested further information about those elements from the three organizations.

136. The Representative of the WTO pointed out that access to drugs could not simply be limited to issues of IP. The contribution of those three organizations in the area of IP and public health and the efforts to achieve the MDGs were limited. The Representative referred to the report of the UN Millennium Project Task Forces, which contained a section that described issues of IP and how important they were to achieve the results in the area of public health and access to medication in the achievement of the MDGs. He noted that the work done by the organizations in the area of IP and public health, such as the GSPOA, also fell under the umbrella of the MDGs.

137. The Delegation of Egypt welcomed the increased collaboration between WIPO, WHO and WTO on public health and the fact that WIPO was taking the lead according to its mandate and the WIPO Development Agenda Recommendations. The Delegation strongly recommended that, to continue the trilateral cooperation on patents and public health, the briefing by WIPO, WHO and WTO be placed as a standing item on the agenda for future SCP sessions. In its

view, the issue deserved the Committee's sustained, dedicated and intensive attention and focus. The Delegation noted that, although WIPO had been doing several activities directly or indirectly in the field of IP and public health, those activities were a bit dispersed, not consolidated or integrated. In its opinion, they needed to be focused in order to reach the intended results. In that regard, the Delegation considered that WIPO Re:Search constituted a step in the right direction to address market failures, where IP and patent incentives were not sufficient to produce medicines necessary to save and treat human lives. The Delegation was pleased to see several private pharmaceutical actors supporting that initiative. Therefore, the Delegation considered that every effort should be made to enhance and document that initiative through extending the scope to cover other vitally important diseases which heighten health burdens of Member States, such as HIV/AIDS among communicable diseases. The Delegation referred to paragraph 28 of the document, where the WIPO Secretariat had stated: "Frequently, Member States pay particular attention to the protection of test data, either because of general TRIPS commitments or due to more precise obligations under bilateral or regional agreements". The Delegation cautioned WIPO that it should not be directly or indirectly involved in promoting or providing assistance with the implementation of IP standards outside the purview of the WIPO mandate. The Delegation thanked the Representative of the WHO for mentioning that patents were a key to the determination of affordability of medicines and for mentioning new developments about patents and the study which was conducted on patent rights in respect of vaccines. The Delegation noted that it had been the first time that it heard about such important initiatives and that such an important study could also be extended, at a later stage, to medicines for HIV and other non-communicable diseases. The Delegation thanked the Representative of the WTO for his presentation and expressed its hope for taking important decisions on the TRIPS implementation for the benefits of developing and developed countries at the upcoming eighth WTO Ministerial Conference. With respect to the way forward, the Delegation pointed out that WIPO had a niche in monitoring the mechanism relating to the granting of patent protection on technology for medical products. WTO had a niche in monitoring bilateral and regional agreements with TRIPS-plus provisions. WHO had a niche in monitoring medicines' prices and access to medicines. Therefore, the Delegation was of the view that there were benefits of considering further trilateral work on an integrated, perhaps international, monitoring mechanism for patent trends, trade rules and the affordability of medicines. Such an international mechanism could be in line with what was mentioned in paragraph 40 of document SCP/17/4, which stated that the "three organizations meet regularly and exchange information on their respective work programs and discuss and plan, within their respective mandates and budgets, common activities" and that the "trilateral cooperation was intended to contribute to enhancing the empirical and factual information basis for policy makers and supporting them in addressing intellectual property issues in relation to public health".

138. The Delegation of Poland, speaking on behalf of the European Union and its 27 Member States, welcomed the valuable information on the activities and initiatives undertaken by the three organizations in the field of public health. The Delegation informed the members of the SCP about activities of the European Union aimed at assisting the developed countries and LDCs in dealing with public health problems. The European Union had consistently led efforts to widen access to vital medicines in developing countries and to strike a balance between the IPRs of pharmaceutical companies and the need to ensure that medicines were available for countries facing public health crisis. For example, in 2003, the European Union had adopted rules on tiered pricing that prevented the export of drugs sold by EU pharmaceutical companies to developing countries at heavily discounted prices, thus enabling the European pharmaceutical companies to sell their goods to developing countries at prices cheaper than they charge in Europe. In 2002, after the Doha Declaration, the EU had adopted Regulation (EC) No. 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems without waiting for the corresponding amendment of the TRIPS Agreement to be enforced. Thereby, the EU had integrated that amendment to the TRIPS Agreement into its regional law. The Delegation noted that, in consequence, European pharmaceutical companies could apply for a license to manufacture, without the authorization of the patent holder, pharmaceutical products for exports

to countries in need for medicines and facing public health problems. It further noted that the principle of compulsory licensing also allowed a developing country facing a public health crisis, after consultation with the patent holder, to grant a license to a domestic company, without the approval of the patent holder, to import a generic medicine produced by a foreign pharmaceutical company. The Delegation stated that the EU had introduced a "Bolar Exception" regime by 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use so as to promote the development of generics and its rapid entry on the market after the expiration of the relevant patent. The Delegation noted that the EU was one of the key actors in discussions on the GSPOA and intergovernmental discussions to improve medicine access, availability and affordability of human resources for health in the developing world, including true, constructive input to the WHO debate on public health, innovation and intellectual property. Between 2002 and 2010, the European Union had contributed 25 million Euros to the African, Caribbean and Pacific (ACP) countries and WHO partnerships on pharmaceutical policies, which represented one of the most known global and comprehensive actions in that field. Currently, a further contribution of 10 million Euros was being prepared. The Delegation explained that the objective was to develop, implement and monitor national drug policies to improve access to essential medicines, particularly for priority health problems, ensure quality, safety and efficacy of medicines through effective drug regulation, and improved use of health professional as and consumers in Asian and Pacific countries. It noted that the EU was also supporting the development of medical products against poverty-related diseases through different mechanisms, such as the European and Developing Countries Clinical Trial Partnership (EDCTP) or a direct support mechanism. On a bilateral basis, the EU had helped strengthening the drug procurement system in a number of countries to ensure the quality, safety and efficacy of medicines produced in those countries and those imported. Finally, the Delegation stated that the EU was the biggest provider of resources to support health policies in developing countries. For example, the EU was one of the oldest and biggest contributors to the Global Fund to Fight AIDS, Tuberculosis and Malaria: 67 million Euros had been given since 2002, and under the framework program between 2007 and 2013, the EU had allocated a total of 6.1 billion Euros to help R&D programs.

139. The Delegation of the United States of America stated that, under the GSPOA, most of the 108 actions had actually been identified as for governments to implement. The Delegation expressed its wish to join the EU in the future on explaining some of its domestic actions under the GSPOA. As to the suggestion that a briefing by the trilateral organizations would be a regular agenda item of the SCP, the Delegation believed that it was premature to decide on such an agenda item at that time. If it became a standing item, it would be important for all governments, as primary stakeholders, to explain their actions in implementing the GSPOA. In its view, WHO, WTO and WIPO were supposed to help Member States implementing the global strategy.

140. The Delegation of Bangladesh informed the SCP that the Paragraph 6 System of the Doha Declaration, which had been endorsed by the General Council decision in 2003, had established a system of compulsory licensing. In its view, that was a landmark decision by any standard. Noting that from August 2003 to 2011, there had been only one example of putting such a compulsory license into practice, the Delegation requested the Representative of WTO to provide an explanation or any analysis on that issue.

141. The Representative of the WTO recalled that the debate was ongoing in the TRIPS Council and was documented as part of the annual review. The views of WTO Members were diverging. Some were saying that the system was working quite well, despite the fact that it had only been used once. However, there were views that it was not working, since it had only been used once. The Representative explained that the reason for having that discussion in the TRIPS Council was precisely to gather information. He noted that the information on the system's functioning was very much in the hands of WTO Members, and that it was not up to

the WTO Secretariat to prepare an analysis of the functioning of the Paragraph 6 System, as long as WTO Members were still trying to bring together the necessary experience in the TRIPS Council.

142. The Delegation of South Africa, speaking on behalf of the African Group, supported the cooperation of the three organizations. The Delegation stated that it was worth considering the proposal of the Delegation of Egypt that a trilateral briefing and interaction with delegations be included as a permanent agenda item of the SCP, given the wealth of information provided by the three organizations. The Delegation stressed the importance of trilateral organizations undertaking activities which were member-driven or were mandated by Member States. In that regard, the Delegation considered it unfortunate that, within WIPO, that right had not been exercised by Member States, since the Secretariat was undertaking such activities without providing information or feedback other than in the form of biannual program reports in the PBC. The Delegation therefore seconded the proposal made by the Delegation of Egypt, and also supported the suggestion made by the Delegation of the United States of America, although it could not commit that Member States had also to provide their views on their implementation of the GSPOA.

143. The Chair reminded the delegations that having the representatives of the three organizations in the room did not mean that it was possible for the SCP to issue to those representatives orders to implement the member-driven mandates of the three organizations.

144. The Delegation of Algeria, speaking on behalf of the DAG, expressed its agreement with the Chair, and supported the statement made by the Delegation of Egypt concerning the usefulness of briefings from the representatives of the three organizations. The Delegation stressed the importance of having complete and holistic information on the activities of the other organizations. The Delegation shared the view that the issue of access to medicine and health could not be looked at from only one angle and that those three components were very important in order to move forward on the issue of access to medicine and on protecting the health of many people in the world, mainly in developing countries and LDCs, without neglecting it or diverging on it.

145. The Delegation of Slovenia, speaking on behalf of the CEBS, noted that statistical data and past experience clearly showed that the availability of medicine did not mainly depend on patent protection. In its view, further improvements should be made to enhance the availability of medicine. It considered that, first, it was necessary to look at real practical obstacles that hindered access to medicine. The Delegation acknowledged that a balanced result in that area was a result that provided incentives to invent new and better medicines for the betterment of all, and, at the same time, did not impede legitimate public interest aspects, such as access to medicine under customary and fair conditions. In its opinion, the SCP was aware of the continuous efforts made by several international organizations, which had tackled those issues for quite some time. Therefore, the Delegation stated that the SCP should not duplicate the work and focus only on the issues that were IP-related and within the WIPO mandate. It also stated that the CEBS saw a merit in the proposal made by the Delegation of the United States of America. In its view, many elements were worth being scrutinized and should be taken into account as a basis for future work. In particular, the Delegation fully supported an in depth discussions on the positive impact of the patent system on the accessibility of the life saving medicine.

146. The Delegation of Canada supported the right of inventors to benefit from the years of R&D that culminated in drugs that benefited people of all nations, without losing sight of the public interest. In its view, it was in the interest of all people to ensure that sufficient incentives continued to drive the pursuit of new break-through therapies by both public and private actors. The Delegation aligned itself with the statements made by the Delegations of Switzerland and Japan that patents had not had a negative impact on health and that the problems of access and availability to medicines in developing countries and LDCs were a result of a multitude of

factors other than the patenting of new medicines and diagnostic technologies. The TRIPS flexibilities alone were not a panacea to that complicated and multifaceted issue. The Delegation thanked the Delegation of the United States of America for introducing its ideas and looked forward to discussing and exploring those further. The Delegation supported inviting the WHO to present to the SCP. In its opinion, that presentation should include the full range of factors that influenced the availability of, and access to, medicines in developing countries. It also thanked the Delegation of South Africa on behalf of the African Group for the submission of the proposal contained in document SCP16/7. However, the Delegation indicated that it could not endorse the premise that patents had had an adverse effect on access to, and availability of, medicines. The Delegation also supported many of the observations made, indicating that much of the work program detailed in the proposal would be duplicative of work done in other fora.

147. The Delegation of Poland, speaking on behalf of the European Union and its 27 Member States, thanked the Delegation of the United States of America for its proposal on the topic of patents and health, including elements of the work program in that area. The Delegation supported the proposal to invite the WHO to make a presentation to the SCP on the availability of generic medicines in developing countries and LDCs, on the non-patent barriers to the availability of medicines, and on the effect of counterfeited medicines on the availability of genuine medicines. Such a presentation could be undertaken as a first step to help the SCP to make an informed decision on further work in relation to that issue. The Delegation also expressed support conducting a comprehensive study on the positive impact of the patent systems in providing life saving medicines to developing countries. In its view, such a study fitted well to the mandate of the SCP. Furthermore, the Delegation of the United States of America had proposed a comprehensive study to life saving medicines that were currently provided in a generic form, in particular focusing on factors affecting access that were unrelated to patents. The Delegation highlighted the value of conducting such a study and welcomed the approach not to take any action outside the SCP mandate, thus avoiding duplication of work. The Delegation suggested that the study be conducted either by another WIPO body, such as the CDIP, or in cooperation with other international organizations with the relevant findings being presented to the SCP.

148. The Delegation of the United States of America, speaking on behalf of Group B, welcomed the proposal of the Delegation of the United States of America on patents and health.

149. The Delegation of Japan supported the statement made by the Delegation of the United States of America on behalf of Group B as a preliminary reaction, and welcomed its contribution to enrich the discussion on that salient item. The Delegation pointed out that the patent system could serve as a means of providing incentive to inventors, including inventors of medicines. Therefore, in its view, denying the contributions of the patent system to the enhancement of public health would prevent the future development of new medicines. In that sense, the Delegation saw value in the proposal by the Delegation of the United States of America, especially on the second component, which was a comprehensive study on the impact of the patent system.

150. The Representative of MSF noted that he was interested in patents and public health debates, as MSF found itself increasingly encountered in the field with the problem of access to essential medicines. He considered that IP, and specifically patents, affected prices and availability of desperately needed medicines. He considered that the statements that much of the drugs on the Essential Medicines List were off patent were simplistic, as cost-effectiveness was still a key criteria used by the WHO to develop its Essential Medicine Lists. In its view, the ability of the generic manufacturers to produce affordable, quality medicines would be significantly compromised with the full implementation of the TRIPS Agreement in developing countries. He was of the opinion that, from a public health and access to medicine perspective, it was important to keep the current level of generic medicines in developing countries. In that regard, the Representative highlighted the importance of the flexibilities and safeguards

provisions of the TRIPS Agreement, which could play a significant role in development. He affirmed that MSF benefited directly or indirectly from the various flexibilities of the TRIPS Agreement, and the Representative's experience showed that it was crucial to preserve such flexibilities. For example, in Kenya, MSF had used the flexibilities to import generic medicines from India. The Representative had also witnessed the benefits of stricter patentability criteria set out in Section 3(d) of the Indian Patent Law, which had been successfully used to oppose to the "evergreening" of patents. The Representative expressed, however, much concern about the emergence of the so-called TRIPS plus trends, which were undermining the safeguards allowed under the TRIPS Agreement. In its view, the proliferation of that development and Free Trade Agreements (FTAs) threatened the access to medicines in the developing world. For the Representative, of central concern in the proposal of the EU–India FTA were provisions regarding IP enforcement, which went far beyond what was required under the TRIPS Agreement. Furthermore, the Representative noted that the proposed Trans-Pacific Partnership (TPP) Agreement greatly diminished access to medicines to millions of people in the developing world. In that context, the Representative considered that the role of WIPO was extremely crucial to maintain a balanced patent system which essentially took into account the human consequences of a patent regime. The Representative stated that, in its advice and technical support to Member States, WIPO should proactively promote exceptions and flexibilities allowed under different international treaties. In that regard, the Representative referred to the findings and the recommendations of the external review of WIPO's technical assistance in the area of the cooperation for development, which categorically highlighted that "WIPO should present developing countries the range of options and flexibilities available in international laws. It should also explain and/or share experiences of how different options may hinder or advance their pursuit for development targets." Thus, towards that end, the Representative supported the joint proposal of the African Group and the DAG. The Representative urged WIPO Member States to seriously consider that proposal, and to carry out a series of studies on the use of flexibilities and maintaining a patent status database which would be important for treatment providers, like MSF, to identify the options for purchase and import of medicines from different sources and different countries.

151. The Representative of KEI pointed out that in November 2001, the WTO's Ministerial Conference in Doha, Qatar, adopted the Doha Declaration on Intellectual Property and Public Health which stated that "the TRIPS Agreement does not and should not prevent members from taking measures to protect public health". In his view, that landmark Declaration marked a watershed moment in global trend governance by singling out public health and, in particular, health technologies from other trade-related issues. The Representative considered that the Doha Declaration reiterated that health technologies were not just another commodity and might be differentiated from other inventions. That declaration had been precipitated by a request from the African Group in April 2001 for the WTO to hold a special session of the TRIPS Council to clarify the relationship between IP and access to medicines. In its request, the African Group had observed that "as the recent upsurge of public feelings and even public outrage over AIDS medicines has shown, there was now a crisis of public perception about the IP system and about the role of TRIPS which was leading to a crisis of legitimacy for TRIPS. Once the storm was raging outside the WTO and legitimately so, we as members inside the WTO cannot shut our eyes and ears. Each of us, from developing and developed countries, must respond and respond adequately and appropriately". Nearly 10 years after the Doha Declaration, the Representative was of the opinion that it was appropriate that the African Group and the DAG had tabled their proposal on a work program for patents and health at the 16th session of the SCP with the overarching objective that the patent system should be consistent with fundamental public policy priorities, and, in particular, the promotion and protection of public health. To preface its contribution on patents and health, the Representative observed that recommendation 14 of the WIPO Development Agenda stated that " Within the framework of the agreement between WIPO and the WTO, WIPO shall make available advice to developing countries and LDCs, on the implementation and operation of the rights and obligations, and the understanding and use of flexibilities contained in the TRIPS Agreement". The Representative noted that technical assistance experts often failed to distinguish between compulsory licenses

that were granted under the procedures of Part II of the TRIPS Agreement, concerning patent rights, and those granted under Part III of the TRIPS Agreement, concerning the remedies for infringement of those rights. For example, a commonly used mechanism for obtaining a compulsory license in the United States of America was associated with Part III of the TRIPS Agreement, including, in particular, Article 44 of the TRIPS Agreement. The Representative noted that, under the structure of the TRIPS Agreement, compulsory licenses under Article 44 were not subject to the restrictions that existed for Articles 30 and 31 of the TRIPS Agreement. Consequently, the Representative supported the African Group and DAG to request for the International Bureau to organize a technical workshop on state practice involving the compulsory licensing of medical technologies, including the application of Articles 30, 31 and 44 of the TRIPS Agreement. Moreover, the Representative supported the African Group and DAG proposal for the Secretariat to "commission a framework study by independent experts" to document state practice on compulsory licensing including the provision of empirical data on the royalty rates set in each case and an "examination on the extent to which countries use exhaustion of rights to allow parallel trade in medicine". In addition, under the mandate of Recommendation 14 of the WIPO Development Agenda, the Representative requested the Secretariat to undertake technical studies on the following: current implementation of paragraph 7 of the Doha Declaration on TRIPS and Public Health, regarding patents in LDCs, and the methods of implementing paragraph 6 of the Doha Declaration. Furthermore, the Representative expressed his concerns about the increasing attempt by developed countries to lower patentability criteria and increase protection for patent right holders at the expense of public health through bilateral and plurilateral FTAs. He observed that those new standards often went well beyond the requirements of the TRIPS Agreement and could fail to adequately incorporate the Doha Declaration. For example, the United States of America was currently negotiating a regional FTA known as the TPP Agreement with a diverse group of developed and developing countries. In his view, the United States of America had proposed IP text that would lower standards for patentability and require patents on subject matter, explicitly exempted by Article 27 of the TRIPS Agreement, including patents for plants, animals, diagnostic, therapeutic and surgical methods. Additionally, he considered that the United States of America's proposal would increase the monopoly power of patent holders through mandatory patent term extensions, exclusive rights in regulatory test data, and patent linkage. In his opinion, the provisions of the United States of America's proposal would predictably delay entry of generic competition into the market and harm access to affordable medicines. A particular concern for the Representative was the intention to extend the standards set in the TPP Agreement to a wider group of countries than currently involved in the negotiations. The Representative stated that creation of new global patent norms should not occur through non-transparent bilateral or plurilateral trade agreement negotiations. The Representative further noted that the United States of America's proposal also sought to eliminate any form of pre-grant opposition to patents and would allow only post-grant procedures. In his opinion, since pre-grant opposition could serve to improve patent quality and reduce the granting of spurious patents, the elimination of pre-grant opposition systems benefited the patent holder and could increase the costs of challenging patents, even those that never should have been granted.

152. The Delegation of Algeria, speaking on behalf of the DAG, assured that its joint proposal had never been aimed to undermine the patent system. The Delegation had proposed different elements in the work plan towards a body of flexibilities in the patent system and how WIPO could help developing countries to use those flexibilities as part of the patent system. The Delegation indicated that the patent system was composed of many rights, the rights of the right holders and the rights of the users, and that the rights of the different parts that were dealing with the patent system had to be balanced. The Delegation underscored that the use of flexibilities was part of the patent system, trying to deviate from the obstacles for developing countries to have access to medicines. The Delegation supported the idea of having a briefing by the three organizations, and noted that dealing with patents and health was within WIPO's and the SCP's mandate. In its view, other issues could be dealt with in another way within WTO or within WHO, as all issues related to health. The Delegation noted that, at least, an agreement on some elements could be possible, as many different developing and developed

countries were agreeing that WIPO could do something on IP and health and that some element of the work program proposed could be a basis of discussion and adopted. The Delegation did not express its acceptance of all the critics, but recognized the spirit and constructive way the SCP had been working towards an agreement. In 2001, the WTO had come to an agreement on a very important issue, the Doha Declaration. In its view, it was time for WIPO to register its name for history and to take a decision on how to contribute to that issue. The Delegation stated that WIPO was doing a lot of work on health, but also had to do it in its own house.

153. The Delegation of South Africa, speaking on behalf of the African Group, aligned itself with the statement made by the Delegation of Algeria on behalf of the DAG. The Delegation reiterated that the African Group was very committed to the work of WIPO and a balanced system of IP, without thereby diminishing the balance between patent holders as well as public interest or public use. The Delegation stressed the importance of ensuring the balance between the interests of corporate right holders and the public. The Delegation referred to the statements made by the Delegations of Argentina and Chile emphasizing the principle and problem of balance. The Delegation recalled the genesis of that paper, in particular, that no document had existed before the proposal of the African Group. The Delegation stated that there was a misunderstanding that developing countries wanted to weaken the patent system. Referring to paragraphs 2 and 3 of the proposal, the Delegation explained that the texts had been taken from the agreed language in the WTO and the WHO. In particular, paragraph 12 of the GSPOA stated that "International intellectual property agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries. However, developing countries may face obstacles in the use of these flexibilities". The Delegation expressed its surprise to the reactions of some Member States, stating that the proposal was negative to the patent system and misleading because it had referred to obstacles. The Delegation clarified that the proposal addressed one of the ways to resolve the existing problems and was not intended to be the panacea. The Delegation expressed its appreciation for those delegations which had been positive and providing suggestions and comments constructively on every element, namely the Delegations of the United States of America, the Russian Federation and Spain etc. On the issue of duplication, the Delegation recognized the work being undertaken in other fora within WIPO, as referred to in documents SCP/7/3 and CDIP/5/4 Rev. Comparing the documents and the proposal, the Delegation noted that document SCP/7/3 had presented facts, but did not touch on elements of the study per se. It further noted that although document CDIP/5/4 Rev. related to compulsory licensing, the SCP was meant to look at the specific challenges faced by, and the impact on, public health. Therefore, in its view, there were no duplications, and it was appropriate to leave it to the Secretariat to guide the SCP in terms of identifying duplications. The Delegation expressed its readiness to accept the language similar to the agreed language contained in the conclusions of the 16th session on the similar problem of duplication with respect to transfer of technology. On the issue of the suitable platform to address that issue, the Delegation was concerned about the argument that the SCP was not the proper forum to talk about patents and medicines. In that regard, the Delegation supported the view of the Delegation of Chile that the issue had to be discussed in all organizations, which had relevance for health. The Delegation observed that while the CDIP had been established to mainstream the WIPO Development Agenda recommendations, the specific focus of the SCP was to direct the work as to discuss the interface between patents and health. The Delegation thanked the Delegation of the United States of America for outlining its proposal, and requested sufficient time to reflect on that proposal.

154. The Delegation of Zimbabwe stated that the Committee should view the issue in a holistic manner. Specifically, the SCP had to analyze the supply chain and distribution of medicines. As stated by the Delegation of South Africa on behalf of the African Group, the Delegation also considered that it was not possible to discuss medicines without discussing the issue of patents. While a number of delegations had put forward some counter arguments, the Delegation stressed that the SCP should move forward. Referring to the statements made by the Delegation of Switzerland and other delegations, it pointed out that the proposal of the African

Group and the DAG might not entirely reflect the views of certain other delegations, and therefore, it could be enriched by covering the short-term, medium-term and long-term perspectives. In its view, the SCP could not achieve a long-term objective and a tangible outcome if it had no clear work program and mandate. The Delegation referred thereby to the presentations of the three organizations to the SCP on an *ad hoc* basis. The Delegation considered that it was necessary to give WIPO the mandate to continue its excellent work. In that context, the delegation observed that, as long as the GSPOA remained recommendations, WIPO could not be obliged to implement them, unless Member States deliberated and gave WIPO the mandate to do so. The Delegation stated that the suggested work program by the African Group and the DAG could further be enriched by discussing its substantive issues without limiting it to one element. In its view, the proposal of the Delegation of the United States of America could be easily accommodated in the proposal of the African Group and the DAG. The Delegation acknowledged the necessity of being open-minded and having a long-term plan, as pointed out in the proposal of the Delegation of the United States of America and by the Delegation of Switzerland. The Delegation hoped that the 16th session of the SCP came up with a clear mandate on what WIPO should be doing on patents and health. In its view, unless and until a specific mandate was given to WIPO by Member States, it was not sufficient to merely adopt the program and budget in the PBC.

155. The Delegation of Uruguay supported the proposal made by the African Group and the DAG, as far as it would allow the Committee to deal with an issue which was central to the patent system. The Delegation recalled that the TRIPS Agreement allowed Member States to broaden the range of products which could be patented, and many developing countries had welcomed the TRIPS Agreement. The patentability of pharmaceutical products had been a revolution in the patent system that had already existed in many developing countries when the TRIPS Agreement had been approved. The Delegation therefore observed that the current patent system was based upon such enormous change by the introduction of the TRIPS Agreement. The patentability of pharmaceuticals was something quite new and led to a dramatic increase in applications for patents in many developing countries. The Delegation also stated that although the majority of medicines were no longer protected by patents or perhaps had never been protected, the SCP had to recognize that those which were protected by patents affected very important health issues and reaped a major part of the health budgets in developing countries. Furthermore, the Delegation pointed out that the only modification of the TRIPS Agreement since its approval was in the area of public health, despite the fact that many provisions should be revised. The Delegation was of the opinion that it was not possible to claim that the issue of public health was not closely linked to the patent issue nor that the existing patent system was separate from the issue of patenting of drugs. Therefore, it considered that the SCP had the opportunity to look at that issue and it should be looked at it in its broadest sense. The Delegation expressed the opinion that the patent system was facing a crisis due to the proliferation of patent applications which did not fulfill the requirements for obtaining exclusive rights. It observed that some of the patenting strategies were considered anticompetitive and restricted the access of generic drugs to the markets by, for example, the EU. In addition, the Delegation noted that every patent office had thousands of patent applications representing variations of formulae or molecular compositions, which were already known, and apparently the aim of those applications was to extend the patent protection beyond its term of protection. In relation to the matters of public interest related to the patent system, the Delegation was of the opinon that the proliferation of patent applications with those characteristics would have a negative effect upon the goals for which the patent system had been designed. In its view, the current patent system and patenting strategies were stimulating neither technological progress nor true inventions and innovation. It observed that, in some cases, investors encountered more difficulty, since it was difficult to risk investing in an area in which it was likely to encounter a web of patents, which was extremely difficult to untangle, and to identify existing protection. The Delegation stated that the patent system was made up of not only rights but also exceptions and limitations which had always been part of the system and established the balance that allowed the system to function. Consequently, the Delegation encouraged continuing the consideration of those issues.

156. The Chair stated that the proposal of the United States of America had been distributed in the three working languages of the Committee.

157. The Delegation of South Africa, speaking on behalf of the African Group, thanked the Delegation of the United States of America for its proposal concerning patents and health. The Delegation suggested discussing the proposal at the next session of the SCP in order to provide an opportunity for other delegations to examine it. The Delegation noted that the proposal of the Delegation of the United States of America had the nature of a counterproposal to the proposal made by the African Group and the DAG. The Delegation observed that in paragraph 2, the proposal stated that "Resorting to a compulsory license or other non-voluntary mechanisms would not gain the cooperation of the patent owner and the recipient of the compulsory license may not easily be able to successfully manufacture the medicine". The Delegation further quoted the second sentence of paragraph 2 stating that "None of the issues can be solved by IPR flexibilities alone and in particular cannot be solved by the wholesale use of compulsory licensing. To the contrary, the lack of effective patent protection is one factor which prevents the appropriate medicines from reaching the neediest patients in developing countries and LDCs." The Delegation therefore expressed its understanding that that proposal would discourage the use of flexibilities. The Delegation believed that its understanding was also supported by another statement contained in paragraph 4 of the USA proposal, where it stated that "measures that weaken patent protection systems through greater use of flexibilities are not useful in securing better availability of medicines." The Delegation considered that those quoted phrases highlighted the contrast with the proposal of the African Group and the DAG, in which the emphasis was given the use of flexibilities, in particular, compulsory licensing. The Delegation stated that, since flexibilities were included in international treaties, it was difficult to accept the proposal submitted by the Delegation of the United States of America that considered the flexibilities negatively. The Delegation further stated that falsified and substandard medicines, which was referred to in the proposal of the Delegation of the United States of America, was a controversial issue, still under discussion at the WHO. The Delegation therefore concluded that they had difficulty in understanding that topic, without having an understanding of the topic of patents and falsified medicines. The Delegation expressed its wish to have more clarity about the proposal with regard to enforcement, since there was a Committee on enforcement within WIPO. Furthermore, the Delegation noted that the proposal made by the Delegation of the United States of America made a reference to technical issues already discussed, such as fake medicines, safe and effective medicines, pathogens. The Delegation expressed its doubt about the compatibility between the two proposals, considering that the proposal of the African Group and the DAG contained elements that elaborated the agreements which had been concluded, while the proposal of the Delegation of the United States of America introduced new elements on which some reflection was still needed. The Delegation sought clarification on a reference to barriers in the proposal of the Delegation of the United States of America, which, in its view, was the aspect within the mandate of WTO. The Delegation referred to WHA Resolution 56.27 which had explicitly mentioned flexibilities, in particular, its paragraph 1(2) which stated that "to consider whenever necessary adapting national legislation in order to use to the full the flexibilities contained in the Agreement on trade Related Aspects on Intellectual Property Rights." It further referred to paragraph 4 of the Doha Ministerial Declaration in which it stated that "we agree that the TRIPS Agreement does not and should not prevent Member States from taking measures to protect public health". The Delegation was of the view that the TRIPS Agreement could and should be implemented in a manner that WTO Members protected public health. In addition, the Delegation noted that the GSPOA stated that the Doha Ministerial Declaration on TRIPS and Public Health confirmed that the Agreement did not prevent Member States from taking measures limiting IPRs in order to protect public health. The Delegation also made reference to Article 5A(2) of the Paris Convention in which it was stated that "each country of Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example failure

to work". Furthermore, the Delegation referred to Articles 27.3 and 30 of the TRIPS Agreement. The Delegation concluded that the proposal of the Delegation of the United States of America had not taken into account all the quoted provisions in the international legal framework.

158. The Delegation of the United States of America thanked the Delegation of South Africa on behalf of the African Group for having studied their proposal and expressed its appreciation for the comments made on it. The Delegation clarified that it was not their intention to provide an alternative to the proposal of the African Group and the DAG. It pointed out that the Committee should guide the work of delegations who were patent experts so that they could understand the place within the international forum. The Delegation believed that the Committee would have no ability to take actions on the larger picture, however it deemed important to understand the larger picture for their future work. The Delegation stated that, since there was no specific single forum in Geneva, able to look univocally at a big framework such as patents and medicine, its proposal was aiming at requiring a study about the different policy options that governments could take in relation to access to medicine. The Delegation regretted that only few phrases of its proposal had been quoted by the Delegation of South Africa, and clarified that there were many other parts of that proposal supporting the TRIPS flexibilities and the ability to use compulsory licensing and other flexibilities. The Delegation explained that its emphasis was on the fact that flexibilities should not be the only avenue that governments should seek in order to provide access to medicines. It was with that mindset that the Delegation was trying to get some further background information for the Committee's work and to explore different policy options.

159. The Delegation of Zambia supported the statement made by the Delegation of South Africa on behalf of the African Group. The Delegation considered that the focus should be how it was possible making full use of the flexibilities contained in the international treaties on IP, in a positive way, i.e., in recognizing the importance of patent protection. The Delegation noted that it was looking for assistance in order to utilize those flexibilities in a manner consistent with the commitments undertaken at the international level. The Delegation noted that the proposal by the Delegation of the United States of America, on the other hand, focused on the lack of patent protection and on factors impeding access to medicine, as well as the availability of falsified medicines, and considered that it was not in line with the proposal of the African Group and the DAG. The Delegation believed that moving in the direction indicated in the proposal of the Delegation of the United States of America could bear the risk of bringing the Committee to areas which were within the mandate of other organizations. Therefore, the Delegation was of the view that the Committee should stick to its mandate and focus on how countries might be assisted in the implementation of flexibilities through the adoption of a program on elements already present in the IP arena. The Delegation observed that some issues found in the proposal made by the Delegation of the United States of America related to global funding, research and development. The Delegation considered that it was difficult to get headway in some proposals which had been discussed in other fora, and concluded that the Committee should focus more on activities under its mandate.

160. The Delegation of Zimbabwe thanked the Delegation of the United States of America and expressed its support to the statements made by the Delegation of South Africa on behalf of the African Group as well as by the Delegation of Zambia. The Delegation observed that the proposal of the Delegation of the United States of America was an academic paper, in which many citations were from experts from some specific countries, but not discussed in international fora. Referring to paragraph 3 of the proposal, the Delegation stressed the importance of developing other means of rewarding innovation, since the IP system tended to increase the cost of medicines and medical products. With respect to the statement contained in paragraph 5, the Delegation stated that the topic of flexibilities was fundamental. The Delegation pointed out that, since all the countries represented within the Committee had committed to the TRIPS Agreement, discussing that Agreement within the SCP was appropriate. In relation to paragraph 7 of the proposal dealing with the issue of the WHO list of essential medicines, the Delegation noted that the proposal did not mention that the production of generic

drugs had enhanced the access to medicines in developing countries and developed countries alike and that was a result of the use of flexibilities. Furthermore, regarding the phrase in the proposal "many of the medicines of the EML", the Delegation wondered why the proposal had not referred to "all" medicines of the EML. It noted that often the patent life on pharmaceuticals was extended through a new patent due to cosmetic changes of the drug. The Delegation stated that the problem of funding schemes, also dealt with within the proposal, could be more appropriately discussed within other international fora, but not within the SCP. In relation to the Medicines Patent Pool, the Delegation pointed out that, according to the information in its possession, that Pool had not yet been working, and that the only patent pool already working was the one on sewing machines. The Delegation considered that patent pools were facing many difficulties, and that their utility had still to be proved in order to improve access to medicines. Concerning the proposal on global funding contained in the proposal, the Delegation was of the view that while those kinds of initiatives outside the SCP should be welcomed and encouraged, the Committee should focus on its mandate within the ambit of WIPO. In its opinion, with the global financial crisis, it would be difficult to have access to such kind of fund. The Delegation expressed its wish to promote something concrete within WIPO and leaving aside initiatives outside of it. Furthermore, the Delegation considered that an initiative on tiered pricing was not relevant to the work of the Committee. In relation to the issue of falsified and substandard medicines described in paragraph 2 of the proposal, the Delegation stated that there was no agreed definition of that term within the WHO. The Delegation observed that the term "falsified medicine" was used in the United States Food and Drug Administration, while other countries were using other terms. The Delegation therefore considered that it was not appropriate to base the discussion on the topic on which the terminology was still undefined. Noting that WHO had already started examining that issue, the Delegation stated that once WHO came up with a common definition, WIPO would be able to adapt that wording. The Delegation observed that the proposal of the United States of America contained a request for a study on the impact of patent protection in promoting the development of lifesaving medicines. The Delegation pointed out that WHO had commissioned a study which was the basis for negotiations on the GSPOA. Therefore, it requested clarification about the added value of the study proposed by the Delegation of the United States of America. The Delegation state that it was well known that there was a lack of demand, a lack of medical insurance, a lack of adequate regulation on that issue. Furthermore, the Delegation pointed out that the current educational system was not encouraging innovation. The Delegation observed that WTO, WHO and WIPO were all supposed to implement some of the actions contained in the GSPOA and that about 100 were supposed to be implemented by governments. In that context, the Delegation raised the question as to which of those actions WIPO had to implement and how. Finally, the Delegation noted that the proposal was far from being complementary to the proposal of the African Group and the DAG. It expressed its wish that, when discussing the future work of the Committee, delegations would engage in good faith and constructively, since the problem of patents and public health was not limited to only developing countries. The Delegation encouraged a proactive, holistic, non-selective approach in order to address the fundamental human right to affordable medicines.

161. The Delegation of Egypt thanked the Delegation of the United States of America for its proposal which had been supported by Group B, the delegations of the European Union and the CEBS, and observed that such a wide support could be the indication of an emerging consensus within the SCP about a work program on patents and health in general terms. Furthermore, the Delegation expressed its appreciation to the Delegation of the United States of America for having affirmed its commitment to flexibilities. The Delegation expressed its concern about the proposal in which it stated that weakening the patent system through a greater use of flexibilities was not useful in securing better availability of medicines. The Delegation believed that flexibilities did not undermine the patent system, since they existed together and were enforced together. In its view, countries had the obligation to protect IPRs, but also to limit them in certain cases through the use of flexibilities. Therefore, the Delegation considered it important that the Delegation of the United States of America had expressed its commitment to flexibilities. The Delegation expressed its wish to go through the proposal by the

Delegation of the United States of America more carefully. The Delegation noted that the proposal of the African Group and the DAG was very specific and, in particular, focused on the enhancement of the capacity of WIPO Member States to use IP flexibilities. The Delegation observed that flexibilities already existed in the multilateral legal framework. It explained that their proposal was aiming at understanding a better use of flexibilities and was not asking for the adoption of new flexibilities. The Delegation observed that, on the other hand, the proposal of the Delegation of the United States of America seemed to address the issue of factors affecting or relating to access to medicines, which represented a very debated topic. The Delegation therefore asked for more time to analyze those elements. The Delegation raised some questions about the proposal. Firstly in relation to the reference in the first paragraph stating that only 4% of the medicines contained in the list of essential medicines were covered by patents, the Delegation asked which of those medicines were mostly needed, and what the situation in relation to the medicines not contained in that list was. Secondly, the Delegation requested clarification about the medicines covered by patents but not contained in the list. The Delegation noted that alternative approaches to flexibilities was a way that was worth explored. In that regard, it stated that, for example, patent pools, even if they had not yet been massively used by companies, should be encouraged. The Delegation pointed out that the WIPO initiative limited its focus on certain diseases such as HIV/AIDS, and requested clarification about the other diseases. The Delegation further asked which business models might be relied upon in relation to that topic and mentioned, for example, the initiative of GlaxoSmithKline concerning its pricing policy. The Delegation requested clarification about the relationship between the pricing policy and patents. In relation to efficient regulatory review, the Delegation observed that each country had its own system, and wondered which would be the ideal period of time to conduct such control, since it had different length according to countries and kind of medicines. With respect to enforcement, the Delegation observed that that topic might be better analyzed within other Committees such as the Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications (SCT) or the Advisory Committee on Enforcement (ACE). In relation to the proposal of inviting WHO experts to make presentations, the Delegation considered that such an initiative had a very narrow aspect, since it was limited only to non-patent barriers to access to medicine. In its opinion, since patent barriers had been excluded from the proposal, the study in question would have a very limited value. In relation to the study on the positive impact of patent system in providing lifesaving medicines, the Delegation observed that such impact might be positive or negative and that it would be of interest knowing the result of such a study. The Delegation however noted that the Commission on Intellectual Property and Innovation and Public Health at the WHO had already produced a study on that topic, which had focused on the interplay between the patent system and the production of medicine. It observed that the result of the study had been a mixed one, in the sense that it had turned out that patents could be an incentive to production to medicines, but not in developing countries or LDCs where there was no market and where the purchasing power was very weak. The Delegation expressed its doubt about the content of the study proposed, because of the risk of duplication of the effort made in relation to the WHO study. Furthermore, the Delegation was of the view that the third item of the proposal was outside the scope of the SCP, however, it was open for discussion in the following session of the Committee.

162. The Delegation of the Russian Federation supported the proposal made by the Delegation of the United States of America with respect to a presentation by WHO experts about the access and use of drugs particularly in developing countries, in order to have an idea on the impediments to access to medicines. The Delegation considered that impediments to access to medicines was an important aspect, since it was closely connected to the existence of falsified medicines, which further complicated the access to both patented and non-patented medicines. The Delegation believed that such a presentation would be an excellent basis for further discussion on the topic. Concerning a study on the positive impact of the patent system on the supply of medicines to save lives of individuals in developing countries, which had been suggested by the Delegation of the United States of America, the Delegation observed that there was an understanding expressed within the Committee that the patent system had not necessarily to be seen as a way of limiting access to drugs, given the existence of the TRIPS

Agreement. The Delegation was of the view that it was important to have a better understanding of the comprehensive reasons which limited the access to both patented and non-patented medicines. The Delegation pointed out that such a study would help the Committee to have a more objective picture of the influence of the patent system on the accessibility to patented and non-patented medicines. The Delegation stated that the proposal by the Delegation of the United States of America should be looked at together with the proposal made by the African Group and the DAG. The Delegation believed that the Committee should take into account the results of the work carried out by other international organizations and NGOs on those issues.

163. In response to the statement made by the Delegation of Zimbabwe, the Delegation of the United States of America reiterated that the Committee should adopt a holistic approach to the solutions they were seeking. The Delegation stressed the importance of not looking only at one single issue affecting access to medicine, but being able to view the larger picture. While the Committee did not have the mandate to take actions on all the aspects of the larger picture, the Delegation was of the view that it was within the Committee's capacity to understand, at least in a general way, all of the components that had an influence on access to medicines. The Delegation therefore thanked the Delegation of Egypt for their general support in terms of the need for more work to inform the Committee's decision making, and other Delegations that were seeking to have a better understanding of the bigger picture that the Delegation of the United States of America was asking for the future work of the SCP.

164. The Delegation of South Africa reiterated that it was more appropriate to look at the proposal made by the Delegation of the United States of America at the next session of the Committee, given its recent submission. The Delegation however was of the view that, given the intervention of different Member States, the Delegation of the United States of America should revise its proposal. The Delegation believed that, beyond the fact that the proposal had the structure of an academic paper, it did not fit well with the proposal submitted by the African Group and the DAG. The Delegation observed that the proposal made by the Delegation of the United States of America had the nature of a counterproposal rather than a complementary proposal. The Delegation reiterated that, instead of the references found in the proposal, it would better adopt the international language of the UN. Furthermore, the Delegation pointed out that there was a need to make a clear delineation of mandates, because the SCP should deal only with the issue of patents and health, not intellectual property and health. For example, while there was a reference to fake medicines in the proposal made by the Delegation of the United States of America, this was a trademark issue, not a patent issue. The Delegation believed that the two proposals should not be linked, since they were based on two different concepts: the proposal of the African Group and DAG was focused on flexibilities, while the proposal of the United States of America had a small focus on flexibilities and contained other proposals in respect of which more clarity was needed. Regarding the presentation by WHO experts suggested in the proposal by the United States of America, the Delegation considered that it was not appropriate to invite someone from the WHO to make a presentation without having understood the whole concept of the proposal submitted by the Delegation of the United States of America. The Delegation believed that the background and the information contained in the above proposal did not provide a good picture. The Delegation was of the opinion that a better understanding of the proposal by the United States of America was required before organizing any activities based on it.

165. The Delegation of Iran thanked the Delegation of the United States of America for its proposal and its contribution to the Committee. The Delegation however was of the view that the proposal was not balanced and was looking at the problem only from one single angle. Noting the intervention made by the Delegation of South Africa, the Delegation considered that the reference to enforcement contained in that proposal was particularly irrelevant. The Delegation pointed out that the issue of what falsified medicine was and what its interplay with the other medicines was, were not topics covered by the mandate of the SCP. The Delegation considered that the Committee should explore the ways in which patents could help, or provide

a solution to, access to medicine through a decrease in cost. The Delegation noted that the proposal by the United States of America considered that the patent system did not constitute a problem in that sense. The Delegation however observed that there was literature not in line with that statement and, on the contrary, deemed patents as a major obstacle in that area. The Delegation believed that the SCP could be a relevant forum to discuss that issue, even if it considered that the discussion within the Committee should be limited to patents as an obstacle, as well as an incentive, to access to medicine.

166. The Delegation of Cameroon supported the statement made by the Delegations of South Africa on behalf of the African Group, and asked for equal treatment in order to fix equitable objectives and reach equitable results in the long run.

167. The Delegation of Brazil thanked the Delegation of the United States of America for its proposal. The Delegation stated that it would analyze the proposal carefully. While having no comments at that moment, the Delegation expressed its appreciation for the intense debate that was taking place within the Committee, because it showed the centrality of WIPO in the question of patents and health. The Delegation considered that the SCP had a privileged place in that debate concerning patents, and supported the adoption of a work program on that issue. The Delegation also stated that the work program should be focused on patents, which was the subject matter of the Committee. In its opinion, the work program should be balanced and encompass the interests of all delegations in order to attain the real needs of WIPO Member States.

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

168. The discussions were based on document SCP/17/5.

169. The Delegation of Poland, speaking on behalf of the European Union and its 27 Member States, reiterated the importance of free communications between professional representatives and their clients in the framework of intellectual property matters, which entailed necessarily that the confidentiality of communications was ensured for both parties vis-à-vis third parties and particularly in the event of judicial proceedings. The Delegation expressed its belief that the convergence of diverse systems among Member States would be beneficial for users of the patent system irrespective of the level of development of individual Member States. Therefore, the Delegation expressed its support for the continuation of the work in the Committee, in particular, in respect of the possible remedies to the problems concerning cross-border privileges through, for example, extending the privilege or confidentiality internationally.

170. The Delegation of Switzerland noted that most of the countries did not provide laws and rules dealing with the cross-border aspects of confidentiality of communications between clients and patent advisors. The Delegation explained that, even in Switzerland in which a new legislation on patent attorneys and professional secrecy obligation had been enacted as of July 1, 2011, the question as to whether the relevant provisions of the new Patent Attorney Act could be invoked for preserving the confidentiality of the communications with foreign patent attorneys or not was not resolved. Considering the importance of the confidentiality of communications between clients and patent advisors in cross-border cases and the fact that only a few countries provided clear legislation in that field, the Delegation expressed its strong support for the submission of AIPPI, in which the continuing work of WIPO and the Member States was commended and the idea of the establishment of minimum standards of protection was launched. The Delegation expressed its support for the idea of minimum standards, which should not be mandatory but should give WIPO Member States guidelines on how to best address the topic and define national standards. In addition, the Delegation was of the view that the minimum standards should also reveal how countries had solved those problems with cross-border communications and confidentiality at the national level. Therefore, concerning the

future work, the Delegation suggested that the Secretariat prepare, with the help of the interested parties involved, such as, for example, AIPPI, a document describing possible minimum standards on the subject for the next session of the SCP.

171. The Delegation of France aligned itself with the statement made by the Delegation of Poland on behalf of the European Union and its 27 Member States and recalled the importance for French users of the issue under consideration. The Delegation therefore suggested the continuation of the work within the Committee, and expressed its interest in pursuing international and national mechanisms that would protect confidentiality of communications between clients and their advisors.

172. The Delegation of the Russian Federation referred to paragraph 24 of document SCP/17/5, which included the materials provided by the Delegation, i.e., the provisions of the Code of Arbitration Procedure of the Russian Federation, the Federal Law on Patent Attorneys, the Federal Law on Advocatory Activity and Advocacy in the Russian Federation, etc. In its view, those provisions demonstrated that a limited privilege for patent attorneys existed in its country, since conventional information in possession of a patent attorney could be made known to third parties following a court decision and/or where that was directly established by federal law. The Delegation considered that document SCP/17/5, in particular, the proposals put forward in paragraphs 28 to 32 of that document, were of interest to the Delegation and a good basis for further examination of the issues. Further, the Delegation reiterated its proposal to draft appropriate recommendations for minimum standards, which it had made at the 16th session of the SCP and as reflected in paragraph 297 of document SCP/16/9.

173. The Delegation of Spain supported the statement made by the Delegation of Poland on behalf of the European Union and its 27 Member States. The Delegation considered that the lack of uniformity regarding the recognition of confidentiality of communications between clients and patent advisors had raised a number of problems. In its view, free communications between clients and their patent advisors were necessary so that IP advice given by patent advisors was of the highest possible quality. The Delegation stated that such free communications did not exist if the confidentiality was not recognized at the international level. The Delegation observed that, since the international situation had been rapidly changing in a way that more and more inventors from emerging countries wished to protect their inventions in other countries, they would also be benefiting from the international recognition of confidentiality of communications between clients and patent advisors. Therefore, the Delegation stated that it could not understand the reasons for the strong opposition against discussing this topic, which would benefit the whole international community. In its view, there was no contradiction with the requirement of sufficiency of disclosure where an inventor was given the exclusive monopoly of the invention during a limited period of time in exchange of the divulgation of the invention in a manner sufficiently clear and complete for a person skilled in the art to carry out the invention. The Delegation considered that if no common norm was established, it was desirable to find a solution to the problem through international cooperation. The Delegation explained the situation in Spain on the issue of confidentiality of communications as follows: (i) confidentiality of communications between Spanish lawyers and their Spanish or foreign clients was recognized; (ii) industrial property agents who were not lawyers had an obligation of confidentiality with clients, but that was not recognized in the court procedures; and (iii) confidentiality of communications with foreign industrial property professionals, except those lawyers who were entitled to act before the Spanish courts, were not recognized. The Delegation supported further work on the topic, searching for solutions to the problem, especially with respect to the following issues: (i) the nature, type and scope of communications which were confidential; (ii) the qualification of patent advisors whose communication with clients would be protected; (iii) possible exceptions and limitations to the privilege of confidentiality; and (iv) particularly, how to extend the confidentiality of communications at the international level. The Delegation considered that it would be desirable to establish minimum standards on those issues.

174. The Delegation of Denmark stated that the issue of securing the confidentiality of communications between clients and patent advisors was of high importance for patent advisors, users and the patent office of its country which strived to provide the best framework and conditions for all. In relation to the future work, the Delegation supported the statement made by the Delegation of Poland on behalf of the European Union and its 27 Member States as well as the suggestions made by the Delegation of Spain.

175. The Delegation of the United States of America expressed its support for further analysis of information contained in document SCP/17 5. Specifically, the Delegation suggested the preparation by the Secretariat of an analysis of such information for further study and discussion of possible remedies and courses of action to address the issue at the next meeting of the SCP. The Delegation also suggested further discussion among Member States regarding best practices, practical solutions and national experiences on that topic, which could be used on a fully voluntary basis by Member States. In addition, the Delegation strongly supported the views of AIPPI expressed in its submission on the issue.

176. The Delegation of Australia noted that document SCP/17/5 and other documents produced within the SCP showed that, although most countries recognized some level of confidentiality between patent applicants and their advisors, few countries had explicit regulations concerning foreign patent advisors. The Delegation considered that it was an issue that would gain prominence as the globalized nature of trade and transfer of technologies, which were both supported by intellectual property, increased. The Delegation suggested that WIPO and the SCP engage in further work proactively. The Delegation clarified that it was not suggesting that a totally uniform solution was ultimately achievable. However, in its opinion, further work would be of great use to all SCP members, and might forewarn members of issues that might arise in the future and give them the benefit of others' experience when deciding how to deal with them in their own jurisdictions. In summary, the Delegation expressed its support for the preparation of further study by the Secretariat, which would build upon document SCP/17/5 and identify possible mechanisms that could be considered by Member States in their own jurisdictions.

177. The Delegation of Japan noted that, as described in document SCP/17/5, many common law and civil law countries did not recognize confidentiality in cross-border cases or did not explicitly express whether it was recognized or not. There were also countries which had not clearly decided the future direction. The Delegation considered it important to realize a system where applicants could file patent applications across different jurisdictions in a safe manner. Therefore, the Delegation supported further discussions on the topic.

178. The Representative of CEIPI stated that he was very interested in the agenda item under discussion being pursued. The Representative expressed the wish that the Committee entrust the International Bureau with the task to study adequate measures in order to solve the problems relating to the cross-border aspects of confidentiality of communications between clients and patent advisors.

179. The Representative of CIPA and IP Foundation stated his interest in developing a system across the globe with a well-functioning, cross-border confidentiality. He also considered that the more global the IP world got, the more vital it would be not only for the big players but also for people in developing countries. He noted that, if a patentee from a developing country wished to enforce his patent in, for example, the United States of America, he would not be able to preserve the confidentiality of his communications if there had not been a system in place at his home country. The Representative clarified that the issue was not about the confidentiality of documents that had to be produced in nearly all jurisdictions, but about the confidentiality of communications that were subject to confidentiality.

180. The Representative of IPIC expressed his belief that confidentiality of communications between clients and patent and trademark agents was an important part of a well functioning patent and trademark system. Because of the importance of privilege and the international

nature of patent protection, the Representative encouraged the Committee to continue examining the issue of confidentiality and privilege, and to seek mutual understanding and cooperation among Member States in support of the protection of confidential client/agent communications.

181. The Representative of GRUR expressed his support for the position of AIPPI and FICPI regarding the issue of protection of confidential information produced between clients and their patent attorneys, giving special legal advice in the field of industrial and intellectual property, with a focus on trans-border communications. The Representative was grateful to a number of delegations, including the members of the European Union, for supporting retaining the issue on the agenda of the Committee. The Representative considered that the legal status and privilege of lawyers and attorneys at law in respect of confidential information should be accorded or extended without discrimination also to patent attorneys and other intellectual property law advisors. He reiterated that the protection of privilege generally available to lawyers or attorneys in free practice was, in essence, a human rights issue which was closely interrelated with the right of any party to have fair proceedings and due process under the rule of law. Further, the Representative was of the view that the issue should be considered on the basis of the principle of non-discrimination, since patent attorneys had a similar professional qualification and training to that of lawyers. Patent attorneys gave legal special advice in special fields of law, which required special training, special expertise and experience in sciences and engineering. Therefore, in his view, it appeared to be mandatory to consider the extension of protection under the principle of due process and non-discrimination. Starting from those principles and taking into account a prominent international character of intellectual property in the activities of patent attorneys related thereto, the Representative observed that the simple national approaches advocated by many delegations during the previous meetings would not be attainable in view of, for instance, the PCT system with its distribution of responsibilities between Receiving Offices, the International Searching and Preliminary Examining Authorities and Designated and Elected Offices. The Representative clarified that the said two principles had their exceptions and limitations: for example, neither applicants nor their attorneys were entitled to willfully conceal knowledge about the state of the art available to them before the patent office or court, which would be rightly considered as fraud on the patent office or obtaining a patent by false pretenses. In his view, further elaboration of the details would be necessary in the minimum standards mentioned by several delegations. According to the Representative, one of the reasons why many countries were reluctant to discuss the issues in the WIPO body was the relatively small number of patent attorneys, as compared with the sometimes huge number of lawyers or attorneys-at-law in several countries, including Germany. However, the Representative observed that, at least in Germany, contribution of patent attorneys to a sound and viable patent system on the protection of innovation was fully respected and acknowledged, and therefore, the legal situation of the profession and its problems deserved and received the fullest attention. Further, the Representative noted that activities of professional patent attorneys were not well known among the general public, and frequently ignored, which was particularly true for the specific activities in the field of patents. The Representative also observed that the professional concerns and problems of patent attorneys were of no interest for most of the international organizations, including the WTO in spite of the GATS Agreement. The Representative therefore noted that WIPO remained the only proper international forum where patent attorneys' advice and contributions to the efficiency of the systems administered by WIPO was fully respected. While patent attorneys could continue trying to find solutions only at the national or bilateral level, the Representative considered that, in view of their close partnership with WIPO and the services WIPO offered to the world, there was a good reason to bring their concerns and discuss the issues in the SCP.

182. The Representative of FICPI noted that client-patent advisor privilege should be considered in the global context, since most patent matters were no longer related to just one country but were of international in character. The Representative expressed his belief that, for a proper functioning of the IP systems throughout the world, it was of the utmost importance that IP advisors and their clients could have frank, open and honest communications so that a client

could obtain the best opinion and advice. In his view, documents SCP/16/4 and SCP/17/5 provided a promising starting point for future work. The Representative stated that the notion that the client-attorney privilege was a privilege awarded to the client, not to the attorney, should be no different for client-patent advisor privilege. The Delegation observed that, while some of the delegations feared that awarding client-patent advisor privilege could lead to a deterioration of the disclosure of inventions in patent applications, the distinction should be made between the sufficiency of disclosure in patent applications as required in national and international patent laws and treaties and the issue of privilege. Since the lack of disclosure should lead to refusal of the grant of a patent or nullity of an already granted patent, the Representative noted that client-patent advisor privilege would not lead to changes in the completeness of disclosure in patent applications. In conclusion, the Representative strongly supported further work on the issue.

183. The Representative of ICC reiterated that the issue under consideration was a true cross-border issue which was so important both for right holders, for parties potentially affected by others' patent rights, and for society at large as having the general interest of justice. In his view, the need for international actions on the issue was clearly demonstrated by the information provided at the SCP session. The Representative urged the Committee to keep the topic of client-patent advisor privilege on the agenda for continued work, especially on the cross-border aspect and on available remedies. Further, the Representative encouraged Member States to provide information on the status of their countries, if they had not done so.

184. The Representative of APAA noted that her organization had adopted a resolution on the issue at its 56th Council Meeting two years ago. Considering the fact that IP was international in character, that a client needed to have full and frank communications not only with the domestic patent advisors but also with patent advisors in other countries, and that IP related litigations had become more international, for example, the patent dispute between Samsung and Apple in different jurisdictions, the Representative stated that a client might face a high risk that confidential communications between clients and patent advisors which were protected in one country were forced to be disclosed in another country during litigation, thereby potentially undermining clients' ability to obtain suitable legal advice on IP-related matters. The Representative expressed her support for a continuing assessment of current and prospective problems under the diversified legal system and for studying the feasibility of setting minimum international standards for future recognition of confidentiality of communications between clients and patent advisors, in an accelerated manner.

185. The Representative of ABA expressed its support for the submissions of AIPPI regarding the cross-border aspects of confidentiality communications.

186. The Representative of IPO stated that his organization supported the recognition that the attorney-client privilege applied to cross-border communications between clients and international patent professionals around the world. Therefore, he supported further work of the Committee on the issue.

187. The Representative of AIPPI referred to his submission which had been posted on the SCP electronic forum, and observed that the responses of the Member States and observers to WIPO’s inquiries on cross-border aspects of confidentiality and potential remedies, as reported in document SCP/17/5, were consistent with AIPPI's findings as submitted to WIPO in October 2010. He further stated that the responses of the Member States and observers and AIPPI's findings showed that many, if not most, countries did not provide such protection, had no laws proposed to provide such protection or there were no proposed remedies. The Representative expressed its support for studying remedies in the SCP, since the problems had been well-established in the SCP and the SCP process had the potential of obtaining the inputs from all Member States. In conclusion, the Representative urged all Member States to mandate WIPO to study and report to the SCP on remedies and preferred courses to solve the problems. In his view, that would allow all Member States to contribute to the process of analyzing potential remedies.

188. The Delegation of Algeria, speaking on behalf of the DAG, noted that the client-patent advisor privilege had not been recognized in all countries, and that there were a variety of approaches, treatments and legal judicial practices existing even in those countries with a similar legal system. The Delegation reiterated that the DAG did not share the view that the Committee could come to some common understanding, which might become the basis of pursuing the topic further. The Delegation considered that, in many countries, the law of privilege was a matter that fell within the purview of the law of evidence and not substantive patent law. Hence, it should not be discussed in the Committee. The Delegation reiterated the position of the DAG, which was reflected in the draft Report of the previous session of the SCP, namely, paragraph 298 of document SCP/16/9 Prov.2.

189. The Representative of AIPLA expressed its support for the suggestions made by the Representative of AIPPI with regard to client-patent advisor privilege for communications involving legal advice on patent matters. The Representative considered that continued study in the Committee was important to clarify and catalog mechanisms and remedies involving protection for client-patent advisor communications. For example, the Representative stressed the importance of clarifying whether confidential disclosure agreements alone were adequate to provide protection, since courts in one country who decided on the issue of privilege and scope of protection would look to the national standards in a second home country for guidance, and optimally would look to international standards based on the discussions in the Committee.

190. The Delegation of South Africa, speaking on behalf of the African Group, recalled the position of the African Group on the topic, which was reflected in the draft Report of the previous session of the SCP, i.e., paragraph 307 of document SCP/16/9 Prov.2. The Delegation noted that the main issue that had been raised by the African Group at that time was that the issue under discussion fell within the purview of national law, within the scope of private law and the regulation of professional services. Therefore, in its view, it was not an issue that should be discussed in WIPO. The Delegation also referred to the conclusion of the last session of the SCP, reflected in paragraph 17(b) of document SCP/16/8, which stated that “Some delegations stated that this issue was a matter of national law. Recognizing the differences in national law and procedure, the Chair stated that the Committee felt that there was no consensus on international norm setting or a set of common principles at this stage”. The Delegation therefore stated that, although it could support a study, it was not in the position to support any future work which would involve the setting of international norm or the setting of common principle on the issue.

191. The Representative of JPAA stated that the issue of client-patent advisor privilege was important not only for patent advisors in developed countries, but also for patent advisors in developing countries, because of worldwide activities of patent advisors. Therefore, the Representative supported the view expressed by the Delegation of Switzerland relating to setting up minimum standard, and suggested the Committee to continue discussing the issue in its future sessions.

192. The Delegation of Brazil stated that it shared the concerns expressed by the Delegations of South Africa on behalf of the African Group and Algeria on behalf of the DAG. Quoting the sentence in paragraph 261 of document SCP/14/2 which stated that “it appears that it is neither practical nor realistic to seek a uniform rule that could involve fundamental changes in national judicial systems”, the Delegation considered that a very cautious approach was necessary, since, in many cases including the case in its country, the issue was a matter of constitutional law and civil procedural law, and the involvement of many other aspects made the discussion on the topic very complex.

193. The Delegation of Egypt aligned itself with the statements made by the Delegations of South Africa on behalf of the African Group, Algeria on behalf of the DAG and Brazil, and reiterated its position expressed during the sixteenth session of the SCP.

194. The Chair noted that it was his understanding from the previous session of the SCP that the Committee would not engage in norm-setting rules or setting common principles on the issue of confidentiality of communications with patent advisors, but could continue its discussions. In that regard, the Chair's understanding was that the suggestions of the delegations to look into minimum standards was not that those minimum standards would be set as a matter of norm-setting or as mandatory minimum standards, but just as a voluntary minimum standards for the countries that wanted to deal with the issue and adopt a solution.

AGENDA ITEM 9: TRANSFER OF TECHNOLOGY

195. The discussions were based on document SCP/14/4 Rev.2.

196. The Chair noted that the summary of the Special Seminar on Patents and Technology Transfer, organized by the WIPO Chief Economist in the morning of December 5, 2011, had been distributed in the three working languages of the SCP and posted on the website.

197. The Delegation of South Africa, speaking on behalf of the African Group, welcomed the changes made to document SCP/14/4 Rev.2. The Delegation, in particular, noted paragraph 207, newly elaborated by the Secretariat. The Delegation, however, stressed the need of additional work in terms of soliciting practical experience, in particular, practical cases, to augment the Chapter 11 of the document on impediments and incentives. The Delegation, therefore, supported continued work by the Committee, as proposed in paragraph 207 of the document, and expressed its wish to maintain the agenda item on the Committee's work.

198. The Delegation of the United States of America, speaking on behalf of Group B, thanked the WIPO Chief Economist for the informative Seminar which, in its opinion, had highlighted the role of patents in technology transfer. The Delegation observed that the revised document, SCP/14/4 Rev.2, emanated from lengthy discussions that had taken place during the sixteenth session of the SCP. The Delegation believed that the main themes that had emerged from those discussions were: (i) the perceived insufficiency in document SCP/14/4 Rev. was mostly observed around the lack of specific sections on patents as impediment to technology transfer; (ii) the request for a seminar by the WIPO Chief Economist, which had been held on the first day of the SCP; (iii) the duplication of work between the SCP and CDIP; and (iv) the involvement of organizations with practical experience in technology transfer, including the Licensing Executive Society International (LESI) and the Association of University Technology Managers (AUTM). The Delegation expressed its appreciation to the Secretariat for its work in taking those concerns on board and revising document SCP/14/4/Rev.2 and for having organized the seminar. The Delegation believed that the seminar provided a significant body of information that would be important for IP Offices use of the IP system and the broader public. The Delegation, however, reiterated that there was a need to avoid the duplication of work carried out in other committees. In particular, the Delegation pointed out that a technology transfer project was underway in the CDIP (documents CDIP/6/4 Rev. and CIPD/8/7). The Delegation stated that, in the opinion of Group B, the CDIP was the appropriate forum for further discussions on that topic. Nevertheless, the Delegation believed that the SCP should wait for the results of document CDIP/8/7 in order to take a more informed decision on how to proceed.

199. The Delegation of Poland, speaking on behalf of the European Union and its 27 Member States, observed that the Seminar on Patents and Technology Transfer, organized by the WIPO Chief Economist in the morning of the first day of the Committee, illustrated that patents could facilitate transfer of technology, depending on the business model and the sector concerned, and emphasized that patents were not the only determinant factor of technology transfer. The Delegation, in relation to the future work on the issue, recalled its position presented during the sixteenth session of the SCP, held in May 2011, and during the CDIP in relation to the project on intellectual property and technology transfer. The Delegation observed that extensive work

dealing specifically with the issue of technology transfer was being carried our under the CDIP project, and therefore, it was reluctant to launch any new initiative on that topic before the completion of the CDIP project and the analysis of its results.

200. The Delegation of Brazil considered that document SCP/14/4 Rev.2, which incorporated several comments from Member States, presented a more balanced assessment of the subject. The Delegation welcomed the Seminar on Patents and Technology Transfer as well as the insertion within document SCP/14/4 of a new chapter on incentives and impediments to transfer of technology. The Delegation stated that, in its opinion, when assessing transfer of technology, it was necessary to take into account the issue of the capacity of the countries to absorb technology and what the intervening factors were. The Delegation pointed out that the mere existence of a patent system in a given country did not translate *per se* into a successful transfer of technology. With that regard, the Delegation noted that the revised document addressed situations in which the patent system did not function in the intended manner and hindered access to technology. The Delegation recalled that, 50 years ago, Brazil had made a proposal to the General Assembly of the United Nations on transfer of technology, the outcome of which was the adoption of Resolution 1713(XVI) of December 19, 1961, instructing the Secretary General of the United Nations to prepare a report “on the role of patents in transfer of technology to under developed countries”. The Delegation therefore stressed that the debate on that topic was not new and remained relevant as demonstrated by the ongoing discussions in the SCP and in other fora, such as the United Nations Framework Convention on Climate Change (UNFCCC). The Delegation welcomed a full understanding of the aspects involved, since one of the main benefits that WIPO Member States could get from participating in the organization was the possibility of effective transfer of technology.

201. The Delegation of the Russian Federation noted that document SCP/14/4 Rev.2 focused on the problems of technology transfer in the context of development and illustrated, *inter alia*, the recommendations contained in the Development Agenda. The Delegation considered that the latter was of particular interest for the Russian Federation, in particular, with respect to the establishment and development of technology and innovation centers. The Delegation noted that paragraph 187 of the document included information about the fact that WIPO was encouraging the creation and development of such centers and provided a link on the WIPO website where a list of countries where such centers had been already set up had been given. The Delegation noted that the purpose of such information was to provide innovators with access to reliable and high quality information about technology and other services. The Delegation pointed out that its country had been taking all the measures to set up and develop innovation and technology development centers in the Russian Federation, which included services such as professional training and networking and which would provide also regular refresher courses, as well as a regional network of such centers, the purpose of which would be the exchange of information and best practices in that area. The Delegation specified that the setting up of such technology and innovation support centers in the Russian Federation, with WIPO’s assistance, was discussed at an Inter-Regional Symposium on Problems of Access to Patent Information and Strategy for its Use in Order to Promote Innovations, held in Moscow from November 30 to December 1, 2011, and which aroused a great deal of interest., since the dissemination of patent information was one of the basic tools that could be used to build and develop a national innovation system in the Russian Federation. The Delegation pointed out that the plan that WIPO was helping to set up in relation to the establishment of such centers in its country would improve access to technical knowledge for users from different countries and also from regional and sub-regional organizations dealing with the matter of intellectual property, so that they might use effectively such knowledge and thereby innovation and economic growth would be stimulated and encouraged. The Delegation explained that the project provided for the establishment of one or more centers in the Russian Federation would cover a wide range of services: from the provision of information about patents and technologies, to consultations and advice to be provided to the whole innovative and creative process from the original idea to the marketing of the final product. In its view, the centers would benefit SMEs, individual creators, scientific institutions, schools, universities, and other potential users. The Delegation

stated that the project aimed to achieving the following results: expanding the opportunities for staff of the centers; providing economic and development assistance to those cooperating with the centers; achieving stable financial development of the centers; increasing the level of knowledge of users on the intellectual property system; increasing technology transfer; expanding the possibilities for users in relation to the acquisition, protection and management of their intellectual property rights; and passing on experience of the activities of a center to other centers both within the country and overseas. The Delegation said that, between WIPO and ROSPATENT, a Memorandum of Understanding had been signed on the creation of technology and innovation support centers. The Delegation noted that the terms of that Memorandum regulated issues relating to the organization and provision of centers in the Russian Federation. The Delegation noted that therefore, the Memorandum included details of the responsibilities of WIPO and ROSPATENT in creating a network of centers. In particular, the head office would be located in Moscow on the premises of ROSPATENT, and would act as the main center in the network of centers in the Russian Federation. The Delegation explained that the centers would be created along the following lines: (i) an initial analysis of users' requirements; (ii) a WIPO preliminary assessment procedure; (iii) training of specialists; (iv) launch of centers; (v) additional training for center employees; and (vi) creation of a network of centers. The Delegation noted that, on the basis of the results of the center's activities, reports would be drawn up in order to assess the tasks completed and top take a decision on the suitability of further development of the project. The Delegation observed that the network of centers would be located in institutions to be defined by ROSPATENT for the purposes of enhancing national potential and intellectual property infrastructure. It would be coordinated by ROSPATENT and in turn, in accordance with the Memorandum, WIPO would provide methodological, organizational and technical support for the project to create a network of centers in the regions of the Russian Federation. The Delegation noted that the creation of a network of centers based around ROSPATENT would serve as a key factor in the rapid dissemination of knowledge and would strengthen the national technological base. As regards the Economic Seminar, the Delegation thanked the Secretariat and the Chief Economist for organizing that Seminar, since the issues examined during the Seminar in relation to incentives for, and impediments to, the transfer of technology from the point of view of the patent system, and how practical experience was used in relation to the role of patents in technology transfer, were important for the Russian Federation in future discussions of the issue.

202. The Delegation of Egypt considered the Seminar particularly useful in order to understand the dynamics and the interplay between the patent system and transfer of technology. The Delegation reiterated its statement made during the last session of the Committee, and emphasized that WIPO should continue to focus on the issue of technology transfer. The Delegation expressed its wish to mention three specific points justifying why the SCP needed to continue to focus its work on the interplay between the patent system and the transfer of technology. Firstly, referring to document SCP/14/4 Rev.2 which stated that the patent system would make a positive contribution to the transfer of technology only when the system functioned according to the way it was conceived, the Delegation considered that the question as to what were the situations in which the patent system did not function in the intended manner so that it might have a negative, rather than a positive, effect on the efficient transfer of technology remained open on that point. The Delegation was of the view that the SCP should not leave the discussion open at that stage, but it would be appropriate to continue to address it. The Delegation welcomed the suggestion previously made to conduct more focused studies in that regard to better understand the exact magnitude of the negative contributions to an efficient transfer of technology caused by the use of the patent system. In its opinion, such an important question should be continued to be explored. Secondly, the Delegation observed that the Seminar revealed that the IP system, and in particular the patent system, could be misused by actors, who, instead of adding something to the existing knowledge and favoring the technology transfer, used litigation and enforcement of IPRs in order to get more benefit from the system. The Delegation believed that the SCP should look also at that aspect in order to avoid such misuse happen or affect transfer of technology. Thirdly, with the hypothesis that basic technologies were strongly protected by the patent system, the Delegation considered that

transfer of technology for Government use, not for commercial purposes, should be facilitated, and in particular, should not be subject to extraneous conditions and lengthy negotiations. In the light of those three points, the Delegation expressed its support to the statements made by the Delegations of South Africa, Brazil and the Russian Federation, requesting the continued work on the issue, focusing on the capacity building and the training needs, also of SMEs in LDCs, in order to make the patent system functioning well in relation to technology transfer.

203. The Delegation of the Republic of Korea expressed its wish that delegations would have a good discussion, exchange their standpoints and well understand each other on the key options about technology transfer. The Delegation believed that there was a lot of promise on technology transfer, and that the SCP had to focus on the fact that technology transfer in the framework of the patent system might happen in two different phases: first, before the grant of a patent and, second, after the grant of a patent. In its view, technology transfer before the patent granting, even if it was important for research and development and even if it could have practical effects, fell outside the scope of the discussions. The Delegation therefore considered that patentees were the main actors of technology transfer, since the phase after patent granting fell within the scope of technology transfer in the framework of the patent system. The Delegation noted that although the patent system might not be the best way to achieve technology transfer, nevertheless, it was one method of transferring technology. The Delegation considered that the SCP should focus on the patent perspective of technology transfer. It observed that a patent owner did not want his right to be taken away, and that document SCP/14/4 Rev.2 prepared by the Secretariat was supportive to the patent system. The Delegation expressed its wish that patentees would take part in the process of technology transfer voluntarily, and that WIPO would make use of its role as a match maker in technology transfer, providing transferrable technology from technology providers to technology users.

204. The Delegation of Uruguay observed that the SCP had an important role to play in the area of technology transfer, because the patent system was a fundamental tool in the process of technology transfer. The Delegation noted that one of the functions of the patent system was making the transfer of knowledge and its use possible. The Delegation believed that patents made it possible to convert the knowledge contained in technology into an economic asset and into a transferrable good. The Delegation, however, considered that the proliferation of patent applications did not correspond to the evolution of new inventions. The Delegation noted that an influx of low quality patents was restricting the access to technologies and making technological access more complicated. The Delegation observed that this situation was having a negative impact on developing countries as well as other negative effects on, for example, creating and generating knowledge and R&D activities. The Delegation noted other problems related to the restricted access to technologies, such as hampering technical development, the difficulty in sharing knowledge and in accessing relevant technologies and the complexity of assessing the quality of technologies. Furthermore, the Delegation pointed out that it was not easy to negotiate technology transfer agreements when technologies were protected by patents. The Delegation observed that that phenomenon, from an economic perspective, led to a significant increase in the cost of transactions, given that such kind of negotiation required a specialized knowledge, usually available by a team of specialists. The Delegation was of the view that, usually, those who could take advantage of the exploitation of technology were the major international corporations coming from developed countries, while technologies developed in research institutes and universities in developing countries often turned out to be fruitless. The Delegation observed that inventions of the latter were normally licensed to those major international corporations at conditions not particularly favorable for the licensors from developing countries. The Delegation therefore asked the Committee to undertake studies on the transfer of technologies in order to analyze the repercussions on the transfer of technology of those negative features which the patent system had gradually taken on, in particular in developing countries. The Delegation recognized that the Secretariat had made a considerable headway on that point, through the illustration of how such problem interacted with the patents system and its repercussions on technology transfer. The Delegation stated that it was important to look at that question from a systemic point of view. The Delegation stressed the

necessity of having good quality patents with proper details and with claims drafted in a clear and comprehensible way, and not in a vague and complicated manner which would make it difficult to understand the invention. In its view, all those aspects made it difficult to have fluid, smooth and effective negotiations on transfer of technology. The Delegation pointed out that, although the work carried out by the Secretariat helped the Committee to move forward in relation to certain aspects concerning the so-called ”development dimension”, those considerations had not yet been included as an integral part of the technology transfer process. The Delegation believed that the aspects taken into consideration in the study prepared by the Secretariat were secondary, and that the focus should have been on the improvement of fluidity of royalties from developed to developing countries. Noting that, in the last 20 years, enormous changes had taken place, the Delegation observed that WIPO should step up its efforts on those topics, and commended the recent study “World Intellectual Property Report: the Changing Face of Innovation” that represented an excellent example in that direction. The Delegation requested the inclusion in the study of the aspects dealt with in its intervention and to take them into consideration in the further discussions of the Committee. The Delegation believed that that would help the Committee in the analysis the problems related to the international patent system and technology transfer.

205. The Delegation of Australia pointed out that, before deciding whether the item of technology transfer should be kept on the agenda of the SCP or not, the Committee should wait for the result of the work of CDIP on the same topic, in particular, the project described in document CDIP/6/4 Rev. The Delegation believed that the study to be carried out under that project was expected to deal with both the positive and negative aspects of the patent system in respect to technology transfer.

206. The Delegation of South Africa noted that paragraph 207 stated that the Secretariat should take into account the activities done in other bodies of WIPO, specifically the CDIP. In its view, that paragraph was particularly clear in relation to the practical way forward.

AGENDA ITEM 10: REVISED RULES OF PROCEDURE

207. The discussions were based on document SCP/17/6 and 6 Rev.

208. The Delegation of Spain expressed its gratitude to the Secretariat for extending the language coverage to all six UN languages. The Delegation recognized the special efforts made by the Secretariat and the challenge involved, as well as the key role that multilingualism played in the UN. As regards the proposal for the revision of the Rules of Procedure, the Delegation reminded the Committee that the purpose of that reform was to lead to a balanced use of the six official languages and guaranteed coverage of the Committee's proceedings in all six languages. In its view, that had to be reflected in the Rules of Procedure. The Delegation expressed its understanding for the reasons why the proposal had mentioned exceptionally voluminous documents. However, that possibility should be used only in exceptional cases, such as, for example, a case similar to a document of about 700 pages compiling replies to the questionnaire on exceptions and limitations. The Delegation urged that, under no circumstances, that should be an excuse for not translating documents that were longer than usual. It noted that, in any case, if a Member State were to request a translation of an exceptionally voluminous document into one of the languages, that should be considered to be done as quickly as possible, to avoid situations such as the one where requests to translate an exceptionally voluminous document had taken up more than six sessions of the Committee. The Delegation stated that those concerns should be reflected in the text of the Rules of Procedure in order to avoid such situations. To give another example, the Delegation noted that, while the document of 700 pages was an exceptionally voluminous document, in other Committees, documents of 10 or 20 pages had not been translated and only a summary had been prepared, invoking the reason of exceptionally voluminous documents. Furthermore, the

Delegation stated that the Secretariat should further keep an eye on the quality of the translation of the documents and that the extension of languages should not compromise the quality of translation.

209. The Delegation of China expressed its support for the revised Rules of Procedure, namely, providing multilingual documents.

210. The Delegation of South Africa, speaking on behalf of the African Group, supported the amendments to the Rules of Procedure.

211. The Delegation of France expressed its understanding for the reason underlying the rule on exceptionally voluminous documents, but shared the concern expressed by the Delegation of Spain. In its opinion, it was important that that rule remained an exception and only concerned truly voluminous documents.

212. The Delegation of Algeria, speaking on behalf of the DAG, supported the recommendations in the document and adoption of the amendment of the Rules of Procedure.

213. The Delegation of Panama, speaking on behalf of GRULAC, supported the statement made by the Delegation of Spain.

214. The Delegation of Switzerland referred to the lengthy discussions held during the Program and Budget Committee (PBC). The problem with the length of documents had been discussed at the PBC in order to determine how long a document had to be to be considered voluminous. In its view, the discussion on establishing more precise rules about the length of documents should take place in the PBC, because of the great financial implications. The Delegation expressed its understanding for the fact that delegations wished to see documents in all languages, but the budgetary policy had been developed and, at the same time, one had to introduce rationalizations to the documents in order to restrain the costs. At that stage, the Delegation was not in favor of amending the rules which had been decided by the PBC. It was planned to review the budgetary implications of the adopted language policy in the first couple of years so as to go back to the decision of the PBC. In that regard, the Delegation stated that the SCP should adopt the existing rule, and should not add further clarification to the rule which might jeopardize the discussion taking place within the PBC. In its opinion, clarification should be given in the body that determined budgetary policy as a cross-cutting decision affecting all Committees.

215. The Delegation of Portugal supported the intervention made by the Delegation of Spain.

216. The Delegation of Spain proposed to keep the first part of the text, where the coverage was extended to the six UN languages and add a reference to the language policy of the Organization. In its view, the exception applied to voluminous documents should not be included as something that had been recommended by the Assemblies as the “one and only” exception.

217. The Chair proposed to refer back to the decision of the Assemblies rather than focusing on a subset of exceptions. Against this background, revised draft Rules of Procedure (document SCP/17/6 Rev.) were prepared by the Secretariat and submitted to the Committee for its consideration.

218. The SCP adopted the special rules of procedure set out in paragraphs 4 and 5 of document SCP/17/6 Rev.

AGENDA ITEM 11: FUTURE WORK

219. The Chair presented his suggestions to the Committee on future work relating to each topic.

220. The Committee discussed, in particular how to accurately reflect, in respect of future work, the discussions held on each topic and the way forward, for example, the format of the compilation of the responses to the questionnaire on exceptions and limitations to patent rights, the scope and nature of the study on cross-border issues regarding the confidentially of communications between clients and their patent advisors, the modalities of a study on patent-related incentives and impediments to transfer of technology and the possibility of organizing a seminar related to transfer of technology to complement that study.

221. With respect to exceptions and limitations to patent rights, the Delegation of Brazil submitted a non-paper containing its proposal on the future work of that agenda item.[1] There

[1] **Context**

Brazil presented a proposal for a Working Program on Limitations and Exceptions to patent rights (SCP/14/7) at the 14th Session of the Standing Committee on the Law of Patents (SCP). Given that the establishment of such a working program would be an important step in the implementation of the Development Agenda, the delegation of Brazil calls for its adoption by the SCP.

Three Phases

The proposed program consists of three phases, as described below:

The first phase shall promote the exchange of detailed information on all exceptions and limitations provisions in national or regional legislations, as well as on the experience of implementation of such provisions, including jurisprudence. The first phase shall also address why and how countries use – or how they understand the possibility of using – the limitations and exceptions provided in their legislations.

The second phase shall investigate what exceptions or 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 third phase shall consider the elaboration of an exceptions and limitations manual, in a non-exhaustive manner, to serve as a reference to WIPO Members.

Additional analysis on the responses to the questionnaire

While replies to the questionnaire approved by members during the 16th Session contain a good deal of valuable information, analysis of that information is yet to be undertaken in-depth. Replies to the questionnaire are in fact only the first part of the first phase.

Debates carried out under Agenda Item 5, "Exceptions and Limitations", have highlighted the need for further analysis of the information provided by Member States that have already answered the questionnaire.

Document SCP/17/3 compiles answers submitted by 48 Member States and one Regional Patent Office. It provides only a panoramic view of the rich material available to the SCP, being a preliminary report. It must be enhanced with additional analysis of the data provided in answers to the questionnaire.

Following the request from the Secretariat for further guidance on the subject, we would like to take this opportunity to submit the following suggestions, in a non-exhaustive manner. These suggestions are meant to complement the coverage of the 1st phase:

[Footnote continued on next page]

was a general understanding within the Committee that, when preparing a new document presenting the answers to the questionnaire on exceptions and limitations to patent rights, the Secretariat would interpret or analyze neither the responses to the questionnaire, nor the respective national/regional laws.

222. The Delegation of Brazil suggested that, with respect to the future work on exceptions and limitations to patent rights, the Brazilian proposal be referenced as remaining on the table for discussion at the following session of the SCP.

223. The Chair clarified that, although the proposal by Brazil was not referenced in the part of future work, that proposal would be included in the agenda of the eighteenth session of the SCP and consequently, would remain on the table for future discussion.

224. 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.

225. After some discussions, the SCP agreed that the future work of the SCP would be carried out as follows:

(a) Exceptions and Limitations to Patent Rights

(i) This topic will remain on the agenda of the 18th session of the SCP.

(ii) The deadline for further submissions of, or supplements to, answers by member States and regional offices to the questionnaire (document SCP/16/3 Rev.) is extended to March 9, 2012.

(iii) The Secretariat will post the answers received on the SCP electronic forum.

(iv) The Secretariat will prepare, for SCP/18, a new document which will present the answers contained in document SCP/17/3 and 3 Add, as well as those received by the above deadline, in a revised format, allowing an easier understanding of the material, presenting statistics and reorganizing the information provided in clusters, based on, for example, the sections of the questionnaire.

[Footnote continued from previous page]

- A detailed statistical analysis of the responses, with a view to identify some trends, such as exceptions & limitations that are widely adopted and others that
are less frequent. An additional mapping of the answers could describe the legal provisions regarding the different categories of exceptions'.
- An examination of what the public policy objectives underpinning the exceptions & limitations are. Can these objectives be clustered in categories?

- An assessment of the difficulties faced by Member States when actually implementing the E&L to patent rights. It would be interesting to have qualitative indication as to why some exceptions are widely used while some others are not.

- Some exceptions & limitations have been implemented by Court decisions in certain cases. What were the grounds for such decisions? What were the public policies concerns at stake?"

(b) Quality of Patents, including Opposition Systems

(i) This topic will remain on the agenda of the 18th session of the SCP.

(ii) The proposals submitted by the United Kingdom and Canada (document SCP/17/8) and Denmark (document SCP/17/7) were discussed at SCP/17, but no consensus was reached. Those proposals and the proposal by the United States of America (SCP/17/10) will be discussed at the next session of the SCP.

(iii) The Secretariat will invite member States and observers of the SCP to submit written comments on the three proposals, and any other comments or submissions, by February 28, 2012. Member States' comments will be translated into all working languages of the SCP if they are received not later than February 28, 2012. If such comments are received after that date, best efforts will be made to provide such translations. Comments from observers will be posted in the languages they are received. Observers are invited to submit their comments in as many working languages of the Committee as possible. The Secretariat will post the comments received on the SCP electronic forum and will compile them in a document to be submitted to the next session of the SCP.

(iv) The Secretariat will revise document SCP/17/9 (Opposition Systems), taking into account the comments made, and any additional information to be submitted, by Member States, in particular, information on administrative revocation and invalidation mechanisms, and other similar procedures not addressed in the above document.

(c) Patents and Health

(i) This topic will remain on the agenda of the 18th session of the SCP.

(ii) The proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group (document SCP/16/7) was discussed at SCP/17, but no consensus was reached. The proposal will be further discussed at the next session.

(iii) The proposal submitted by the Delegation of the United States of America (document SCP/17/11) will be discussed at the next session.

(iv) The Secretariat will invite member States and observers of the SCP to submit written comments on the two proposals (documents SCP/16/7 and SCP/17/11), and any other comments or submissions, by February 28, 2012. Member States' comments will be translated into all working languages of the SCP if they are received not later than February 28, 2012. If such comments are received after that date, best efforts will be made to provide such translations. Comments from observers will be posted in the languages they are received. Observers are invited to submit their comments in as many working languages of the Committee as possible. The Secretariat will post the comments received on the SCP electronic forum and will compile them in a document to be submitted to the next session of the SCP.

(v) The Secretariat will prepare, for the 18th session of the SCP, a document listing projects and activities, including their status or outcome, on patents and health in WIPO, the WTO and WHO, and citing the relevant documents of the three organizations.

(vi) In the event the SCP decides to invite the WTO and WHO to future sessions of the SCP, Member States will be informed well in advance.

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

(i) This topic will remain on the agenda of the 18th session of the SCP.

(ii) The Secretariat will expand its study (document SCP/17/5) to explain approaches to cross-border issues and possible remedies identified in the area of confidentiality of communications between clients and patent advisors.

(e) Transfer of Technology

(i) This topic will remain on the agenda of the 18th session of the SCP.

(ii) The Secretariat will 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 (SCP/14/4 Rev.2) through practical examples and experiences. The SCP may consider the possibility of organizing a seminar to complement the study.

(iii) The Secretariat will assist Member States in facilitating the complementary and non-duplicative nature of the work undertaken by the SCP and CDIP on the issue of transfer of technology.

226. The Secretariat informed the SCP that its eighteenth session would be held in May or June 2012, in Geneva.

AGENDA ITEM 12: SUMMARY BY THE CHAIR

227. The Chair introduced the draft Summary by the Chair (document SCP/17/12 Prov.).

228. The Delegation of Brazil reiterated its understanding that a new document that would present the responses to the questionnaire on exceptions and limitations to patent rights would be an executive document, which would assist Member States in more easily understanding the information contained in the voluminous responses.

229. The Chair clarified that, with respect to the study on patent-related incentives and impediments to transfer of technology, the “practical examples and experiences” to be contained in the study would include practical cases.

230. After some discussions, the Summary by the Chair (document SCP/17/12) was noted and agreed.

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

AGENDA ITEM 13: CLOSING OF THE SESSION

232. The Chair closed the session.

233. The SCP unanimously adopted this report, during its eighteenth session, on May 21, 2012.

[Annex follows]

LISTE DES PARTICIPANTES/LIST OF PARTICIPANTS

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