

Standing Committee on the Law of Patents

Twenty-First Session
Geneva, November 3 to 7, 2014

DRAFT REPORT

prepared by the Secretariat

INTRODUCTION

1. The Standing Committee on the Law of Patents (“the Committee” or “the SCP”) held its twenty-first session in Geneva from November 3 to 7, 2014
2. The following States members of WIPO and/or the Paris Union were represented: Afghanistan, Algeria, Argentina, Australia, Austria, Bangladesh, Benin, Brazil, Burkina Faso, Cambodia, Cameroon, Canada, Chile, China, Colombia, Costa Rica, Côte d’Ivoire, Cuba, Czech Republic, Democratic People’s Republic of Korea, Denmark, Dominican Republic, Ecuador, Egypt, El Salvador, Estonia, Ethiopia, Finland, France, Germany, Ghana, Greece, Guatemala, Holy See, Hungary, India, Indonesia, Iran (Islamic Republic of), Ireland, Italy, Japan, Jordan, Kenya, Kuwait, Latvia, Lebanon, Libya, Lithuania, Madagascar, Malaysia, Mauritania, Mexico, Monaco, Montenegro, Morocco, Nepal, Norway, Oman, Pakistan, Panama, Paraguay, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Saudi Arabia, Senegal, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Tajikistan, Thailand, Trinidad and Tobago, Turkey, Ukraine, United Kingdom, United Republic of Tanzania, United States of America, Uruguay, Viet Nam, Yemen and Zimbabwe (87)
3. The Representative of Palestine took part in the meeting in an observer capacity.
4. Representatives of the following intergovernmental organizations took part in the meeting in an observer capacity: the African Union (AU), the Eurasian Patent Organization (EAPO), the European Patent Organisation (EPO), the Patent Office of the Cooperation

Council for the Arab States of the Gulf (GCC Patent Office), the South Centre (SC), the World Trade Organization (WTO) and the World Health Organization (WHO) (7).

5. Representatives of the following non-governmental organizations took part in the meeting in an observer capacity: American Intellectual Property Law Association (AIPLA), Asian Patent Attorneys Association (APAA), Association française des spécialistes en propriété industrielle de l'industrie (ASPI), International Association for the Protection of Intellectual Property (AIPPI), Latin American Association of Pharmaceutical Industries (ALIFAR), Cámara Industrial de Laboratorios Farmacéuticos Argentinos (CILFA), Centre for International Intellectual Property Studies (CEIPI), European Law Students' Association (ELSA International), Institute of Professional Representatives before the European Patent Office (EPI), International Centre for Trade and Sustainable Development (ICTSD), International Chamber of Commerce (ICC), CropLife International, International Federation of Pharmaceutical Manufacturers Associations (IFPMA), International Federation of Intellectual Property Attorneys (FICPI), Japan Intellectual Property Association (JIPA), Japan Patent Attorneys Association (JPAA), Knowledge Ecology International, Inc. (KEI) and Médecins Sans Frontières (MSF) (18).

6. A list of participants is contained in the Annex to this report.

7. The following documents prepared by the Secretariat had been submitted to the SCP prior to the session: "Draft Report" (SCP/20/13 Prov.2); "Draft Agenda" (SCP/21/1 Prov.2); "Report on The International Patent System: Certain Aspects of National/Regional Patent Laws" (SCP/21/2 Rev.); "Exceptions and Limitations to Patent Rights: Acts for Obtaining Regulatory Approval from Authorities (SCP/21/3); "Exceptions and Limitations to Patent Rights: Compulsory Licenses and/or Government Use (Part I)" (SCP/21/4 Rev.); "Exceptions and Limitations to Patent Rights: Compulsory Licenses and/or Government Use (Part II)" (SCP/21/5 Rev.); "Exceptions and Limitations to Patent Rights: Farmers' and/or Breeders' Use of Patented Inventions" (SCP/21/6); "Exceptions and Limitations to Patent Rights: Exhaustion of Patent Rights" (SCP/21/7); "Study on the Role of Patent Systems In Promoting Innovative Medicines, and in Fostering the Technology Transfer Necessary to Make Generic and Patented Medicines Available in Developing Countries and Least Developed Countries" (SCP/21/8, SCP/21/8 Summary); "Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents" (SCP/21/9); "Patents and Transfer of Technology: Further Practical Examples and Experiences" (SCP/21/10); and "Proposal by the Delegations of the Republic of Korea, the United Kingdom and the United States of America regarding Work Sharing between Offices in order to Improve Efficiencies of the Patent System" (SCP/20/11 Rev.).

8. In addition, the following documents prepared by the Secretariat were also considered by the Committee: "Proposal from Brazil" (SCP/14/7); "Proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group" (SCP/16/7); "Corrigendum: Proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group" (SCP/16/7 Corr.); "Proposal by the Delegation of Denmark" (SCP/17/7); "Revised Proposal from the Delegations of Canada and the United Kingdom" (SCP/17/8); "Proposal by the Delegation of the United States of America" (SCP/17/10); "Patents and Health: Proposal by the Delegation of the United States of America" (SCP/17/11); "Questionnaire on Quality of Patents: Proposal by the Delegations of Canada and the United Kingdom" (SCP/18/9); "Proposal by the Delegation of the United States of America regarding efficiencies of the patent system" (SCP/19/4); "Proposal of the Delegation of Spain and other Member States of The European Union for the Improvement of Understanding of the Requirement of

Inventive Step” (SCP/19/5 Rev.); and “Proposal by the Delegation of Brazil regarding exceptions and limitations to patent rights” (SCP/19/6).

9. The Secretariat noted the interventions made and recorded them on tape. This report summarizes the discussions reflecting all the observations made.

GENERAL DISCUSSION

AGENDA ITEM 1: OPENING OF THE SESSION

10. The twenty-first session of the Standing Committee on the Law of Patents (SCP) was opened by the Deputy Director General, Mr. James Pooley, who welcomed the participants. The session was chaired by Mr. Mokhtar Warida (Egypt). Mr. Marco Aleman (WIPO) acted as Secretary.

11. The SCP unanimously elected Mrs. Bucura Ionescu (Romania) and Mr. Victor Portelli (Australia) as *ad hoc* Vice Chairs for the twenty-first session.

AGENDA ITEM 2: ADOPTION OF THE AGENDA

12. The SCP adopted the draft agenda (document SCP/21/1 Prov.2).

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

13. The Committee adopted the draft report of its twentieth session (document SCP/20/13 Prov.2) as proposed.

AGENDA ITEM 4: REPORT ON THE INTERNATIONAL PATENT SYSTEM

14. Discussions were based on document SCP/21/2 Rev.

15. The Secretariat noted that since the twentieth session of the SCP, information concerning certain aspects of patent laws had been received from the following Member States/Territories: Costa Rica, Georgia, Germany and Hong Kong (China).

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

GENERAL DECLARATIONS

17. The Delegation of Japan, speaking on behalf of Group B, congratulated the Chair's continuous dedication to the SCP and congratulated the *ad hoc* Vice Chairs on their election. The Delegation expressed its thanks to the Secretariat for its hard work in preparing the current SCP session. Group B wished to attach great importance to the SCP, and expressed its belief that the Committee must be apprised of technical discussions on the issues of substantive patent law in line with its core mandate. The Delegation stated that discussions at the current SCP session should be beneficial for the real world from the

perspective of the objective of WIPO. The Delegation further expressed its strong belief that further work should be pursued on the issues of quality of patents, including opposition systems and confidentiality of communications between clients and their patent advisors, which could link the benefit to the real world, including innovators and practitioners, where WIPO should have its primary effect. Under the agenda item "Quality of patents, including opposition systems", the Delegation noted that Group B looked forward to the sharing session regarding Member States' experiences on international work sharing and collaboration. Group B expressed its belief that the further deepening of the understanding on the fundamental nature of international work sharing and collaboration could give answers to the concerns that had been expressed by some Member States so far, and establish common grounds for further work in that field. The Delegation further noted that, the sharing session of the SCP could function as one of the places for such exercise. The Delegation stated that international work sharing and collaboration was one of the most urgent and important issues in the real work as a solution to enable the efficient and timely examination, which was an essential component for innovation and technology transfer, within the constraints of intellectual property offices. Furthermore, the Delegation noted that this subject was not only a matter for developed countries, but for all Member States irrespective of the level of development because the ultimate goal of that subject was not work sharing and collaboration as such, but rather a realization of the developments through timely grant of appropriate rights. Group B further stated that Member States had to bear in mind that WIPO and its Member States had responsibilities to cooperate to solve that urgent issue and contribute to the development in a real sense in a way that WIPO should do from the viewpoint of the objective of WIPO. Group B expressed its expectation that the exercise at the current SCP session could be a first step that would lead to continued discussion and collaboration on that important subject as had been suggested by some Member States of Group B at the previous SCP session. Furthermore, the Delegation stated that it was critical for such discussions to continue in the multilateral context due to the nature of the issue. With respect to the confidentiality of communications between clients and their patent advisors, Group B looked forward to hearing voices from real world experiences, namely patent advisors and their clients. The Delegation noted that the perspectives of patent advisors and clients could feed the discussion at the current SCP session and indicate what Member States had to do further on that subject at the international level. In conclusion, the Delegation expressed its readiness to engage further in discussions on other topics of agenda with a constructive spirit and in a forward-looking way.

18. The Delegation of Pakistan, speaking on behalf of the Asian Group, expressed its confidence that the SCP would make progress under the able stewardship of the Chair. The Delegation also expressed its appreciation for the work done by the Secretariat in preparing the documents for the current SCP session. The Delegation remained committed to continuing discussions on important topics, including exceptions and limitations to patent rights, patent and health, quality of patents and transfer of technology. The Delegation hoped that discussions would be constructive and fruitful and all issues would be considered in a balanced, efficient manner and yield tangible results. The Delegation further stated that progress in any matter in the international arena, including international harmonization of patent laws, could succeed only if it was inclusive, giving due account to the differences in the levels of social, economic and technological development, flexibilities provided under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), respect for intellectual property law and the needs of all Member States. The Delegation noted that finding the optimum balance between the private interest of right holders and public interest was essential. The Delegation welcomed the half day Seminar on Exceptions and Limitations to Patent Rights and looked forward to a fruitful discussion. The Delegation further stated that the right to health was a basic human right and that the provision of basic health care was important for all countries, but especially so for resource-constrained

developing countries and least developed countries (LDCs). The Delegation hoped to see a fruitful discussion and a spirit of understanding on all proposals. Further, the Delegation stated that reaching an agreement on the balance between patent rights and the right to health would furnish the way to meet health needs and would also promote further innovation in that area. The Delegation hoped that the discussion and exchange of best practices and national experiences in the current SCP session could provide guidance to improve and further enhance the efficiency of the current patent system in a manner that took into account diverse needs and interests. The Delegation noted that members of the Asian Group would intervene in the current SCP session in discussions on specific agenda items. The Asian Group looked forward to engaging in discussions under the stewardship of the Chair.

19. The Delegation of the Czech Republic, speaking on behalf of the Group of Central European and Baltic States (CEBS Group), welcomed the Chair and congratulated the *ad hoc* Vice Chairs on their election. The Delegation thanked the Secretariat for preparing the documents for the current SCP session, as well as the two half day Seminars and the sharing session. The Delegation stated that following an opening statement of the CEBS Group at the fifty-fourth WIPO General Assemblies, the CEBS Group continued to pay great attention to the SCP as an important forum where all patent issues could be discussed. The Delegation hoped that the SCP would further enhance its efficiency. The Delegation expressed its belief that the results of the Committee's work would enable it to concentrate on fruitful discussions related to substantive issues concerning the law of patents towards international patent harmonization. The CEBS Group remained committed to continued and improved discussions on all topics under the current work program of the SCP. The Delegation also reiterated that any duplication of work should be avoided within all WIPO bodies and with other relevant international organizations such as the WHO or WTO. The Delegation continued to attach great importance to the quality of patents, including opposition systems. In that context, the Delegation highlighted two studies to be prepared by the Secretariat and submitted to twenty-second session of the SCP, namely, the study on sufficiency of disclosure and the study on inventive step. The Delegation was convinced that work on such topics would be of benefit to all users of the patent system. The CEBS Group stated that it was well aware that work sharing between patent offices continued to play a significant role in the development of patent systems and in improving its efficiency. Further, the Delegation looked forward to the scheduled sharing session of Member States' experiences in that field, and expressed its continued support for the proposal made by the Delegations of the United Kingdom, the United States of America, the Republic of Korea and Japan (document SCP/20/11 Rev.). The CEBS Group reaffirmed great interest in the work on confidentiality of communications between clients and their patent advisors in relation to the cross-border aspects. The Delegation stated that it looked forward to the half day Seminar on the Confidentiality of Advice from Patent Advisors and practical experiences of clients as well as patent advisors. The CEBS Group expressed its readiness and commitment to discussions of the other topics on the agenda of the twenty-first SCP session, and further remained open-minded about any other discussions.

20. The Delegation of Belarus, speaking on behalf of the Caucasian, Central Asia and Eastern European Countries (CACEEC), congratulated the Chair on his return and congratulated the *ad hoc* Vice Chairs on their election. The Delegation expressed its support for the activities of the SCP because it believed that the SCP was a key element within WIPO and had always given it a great deal of importance. The Delegation noted that the activities of the SCP were very diverse, but very important. The Delegation further noted that at the twentieth session of the SCP, it had seen that the Committee could tackle various themes and subjects. The Delegation hoped that practice would be continued and further hoped that the issues would be tackled in other fora, which were perhaps not always as

efficient as WIPO. The Delegation stated that the relationship between patent offices were vital for the smooth functioning of the system. The Delegation expressed its belief that the issue of patents and health was very important from the point of view of the efficient use of the patent system. The Delegation further stated that the development in the area of patents and health would help Member States to consolidate their activities and improve healthcare. The Delegation emphasized the importance of striking a balance in that regard between the national systems. The Delegation welcomed the fact that the Committee had worked hard to move that issue forward. Regarding the half day seminars that would be held during the current SCP session, the Delegation stated that the Committee would have a good exchange of the experience of knowledge in order to better understand each other and ensure appropriate inclusiveness. The Delegation noted that CACEEC was very active in those activities. Further, it hoped that positive results would be achieved. As for the future work of the Committee, the Delegation expressed its hope that the Committee would continue to have a balanced approach in order to achieve its goals.

21. The Delegation of Paraguay, speaking on behalf of the Group of Latin American and Caribbean Countries (GRULAC), noted that it was pleased to work with the Chair and that the Committee had taken up issues that were extremely valuable for all Member States. Further, the Delegation stated that the Committee would continue to work on substantive issues on the gradual development of the law of patents in conformity with the mandate of the SCP. The Delegation further congratulated the two *ad hoc* Vice Chairs. The Delegation thanked the Secretariat for preparing the documents for the current SCP session and for organizing informal consultations, which had enabled GRULAC members to have better knowledge of the agenda of the twenty-first SCP session and themes to be discussed. The Delegation stated that the agenda item “exceptions and limitations to patent rights” would foster an exchange of information and experiences between Member States so as to have greater knowledge of the modalities with which exceptions and limitations were implemented in countries with more advanced systems, to assess the differences between different systems, and from the perspective of GRULAC, to identify which were the most appropriate given the level of development and capacity of the respective patent offices. The Delegation noted that at the twentieth session of the SCP, there had been interesting discussions on five exceptions and limitations. Noting that another four exceptions and limitations would be discussed during the current SCP session, the Delegation hoped that the approach would be the same as in the previous session, i.e., to become aware of, evaluate and compare different systems of exceptions and limitations to have greater knowledge of the issue. As a result of those discussions, the Delegation asked the Secretariat to prepare an analysis of the exceptions and limitations that had been the most effective in taking up development related concerns. Further, the Delegation proposed the preparation of non-exhaustive manual on that issue, which would be a reference for all WIPO Member States. GRULAC expressed its interest in the issue of the quality of patents, including opposition systems. The Delegation stated that it was essential to be clear as to the concept of the quality of patents to be able to make progress. The Delegation noted it would carefully listen to work experiences that would be shared so that patent offices in GRULAC countries could follow up with an increasing request for patent applications, which had led to an increasing number of applications containing similar inventions. The Delegation further noted an exchange of views on work between offices would be important. GRULAC also expressed its interest in questions of patents and health, particularly on the Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents (document SCP/21/9). GRULAC understood that the inclusion of more information in patent applications was related to the quality of patents. In addition, GRULAC reiterated its proposal to see progress on the WIPO Model Law for Developing Countries on Inventions. The Delegation noted that there had not been any amendments to that law since 1979. In GRULAC’s view, that instrument could be

revised to include updated issues that had developed in recent years, particularly the role of exceptions and limitations in the implementation of public policies. Given that the Committee had the funds to progress on that issue, the Delegation stated it would like the Secretariat to prepare for the twenty-second session a proposal on a mechanism that the Committee might implement to carry forward that review or revision. In conclusion, the Delegation expressed its support to the Chair for leading discussions that would be enriching and beneficial for all WIPO Member States.

22. The Delegation of Kenya, speaking on behalf of the African Group, expressed its happiness with the Chair and congratulated the *ad hoc* Vice Chairs on their election. The Delegation thanked the Secretariat for its preparation of the current SCP session. The African Group attached a great importance to the work of the SCP, as it was critical in balancing the rights of patent owners and public interest particularly in the area of public health, technology transfer and patent flexibilities, which were essential to achieve public policy objectives especially by providing Member States with the necessary policy space to meet the public interest. The African Group noted it had expressed its position in the past in regard to various issues on the agenda and noted that those positions remained valid. The Delegation stated that it would like to see the Committee adopt a substantive work program on those issues, in particular in the area of technical assistance, which had been included in the proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group (DAG) (documents SCP/16/7 and SCP/16/7 Corr.). The Delegation looked forward to fruitful discussions on all agenda items.

23. The Delegation of China noted that it was pleased to see the Chair leading the work of the SCP and congratulated the *ad hoc* Vice Chairs on their election. The Delegation also thanked the Secretariat for its preparation of the current SCP session. Further, the Delegation expressed its hope that the Committee would make progress on the various subjects before it, for example, exceptions and limitations, patents and health, technology transfer, patent quality and also the contribution of the SCP to the implementation of recommendations for a Development Agenda. The Delegation stated that it would like the current SCP session to be successful thanks to the efforts of all parties. Noting that several Delegations had mentioned a balanced, inclusive approach to the work of the Committee, the Delegation stated that it would like that spirit to prevail during the current SCP session.

24. The Delegation of Italy, speaking on behalf of the European Union and its Member States, welcomed the Chair and congratulated the *ad hoc* Vice Chairs on their election. The Delegation thanked the Secretariat for its preparation of the current SCP session. The Delegation was pleased by the fact that the progress had been made at the previous session of the SCP, that positive conclusions had been reached and that the Delegation had agreed to continue discussions on the basis of the work program, including the topics of the quality of patents, inducing opposition systems, client-patent attorney privilege, exceptions and limitations to patent rights, technology transfer and patents and public health. The Delegation stated that the topics in the work program addressed important and complex issues related to the international patent system, and expressed its hope that discussions would achieve a more efficient and accessible patent system as a whole. The Delegation remained committed to the work of the Committee and looked forward to a constructive session. The Delegation attached particular importance to advancing work on the quality of patents along the lines of proposals of the Delegations of Canada and the United Kingdom, Denmark, the United States of America and Spain as endorsed by all other Member States of the European Union, as it believed that work on that topic would be of interest to Member States across the spectrum of development. The Delegation highlighted its great interest in the topic of work sharing. It stated that work sharing had

the potential to enhance international cooperation and bring a more efficient, effective and higher quality patent system to all, and tackle with problems only solvable through an international approach. The Delegation looked forward to a fruitful sharing of Member States' experiences during the current SCP session. Likewise, the Delegation was keen to progress on the topic of client-patent attorney privilege, as a convergence of differing positions would be of benefit to users of the patent system irrespective of the level of development of individual Member States. The Delegation noted that it would follow with interest the half day Seminar on Exceptions and Limitations to Patent Rights. The Delegation emphasized, however, that the importance of striking an appropriate balance between work on exceptions and limitations to patent rights and on corresponding legal standards that had been used to determine whether an invention was patentable, because those two topics were closely interlinked. Regarding the issue of patents and health, the Delegation expressed its belief that the work products that had been prepared for the current SCP session provided useful material for consideration on that topic. Regarding the transfer of technology, the Delegation expressed its belief that the materials that had been submitted to the Committee reflected many examples of the benefits of the patent system to technology transfer. In closing, the Delegation expressed its hope that the Committee's pursuit of a balanced work program would lead the Committee toward working on discussions on the international harmonization of key aspects of substantive patent law in the long term to which the Delegation was strongly committed, including, *inter alia*, to facilitate work sharing and provide more quality and predictability to the patent system. The European Union and its Member States reiterated a full commitment to cooperate and participate actively and constructively in the discussions of the Committee.

25. The Delegation of the Republic of Korea welcomed the Chair and congratulated the *ad hoc* Vice Chairs on their election. The Delegation also thanked the Secretariat for its hard work in preparing the relevant and updated documents for the current SCP session. The Delegation further appreciated the opening statement by the Deputy Director General. The Delegation stated that it went along with the statement that had been made by the Delegation of Pakistan on behalf of the Asian Group. The Delegation recognized that all the Member States in the SCP had welcomed constructive and fruitful discussions on the technical issues of substantive patents laws and international cooperation. Moreover, the sessions of the SCP over the last few years had provided Member States with an opportunity to share their experiences and insight on such important topics. The Delegation stated that the discussions on those topics had been extremely relevant in helping everyone to benefit from the present patent system. The Delegation stated that any decision or norm setting required open discussions and transparent procedures. In that regard, the Delegation stated that without that basic requirement, the results would not be justified. The Delegation expressed its belief that the Committee should approach all the items on the table with an open mind and sincere interest. Further, the Delegation thought that all the discussions would positively influence the progress of society's infrastructure. The Delegation therefore hoped that the discussions that would take place would be productive and fruitful, and all issues would be considered in an efficient and appropriate process. The Delegation stated that it would participate constructively throughout the current SCP session.

26. The Delegation of India expressed its confidence in the Chair and congratulated the *ad hoc* Vice Chairs on their election. The Delegation also thanked the Secretariat for preparing the documents for discussion in the current SCP session. The Delegation expressed its belief that the development of patent system and the use of patent rights should operate in a balanced and sensible manner, which should meet the objective of providing protection for the moral and material interests of inventors, and at the same time, should meet the objective of promoting the enjoyment of human rights of the other members

of the society as well. Further, the Delegation believed in the view that ultimately a patent was a social product and it had a social function. The Delegation attached great importance to the work of the SCP and noted the work program for the current SCP session, in which important issues such as exceptions and limitations to patent rights, patents and health and transfer of technology had been retained in the agenda of the Committee. The Delegation reaffirmed its views expressed in the twentieth session of the SCP, in particular, on the issues related to exceptions and limitations, quality of patents, patents and health, client-attorney privileges and transfer of technology. On the issue of exceptions and limitations to patent rights, the Delegation reaffirmed its full support to the work program as proposed by the Delegation of Brazil (document SCP/19/6) on exceptions and limitations to patent rights. The Delegation reiterated that that proposed study might focus upon the use of some exceptions and limitations like compulsory licensing, parallel imports, government use, Bolar exceptions, etc., which were extremely important from the point of view of accessibility and affordability of medicines in developing countries and LDCs. The Delegation welcomed the organization of the half day Seminar on Exceptions and Limitations to Patent Rights. With regard to quality of patents, the Delegation considered that the quality of examination of patent applications needed to be improved substantially in conformity with the policy objective of a country so that a huge social cost of granting patents to insignificant improvements would not be created. In its view, low quality patent examination would only lead to litigation and would create barriers to the dissemination of knowledge and transfer of technology. Further, the Delegation was of the view that the sharing of work of other patent offices was not the remedy for improving the quality of patents and, it could not be considered to be a solution for addressing backlog. Rather, the Delegation stated that the sharing of work of other offices could weaken the examination process and capability of patent offices in developing countries. The Delegation expressed its opinion that steps should be taken to build capacity among patent offices of developing countries to enable them to perform their *quasi*-judicial functions, according to their national laws, in the best manner possible. The Delegation further expressed its strong belief that work sharing would adversely affect the capacity of the patent offices in developing countries to examine applications and therefore, that should not become an area for norm setting in future. Regarding the issue of patents and health, the Delegation stated that in order to meet the requirement of public with respect to patented drugs and to provide the life-saving drugs at an affordable price in developing countries and LDCs, there was a need not only to study the TRIPS flexibilities and the effective implementation or utilization of compulsory licensing provisions under patent law, but also to study the impact of the grant of compulsory licenses and consequential impact on availability and prices of patented drugs. The Delegation took note that the Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents (document SCP/21/9), described, *inter alia*, general information about INN and the particularity of searching pharmaceutical substances disclosed in patent documents in order to discuss feasibility of the disclosure of INN in patent applications and patents. The Delegation conveyed its sincere thanks to the Secretariat for the preparation of that document. The Delegation noted that it would like to express its view in detail on that study and on other documents during the discussion of that document. The Delegation also noted the Study on the Role of Patent Systems in Promoting Innovative Medicines, and in Fostering the Technology Transfer necessary to Make Generic and Patented Medicines available in Developing Countries and Least Developed Countries (document SCP/21/8), and expressed its wish to meaningfully engage in discussion. On the issue of transfer of technology, the Delegation expressed its belief that the protection and enforcement of patent rights should promote technological innovation and transfer of technology, achievable by patent specifications independent of any know-hows, in the country where the rights were protected, and thereby would provide a mutual advantage to producers as well as to the users of technological knowledge. Therefore, the Delegation stated that in order to create a balance of rights and obligations, the protection and

enforcement of patent rights *vis-à-vis* the technological content of patent specifications should be conducive for the socio-economic developments of the country. The Delegation expressed its satisfaction on the progress made by the SCP in bringing out reasonable studies with a clear picture on the existing situation across countries on the subjects under consideration. The Delegation extended its full cooperation and expressed its readiness to participate constructively in the Committee's discussions.

27. The Delegation of Pakistan wished to align its statement with the statement of the Asian Group. The Delegation expressed its belief that the agenda of the current SCP session was of paramount importance, especially to developing countries, as it highlighted the need for a balanced patent system that promoted innovation and also gave due consideration to public welfare especially in the field of health. The Delegation believed that although there was consensus on the right to health as a basic human right, there was a need to ensure that the provision of public welfare would be facilitated through tangible practical means, especially in resource constrained countries. The Delegation stated that patent protection should not hinder the public health objectives of any country. Further, the Delegation stated that Articles 7 and 8 of the TRIPS Agreement read with the Doha Declaration on TRIPS and Public Health struck a balance between rights and obligations. The Delegation further stated that WIPO should provide technical assistance and support to developing countries and LDCs to effectively implement exceptions and limitations. The Delegation expressed its strong support for the proposal by the Delegation of Brazil for further work to evaluate the questionnaire responses on exception and limitations to develop a better understanding of which practices served development objectives. The Delegation also supported the proposal by the Delegation of South Africa on behalf of the African Group and the DAG for a concrete work program on patents and health. Furthermore, the Delegation stated that technology transfer remained an issue of significance for the developing world. Noting that the impediments in transfer of technology were mainly the weak interaction between linkages with the industry for the commercialization of inventions and the lack of awareness regarding the marketing potential of the invention, the Delegation requested the Secretariat to work on the impediments to transfer of technology in developing countries. The Delegation looked forward to contributing on specific agenda items in the course of the discussions of the current SCP session.

28. The Delegation of the Dominican Republic congratulated the Chair and expressed its readiness to collaborate. The Delegation stated that regarding the application of exceptions and limitations to patent rights, it had experiences on the acts in the private spheres for noncommercial uses, acts for obtaining experiments and the uses necessary for approval by the sanitary authority and the subsequent marketing of a product after the expiry of patents. The Delegation stated that regarding patents and health, it was concerned about access to antiretroviral drugs for HIV/AIDS. The Delegation noted that for the time being, the HIV office in the Dominican Republic had been analyzing exceptions and limitations to patent rights so as to seek mechanisms which would enable the population to have access to those drugs. The Delegation stated that it was extremely important for it to find out the experiences of other countries, particularly good practices. The Delegation expressed its support for the proposal by the Delegation of Brazil on effective exceptions and limitations and for a manual, which would be extremely useful for Member States. The Delegation subscribed to the statement made by the Delegation of Paraguay on behalf of GRULAC as a whole.

29. The Representative of the ICC noted that it represented small and large businesses in all sectors in some 130 countries from all over the world at different levels of development. The Representative further stated that those businesses could be holders of intellectual property rights, in particular patent rights, or they could find themselves in situation where

they were confronted by such rights of others. He stated that given the increasingly international nature of activities relying on intellectual property rights, a forum, in which patent issues could be discussed at an international level, such as the SCP, could be of great value. The Representative expressed his view that such discussions were particularly useful when focused on practical issues that helped ensure that a patent system worked effectively to support innovation and growth. The Representative noted that those issues included patent quality, international work sharing and confidentiality of communications between clients and their patent advisors and also that other issues could have a direct impact on the improvement of the functioning of the patent system and the facilitation of everyday transactions relating to patents. The Representative stated that work on such practical issues could help the patent authorities in their daily work, especially those with fewer resources, as well as patent holders and those confronted by the patent rights of others. In that regard, the Representative noted that he would be pleased to enhance the understanding of those issues by sharing practical experiences from the ground. Further, he looked forward to helping the SCP work towards international solutions in those areas.

AGENDA ITEM 5: EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

30. Discussions were based on documents SCP/14/7, SCP/19/6 and SCP/21/3, 4 Rev., 5 Rev., 6 and 7.

31. The Delegation of Japan, speaking on behalf of Group B, thanked the Secretariat for preparing the series of documents on how the different exceptions and limitations were implemented in some Member States (documents SCP/21/3, 4 Rev., 5 Rev., 6 and 7). The Delegation stated that those documents provided useful information on the implementation of exceptions and limitations in other countries, which provided a valuable difference where Member States considered arrangements that were adopted to their circumstances. The Delegation noted that exceptions and limitations should be used in very limited and specific circumstances, as was linguistically self-explanatory, with sufficient and concrete justification and with the overarching principle of appropriate patent protection. The Delegation further stated that discussions on exceptions and limitations in a piecemeal manner separated from the context of appropriate patent protection, or a conceptual discussion without factual evidence, would sometimes lead to a discussion for the mere purpose of the discussion or justification as an end in itself. The Delegation stated that in order to avoid that situation, it expected that the half day Seminar on Exceptions and Limitations to Patent Rights during the current SCP session should shed more light on the objective and impartial evidence that supported policy making in exceptions and limitations in particular countries.

32. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, thanked the Secretariat for the preparation of the documents that concerned four exceptions and limitations to patent rights and contained valuable information on how those exceptions and limitations had been implemented in Member States. It further thanked the Secretariat for the preparation of the half day Seminar on those four exceptions and limitations to patent rights. Further, the CEBS Group hoped that the information, presentations and case studies on the practical implementation of exceptions and limitations would be helpful for further discussion within the Committee. The Delegation reiterated its support for a balanced approach to discussion on that issue. The Delegation was convinced that an appropriate balance between the interest of right holders and the interest of the general public should be maintained. Further, the corresponding legal standards that related to the substantive conditions of patentability of an invention, such as novelty, inventive step and industrial applicability, should be taken into account. The CEBS Group also expressed its readiness

to participate constructively in continued discussions on exceptions and limitations to patent rights.

33. The Delegation of Italy, speaking on behalf of the European Union and its Member States, thanked the Secretariat for the preparation of documents SCP/21/3 to 6, which contained a summary of how limitations to patent rights were provided for in national law, as well as the practical challenges in implementation that had been encountered by Member States. The Delegation further thanked the Secretariat for the preparation of document SCP/21/7, which provided information on how exceptions or limitations related to exhaustions of patent rights had been implemented in Member States. The Delegation noted that document SCP/21/7 would serve as a useful evidence for academics, as well as law and policy makers working in that area. Further, the Delegation stated that exceptions and limitations to patent rights maintained an appropriate balance between the right holders and the general public and thus, neither exclusions from patentability nor exceptions or limitations to patent rights should be discussed without corresponding legal standards that were used to determine whether an invention was patentable, such as novelty, inventive step and industrial applicability. The Delegation welcomed the fact that at the twenty-second session of the SCP, some of those legal standards would be discussed. The Delegation looked forward to the half day Seminar on Exceptions and Limitations to Patent Rights and to discussion on that issue.

34. Pursuant to the decision taken at the twentieth session of the Committee, a half day Seminar on Exceptions and Limitations to Patent Rights was held. The Seminar addressed the following four exceptions and limitations: (i) acts for obtaining regulatory approval from authorities; (ii) exhaustion of patent rights; (iii) compulsory licensing and/or government use; and (iv) exceptions and limitations relating to farmers' and/or breeders' use of patented inventions. The Seminar consisted of the following three segments:

- (a) a presentation of documents SCP/21/3 to 7 by the Secretariat;
- (b) presentations by the Chief Economist and two external experts on the effectiveness of exceptions and limitations when addressing developing concerns and how national capacities affect the use of exceptions and limitations; and
- (c) presentations by Member States of case studies on the implementation of the above exceptions and limitations.

35. The Secretariat presented documents SCP/21/3 to 7.

36. The Delegation of Brazil thanked the Secretariat for its preparation of the factual documents. The Delegation noted that the majority of the answers to the questionnaires on which documents SCP/21/3 to 7 were based were provided by developed countries, and that a small number of developing countries had answered the questionnaires. In that regard, the Delegation asked if intellectual property offices from the developing countries had requested support or additional comments in order to answer the questionnaires. The Delegation noted that since there were well known difficulties that developing countries had faced in the implementation of those exceptions and limitations, specifically regarding compulsory licensing under the WTO system, WTO Members had envisaged the creation of a specific system for countries to be capable of implementing that kind of exception and limitation.

37. The Secretariat noted that the countries' replies to the questionnaires (88 in total) included developed countries, developing countries and LDCs. The Secretariat further noted that many of the answers from both developed and developing countries showed a great level of understanding without the need for any assistance. The Secretariat said that, however, on a case-by-case basis and depending on the Member State's interest, there had been some phone calls or e-mail exchanges for clarifications.

38. At the second segment of the Seminar, the Secretariat introduced two external experts, Ms. Margaret K. Kyle, Professor, MINES ParisTech, France and Ms. Jayashree Watal, Counsellor, Intellectual Property Division, World Trade Organization, Switzerland. The Secretariat noted that it was challenging to give proper justice to the effectiveness of the four exceptions under discussion in light of the limited time and especially due to the fact that the economic effects of those exceptions were quite varied and multifaceted. The Secretariat therefore suggested that for the half day Seminar on Exceptions and Limitations to Patent Rights for the current SCP session, emphasis be placed on exceptions and/or limitations on acts for obtaining regulatory approval from authorities and exhaustion of patent rights. The Secretariat stated that from an economic perspective, the question of exhaustion of patent rights was in many ways arguably the most interesting and also the most ambiguous of the exceptions in terms of its effects. Further, the Secretariat noted that the exception and/or limitation on acts for obtaining regulatory approval from authorities was one exception for which there was some evidence, but not as much evidence as one might want and had received relatively less attention, as compared to the exception and/or limitation on compulsory licensing and/or government use. With respect to the exception and/or limitation on compulsory licensing and/or government use, the Secretariat referred interested Member States to the study published by WIPO, the WHO and the WTO entitled "Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade", which summarized the experiences of different countries that had used that type of exception in the context of medicines, including, for example, the experiences of Brazil and Thailand, among others.

39. Ms. Kyle presented the basic economic intuition behind exhaustion of patent rights policies, including the effect on pricing. She noted the economic arguments for and against different types of exhaustion. She further noted empirical, anecdotal and survey evidence on the effects of parallel trade. In conclusion, Ms. Kyle explained how the economic effects of international exhaustion were different across countries and settings.

40. Ms. Watal presented the rationale of the exception and/or limitation on acts for obtaining regulatory approval from authorities. She presented facts from studies of the United States of America and European Union markets. She also explained Article 30 of the TRIPS Agreement as well as the economic arguments regarding the exception and/or limitation on acts for obtaining regulatory approval from authorities that had been made in the WTO dispute Canada — Patent Protection of Pharmaceutical Products (WTO document WT/DS114/R). In conclusion, she remarked on the economic implications of the exception and/or limitation on acts for obtaining regulatory approval from authorities.

41. The Delegation of Brazil expressed its thanks for the extensive and interesting presentations. Noting that Ms. Kyle had mentioned the flows of parallel imports and how they could improve competition, the Delegation asked whether there was any data on the market failure for access to medicines for rare diseases. The Delegation understood that regarding the market structure for medicines to treat rare disease, there would be a different effect from a general analysis of parallel importation or the exhaustion of rights.

42. Ms. Kyle noted that she was unaware of any studies focusing specifically on the effect on rare diseases or any specific link between exhaustion and R&D efforts for medicines to treat rare diseases. Ms. Kyle further stated that in general, it was difficult to isolate the effect of exhaustion on R&D efforts because there were so many other factors that moved pharmaceutical profits around. In that regard, she explained that, in general, there was not a clean experiment in the data that would say that parallel trade had directly contributed to a change and profits, and that that change in profits had led specifically to a reduction in R&D.

43. The Delegation of Brazil noted that Ms. Kyle had mentioned, for example, that the general trend of parallel imports would be the flow of medicines from lower income countries to higher income countries. The Delegation further noted that regarding markets that were very specific, for example, markets for medicines for rare diseases, the offer would be more clearly available in developed countries or countries with large populations, while countries with small populations would not have had access to those medicines. The Delegation asked whether the exhaustion of rights could play a role in providing medicines to small markets or medium-sized markets.

44. Ms. Kyle noted that in that case, the question was not of exhaustion of rights but was a question of receiving regulatory approval in the small market. She also noted that in general, a patent holder might not see it as worthwhile to go through the process of receiving regulatory approval in a sufficiently small market in which sales volumes were expected to be very low. She further noted that it would be difficult for any other firm that wanted to sell that drug in that country to do so because presumably, that firm would also need regulatory approval.

45. The Secretariat noted that the market that was potentially interested in parallel trade was not necessarily the one that was deciding the policy because it was always the importing market that decided on when parallel trade was allowed. The Secretariat further noted that regarding a small country interested in possibly attracting parallel trade or lower prices, what other countries were doing in terms of their parallel import policy could be much more important than the parallel import policy in that small country.

46. The Delegation of Pakistan expressed its appreciation for the comprehensive presentations. The Delegation recalled the European Union's economic argument explained by Ms. Watal in her presentation that both trademark companies and generic companies were in business for profit. The Delegation stated that, from a clearly economic perspective, the Bolar exception allowed generic companies to free ride on the trademark companies' efforts. The Delegation further stated that from a developing country perspective and from a public health provision perspective, generic drugs were extremely important because they made essential medicines affordable. The Delegation noted that in Pakistan, for example, where hepatitis was on the rise, the trademarked drugs were so expensive that half or probably more than three quarters of the population could not afford them. The Delegation stated that it was generic drugs that provided treatment to patients, and it was a matter of life and death. The Delegation asked whether, considering the European Union argument and the current patent system, there were other options, if any, for developing countries to balance public welfare, especially regarding the provision of healthcare versus profit and economic rationale.

47. Ms. Watal noted that the European Union had made its arguments specifically for the Bolar exception. Further, Ms. Watal noted that Canada had won the case. Now, it was more or less clear in WTO jurisprudence that the TRIPS Agreement allowed for the Bolar exception. Ms. Watal also remarked that a number of countries had adopted an exception and/or limitation on acts for obtaining regulatory approval from authorities. She noted that it

had been shown that the economic argument that had been raised by the European Union would not convince a WTO dispute settlement panel and added that the European Union had adopted a Bolar exception.

48. The Delegation of Pakistan referred to a Transpacific Partnership Agreement which was aiming to extend the duration of patents for patented drugs, and that generic companies would not have access to the R&D data of patented drugs. The Delegation stated that seemed to be an extension of the issue regarding the regulatory review exception and/or limitation in the WTO dispute.

49. Ms. Watal noted that in general, it was true that there were some jurisdictions, including WTO Member jurisdictions, which had a patent term restoration or a patent term extension along with the regulatory review exception although they were not requirements under the TRIPS Agreement. She further explained that while generic companies did get a flexibility of being able to use the patented invention, years before the patent expired, the patented products did get an extension of the patent term to make up for the regulatory review.

50. The Delegation of Algeria expressed its thanks for the interesting presentations. The Delegation noted that Ms. Kyle's presentation had shown that the penetration rate of generic medicines in the United States of America market was 80 percent or higher, than in Japan where the rate was 20 percent. The Delegation wanted to know what analysis could be conducted on the patent systems in the two countries. The Delegation further asked whether it could be said of a market in which the penetration rate of generic medicines was 80 percent that the patent system of that market was oriented toward exceptions that related to exhaustion of patent rights. Additionally, the Delegation asked whether it could be said of Japan, in which the penetration rate of generic medicines was 20 percent, that the patent system was more oriented toward patent protection and less toward public health.

51. Ms. Kyle highlighted the differences in pharmaceutical policies across countries. Although Japan and the United States of America had, for example, some minor differences between their respective patent laws, she stated that the difference in the penetration of generic medicines in the two countries was, in her view, not linked to differences in patent policy *per se*, but rather was linked to other aspects of pharmaceutical regulation. She noted that in the United States of America, people paid more out of pocket. There was no national system of health insurance, which made patients more price sensitive, and there were mandatory generic substitution laws, among other policies that increased the incentives for generic pharmaceutical firms to challenge patents and enter the market. Ms. Kyle noted that in Japan, many of those policies did not exist. She noted that there were other policies in place that preserved branded-medicines positions, which were not necessarily linked to patents. Noting that a number of questions that Delegations had asked were related to access to medicines, she clarified that patents were one part of the story, but were certainly not the entire story.

52. The Delegation of Egypt expressed its thanks to the presenters. It noted a reference in the presentation on the exception and/or limitation on acts for obtaining regulatory approval from authorities in the context of the WTO dispute involving Canada and the European Union to the impact of the Bolar exception on export markets. The Delegation asked whether the scope of the Bolar exception covered only acts for obtaining approval from domestic authorities or whether it could be extended to cover acts for obtaining regulatory approval in export markets as well. The Delegation noted that extending that exception to cover acts for regulatory approval in export markets would improve the process.

53. Ms. Watal noted that information was available in document SCP/21/3. Further, she noted the importance of knowing whether an exception and/or limitation on acts for obtaining regulatory approval from authorities included acts for obtaining regulatory approval in foreign jurisdictions.

54. The Delegation of Egypt asked if the issue of whether exception and/or limitation on acts for obtaining regulatory approval from authorities covered acts for obtaining approval in foreign jurisdictions had been addressed in the WTO dispute involving Canada and the European Union.

55. Ms. Watal responded that there was a discussion in the WTO dispute involving Canada and the European Union, but noted that that particular aspect had not been at issue in the dispute.

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

57. The Delegation of Brazil expressed its thanks to the presenters for their contributions to discussions on exceptions and limitations to patent rights, which was an essential part of the intellectual property system. The Delegation also thanked the Secretariat for its work in producing documents SCP/21/3 to 7. The Delegation noted that the responses to the questionnaires, on which documents SCP/21/3 to 7 were based, showed a variety of public policies objectives that exceptions and limitations safeguarded. The Delegation noted that the following objectives could be clearly identified: security concerns, national emergencies, preventing an abuse of rights and also the objective of reaching a balance between rights and obligations. The Delegation stated that those elements should be taken into account in norm-setting activities in order to make the patent system beneficial to society at large and that those elements deserved a full analysis by national authorities. Further, the Delegation stated that it was noteworthy that there were different objectives among national legislations, and specific elements that seemed to indicate that a one size fits all approach did not seem advisable. The Delegation noted that responses to the questionnaires had shed light on the difficulties that were faced by Member States in the implementation of exceptions and limitations. The Delegation stated that the formal inclusion of exceptions and limitations in national legislation was not sufficient to guarantee their operation. Therefore, the Delegation was of the view that the SCP should focus its activities, in particular, on the operation of those exceptions and limitations. The Delegation noted that its recent experience with the compulsory licensing of the antiretroviral drug efavirenz in 2007 was a good example of the use of exceptions and limitations to patent rights. The Delegation noted that in 2007, the Brazilian government had decided to enact a compulsory license for that drug, the patent on which belonged to laboratory Merck Sharp & Dohme. According to Brazil's STD and AIDS program, the antiretroviral drug efavirenz in 2007 had been the most-used imported pharmaceutical for the treatment of AIDS. The Delegation further stated that at that time, 38 percent of people living with HIV/AIDS in Brazil had been treated with efavirenz. The Delegation stated that if the previous pricing practices that had been used by that laboratory in Brazil had been applied, the costs per patient per year would have equaled 580 US dollars, which would have represented an annual budget of 42.9 million US dollars. The Delegation noted that the price of the generic product had ranged from 163 US to 166 US dollars per patient per year. The Delegation noted that that compulsory license had reduced spending in 2007 by about 30 million US dollars. Further, the Delegation noted the estimated savings for the Brazilian government by 2012 had reached \$236.8 million US dollars. The Delegation stated that despite the difficulties that had been encountered in the production of the antiretroviral, the results that had been obtained with the compulsory licensing could be considered a success. The Delegation explained that among the results, there was a

reduction in the price paid by the government that had made possible the sustainability of the Brazilian STD and AIDS program.

58. The Delegation of Ecuador welcomed the Chair. The Delegation also congratulated the *ad hoc* Vice Chairs on their election, and thanked the Secretariat for the presentation of documents SCP/21/3 to 7. The Delegation attached particular importance to the subject of the half day Seminar on Exceptions and Limitations to Patent Rights. The Delegation stated that on October 27, 2009, Ecuador had considered access to medicines of public interest to all Ecuadorians and to that end, had established compulsory licenses. The Delegation noted that compulsory licenses were permission by the government to produce a patented product or to use a patented procedure without the authorization of the originator. Further, the Delegation noted that compulsory licensing was permitted by the TRIPS Agreement, which contemplated compulsory licenses in matters of public interest. The Delegation further said that in 2009, with the purpose of carrying out scientific R&D for the creation of generic drugs at a lower cost, Ecuador had created the pharmaceutical company, Enfarma, which had as its mission to contribute to a greater percentage of the population obtaining access to medicines and the treatment and cure for diseases. Further, the Delegation noted that as of June 2014, five compulsory licenses had been granted for antiretrovirals pharmaceutical products, which were to treat patients with HIV/AIDS. The Delegation stated that according to the data that had been handled by the Ecuadorian Institute of Intellectual Property, there were about 37,000 patients in Ecuador who were infected with HIV/AIDS and there were about 700 deaths per year. The Delegation stated that according to the data, as a result of compulsory licenses, Ecuador had achieved between 30 percent and 70 percent in savings for the Ministry of Health in supplying those drugs that had to be provided by Ecuador. The Delegation considered that compulsory licenses were a legitimate aid used by governments to better manage the market and also to meet the needs that did not have to do with the market, but rather with public health. The Delegation stated that for that reason, countries must use and correctly regulate the mechanism so that it would benefit the government and citizens and create a more healthy market.

59. The Delegation of Japan thanked the Chair and congratulated the two *ad hoc* Vice Chairs on their election. The Delegation also expressed its thanks to the Secretariat for its extensive preparation of the current SCP session and the presenters for their interesting presentations. The Delegation introduced Japan's domestic system relating to the Bolar provision. The Delegation stated that, as the coordinator for Group B had mentioned earlier, exceptions and limitations should be used in very limited and specific circumstances. Further, the Delegation stated that under that principle, Japan should have an exclusive right to work the patented invention. To balance the rights of patent holders with the interests of third parties, the Delegation further noted that the Japan Patent Act also stipulated that the patent right should not extend to working of the patented inventions for the purpose of experiments or research. The Delegation stated that from the viewpoint of balancing the rights of patent holders with the interests of generic manufacturers, whether any acts that had been performed for the purpose of obtaining regulatory approval from authorities could be interpreted as experiments had been questioned. On the basis of a judicial decision, it had been settled that any acts that had been conducted solely for the purpose of obtaining regulatory approval from the authorities were regarded to be experiments and, therefore, were acknowledged to be exceptions to patents rights. The Delegation therefore stated that the low penetration of generic medicines in Japan was not attributable to Japan's patent system.

60. The Delegation of Brazil asked, with regard to the Bolar exception, whether there had been any concern regarding the role of sham litigation as an additional hurdle to the implementation of that exception.

61. Ms. Kyle noted that, while she would not label it sham litigation, there was generally a lot of litigation in the United States of America regarding pharmaceuticals and the entry of generic medicines because the stakes were very high. She explained that one reason why litigation in the United States of America was more pronounced than in Europe was that there was a special policy in the United States of America, called the paragraph 4 challenge, that created incentives for generic pharmaceutical companies to challenge patents. She further explained that the first generic firm to successfully challenge a patent would be rewarded with six months of market exclusivity, which meant that there was a prize for being the first generic company in the market. She noted that generic companies were therefore aggressive in trying to invalidate patents or in persuading courts that they had invented around the patent. She noted the response of originators was to go to court and file other types of patents in order to create more barriers. Ms. Kyle stated that, although she would not call it sham litigation, such litigation was a natural consequence of the patent system where a reward was at stake.

62. The Delegation of Tanzania expressed its appreciation for the Chair. It also thanked the presenters for their informative presentations. The Delegation noted that there were many issues within the presentations that could be looked at in further detail. The Delegation stated that its concern was the application of the limitations and exceptions in particular situations. The Delegation asked how the demarcation line could be drawn. The Delegation noted that there were exceptions and limitations in the pharmaceutical industry and exceptions and limitations of general application. Noting the existence of homogenous and heterogeneous market segments, the Delegation was of the view that how to apply exceptions and limitations should be explored and that different interventions might be needed for certain markets or market segments. When considering cross-border markets, the Delegation thought that exceptions and limitations in the pharmaceutical sector should be distinguished from those in other sectors. Further, the Delegation asked about the situations in markets other than the United States market and the European Union market.

63. The Delegation of India reaffirmed its firm support, as had been particularly stated at the fourteenth and nineteenth sessions of the SCP, to the work program proposed by the Delegation of Brazil in documents SCP/14/7 and SCP/19/6 on exceptions and limitations to patent rights. The Delegation reiterated that the studies in the work program proposed by the Delegation of Brazil in documents SCP/14/7 and SCP/19/6 were extremely important from the perspective of accessibility and affordability of medicines and also for socio-economic growth and development in developing countries and LDCs. The Delegation welcomed the half day Seminar on Exceptions and Limitations to Patents Rights and expressed its appreciation for the presentations made by the Secretariat, Ms. Kyle and Ms. Watal, moderated by WIPO Chief Economist. With respect to documents SCP/21/3 to 7, the Delegation expressed its appreciation for the efforts that were made by the Secretariat in compiling the data from different countries regarding public policy objectives for providing the exceptions, the applicable law and the scope of the exceptions and implementation challenges. The Delegation stated that those preliminary studies had recognized the fact that the nature and scope of the exclusion of certain subjects from patentability and exceptions and limitations to patent rights were relative to the public policy objectives of a country. The Delegation stated that in its opinion, however, those preliminary studies would not serve the purpose of extracting the specific exceptions and limitations, like compulsory licensing, parallel imports, government uses, Bolar exceptions, etc., that were extremely important from the perspective of development concerns of the developing countries *vis-à-vis* patent systems. The Delegation further stated that it would have been useful to describe the impact of those exceptions and limitations on the socio-economic development of those countries. The Delegation further reaffirmed the need to study the various impediments in licensing agreements relating to transfer of technology in greater details so that appropriate

steps could be taken to address that aspect. Therefore, the Delegation believed that there should be a thorough study based upon the questions of the use of patent system for the fulfillment of needs of the developing countries and LDCs from the perspective of accessibility and affordability of medicines and the socio-economic growth and development.

64. The Delegation of Pakistan expressed its support for the work program as proposed by the Delegation of Brazil. The Delegation stated that exceptions and limitations to patent rights were critical, as they assisted in balancing public welfare versus personal interest. The Delegation noted that a comprehensive regulatory review exception enabled generic product manufacturers to expedite marketing approval and thus facilitated access to affordable medicines. The Delegation further noted that exceptions were in line with the TRIPS Agreement, which allowed members to adopt measures to promote public interest for socioeconomic and technological development, as referred to in Article 8 of the TRIPS Agreement. The Delegation expressed its belief that it was important that WIPO's technical and legal assistance to countries raised awareness about the full modality of those exceptions and their limitations. The Delegation requested the Secretariat to broaden the data sample with respect to developing countries to allow for a better comparison.

65. The Delegation of Thailand congratulated the Chair and expressed its thanks to the Secretariat for the preparation of comprehensive documents. The Delegation noted that it was one of the many countries that had used compulsory licensing, as permitted by the TRIPS Agreement, mainly for the purpose of achieving universal access to medicine and healthcare for its population under the government's social security scheme. The Delegation stated that it would be helpful if the Secretariat could provide more detailed cases where such licenses had been utilized by other developing countries, and in particular, regarding clarity on what was fair and equitable remuneration. The Delegation noted that Thailand had announced the use of compulsory licensing on only seven patented drugs instead of nine and requested a correction to be made in document SCP/21/5, paragraph 33.

66. The Delegation of the Iran (Islamic Republic of) expressed its confidence in the Chair's stewardship and thanked the Secretariat for its hard work. The Delegation attached great importance to the exceptions and limitations to patent rights that provided flexibilities in intellectual property systems. The Delegation recognized the need to adapt national legislation on patents based on economic and social situations, and the importance of exceptions and limitations for countries that desired to develop their own system. The Delegation expressed its belief that the negotiations on exceptions and limitations, technology transfer and patents and health would help the Committee to better understand the challenges encountered in developing countries in their economic and social development, and would explore the ways to better adapt the patent system to meet the needs of national development. The Delegation stated that the mandate that had been given to the Secretariat for the preparation of those studies was limited, since it had been confined to inputs received from Member States without evaluating the effectiveness the exceptions and limitations. The Delegation noted that accordingly, there was no wider assessment of whether any of the exceptions and limitations were being used for the purpose of meeting policy goals and society needs, and the studies excluded elements such as the development needs, public health and competition, as found in the proposal by the Delegation of Brazil (document SCP/19/6). The Delegation further noted that in fact, the studies provided a very limited focus on implementation challenges and practical constraints in using the exceptions. The Delegation stated that it should also be noted that the studies drew general conclusions on how most countries used those exceptions based on a very little sample size. The Delegation stated that, for example, on implementation challenges for all of the exceptions, the conclusion that was drawn was that most countries viewed the existing law on exceptions as adequate. The Delegation further stated that given the limited and under-representative sample size, such conclusions might not necessarily adequately fit

other countries, taking into account their particularities and the different levels of development. In that context, the Delegation stated it would be important for the SCP to consider undertaking the work that had been proposed under phase II of the proposal by the Delegation of Brazil to carry out and analyze how those various exceptions and limitations were utilized by different countries in addressing various public policy objectives, particularly public health and food security.

67. The Delegation of Brazil expressed its appreciation to the Chair. The Delegation stated that the subject of exceptions and limitations was of utmost importance in the work of the SCP, as it touched upon fundamental development concerns. The Delegation noted that a number of the Development Agenda recommendations addressed, directly or indirectly, that issue in connection with norm setting, public policy, technology transfer, access to knowledge or impact studies. The Delegation further noted that recommendations 17 and 22 of the Development Agenda stated that WIPO should take into account in its activities the flexibilities of the international intellectual property agreements and should address, in its working documents for norm setting activities as appropriate and directed by Member States, issues such as potential flexibilities and exceptions and limitations for Member States. With that in mind, the Delegation said it had tabled document SCP/14/7 during the fourteenth session of the Committee held in January of 2010. The Delegation noted the document contained a work program on exceptions and limitations divided into three phases. The Delegation further noted that the proposal had received wide spread support, which demonstrated the relevance that had been attached by Member States to the discussion of exceptions and limitations. The Delegation stated that the SCP sessions following the fourteenth session had seen deliberation of the questionnaire to which the majority of Members States had answered and had provided relevant information for subsidizing the second phase of the proposal. The Delegation stated that at the twentieth session of the SCP, the Committee had agreed to request the Secretariat to prepare a document on four exceptions and limitations, and the Secretariat had been asked to organize a seminar for raising the debate in producing more information relevant for the work of the Committee. Turning to the underlying rationale of the exceptions and limitations to patent law, the Delegation stated that exceptions and limitations were intrinsic elements of every law. Further, the Delegation observed that exceptions and limitations served a number of purposes by conferring the necessary flexibility to guarantee national security and to shape public policies to meet, *inter alia*, development, competition and health surveillance goals. The Delegation stated that to build roads, prevent crimes, promote elections or avoid pandemics, for example, governments sought to ensure compliance with the rules that protected private goods and rights as well as to make use of exceptions and limitations. The Delegation considered that in order to fulfill the purposes it had mentioned above, patents were also subject to special treatment. In its view, the patent system must strive for the equilibrium of rights among its users which should, accordingly, not only comprise intellectual property title holders, but also society as a whole, so that the welfare of the society would prevail. The Delegation further noted that society constituted legitimate clients of the patent system. The Delegation said that exceptions and limitations to patent rights were standard parts of laws in legal doctrine. In its opinion, one could therefore argue that there might be substantial convergence among members as to the importance of those flexibilities to the patent system. The Delegation further stated that the existence of different approaches to limitations and exceptions might raise doubts of Member States regarding how and why they could use the policy space and how the use of exceptions and limitations were linked to innovation policies or addressing the public health, nutrition or environmental concerns. The Delegation noted that such differences illustrated the necessity of flexible policy space so that each Member State would be able to adapt its legal framework to its level of development, and thus would reach the goals of the public policy in place. The Delegation considered that that was yet another argument against the international

harmonization of patent laws since harmonized patent laws would impair the ability of states to adjust the legislation encumbered by the attainment of the objectives of the patent system. With respect to exceptions regarding experimental use and scientific research, the Delegation stated that a well-designed law could make use of those exceptions and limitations to attract foreign direct investments. In its opinion, exceptions and limitations did not purport to weaken the intellectual property system, but rather to calibrate it in order to reach a common ground where the interests of both right holders and third parties were adequately addressed. The Delegation stated that in spite of the above, the simple existence of exceptions or limitations was not sufficient by itself in order to evaluate the benefits or obstacles that had been faced by their implementation. The Delegation, therefore, considered that a more thorough investigation should be made with the intent of identifying which exceptions and limitations were potentially more effective in addressing development concerns, and what should be the conditions for Member States to enjoy them to the fullest. The Delegation noted that since national capacities and characteristics affected, to a large extent, the individual abilities of states to use exceptions and limitations, that could be another area for future work of the Committee, provided that it remained in line with the Development Agenda recommendations especially those related to the preservation of policy space.

68. The Delegation of China expressed its thanks for the informative presentations which enabled the Committee to not only think about exceptions and limitations from a legal perspective but also gave due consideration to an economic aspect. It also thanked the Secretariat for preparing comprehensive documents on the basis of feedback from Member States, which were a good reference for all countries. The Delegation stated that those outputs had shown that the SCP attached great importance to the discussion on exceptions and limitations. The Delegation noted that from the documents SCP/21/3 to 7, most countries were of the view that exceptions and limitations were of great importance to public policies. Further, the Delegation noted exceptions and limitations could guarantee the smooth application of patent law and could balance the interests of public and users. On that basis, the Delegation suggested that the Committee further share case studies. The Delegation considered that from those case studies, the Committee could draw positive conclusions to share with each other and move the discussion on the issue forward.

69. The Delegation of Argentina welcomed the Chair and expressed its congratulations to the two *ad hoc* Vice Chairs on their election. It also thanked the Secretariat for organizing the current SCP session. The Delegation stated that exceptions and limitations to patent rights were very important in the sense that they allowed for the balanced and appropriate system, which was an incentive for innovation, and which promoted the use of existing inventions. The Delegation stated that as the Committee had seen in presentations in the half day Seminar on Exceptions and Limitations to Patent Rights, exceptions and limitations allowed Member States to have standards to which they could adapt their intellectual property legislation and national development strategies. The Delegation noted in that regard that states could better enjoy benefits from the national intellectual property system and could satisfy their public policy objectives and their social welfare objectives through the implementation of exceptions and limitations to patent rights. The Delegation hoped the Committee could continue to discuss work on that important item.

70. The Delegation of Chile congratulated the Chair for his work and expressed thanks to the Secretariat for its preparation of the documents for the current SCP session. The Delegation expressed its support for the statement made by the Delegation of Paraguay on behalf of GRULAC. The Delegation stated that it was one of the Member States that had accepted the Secretariat's invitation to answer the questionnaire on exceptions and limitations because it understood how important that was to the patent system. The

Delegation stated that the questionnaires had contributed to the preparation of Secretariat's documents and the half day Seminar. The Delegation also noted that documents SCP 21/3 to 7 would be very useful for comparative law studies and would be very interesting for Chile's Intellectual Property Institute. The Delegation stated that, at the present time, its country had a law in Congress that was reforming its industrial property law and that covered all aspects of exceptions and limitations. The Delegation was convinced that everything it had heard at the current SCP session would be useful in that legislative process. The Delegation stressed the importance of exceptions and limitations to patent rights because they were a fundamental mechanism to keep a balanced intellectual property system. The Delegation, therefore, supported the proposal of the work program that had been put forward by the Delegation of Brazil in document SCP/14/7 as a concrete avenue for the work of the Committee.

71. The Delegation of Egypt attached great importance to the work program for exceptions and limitations to patent rights and the SCP. The Delegation stated that exceptions and limitations were a very important aspect in improving the patent system. The Delegation thanked the Secretariat for the documents prepared for the current SCP session and expressed its appreciation for the valuable information in those documents. The Delegation stated that it looked forward to more elaboration on those studies in order to identify how the exceptions and limitations were being used to meet the policy objectives in at least some specific cases. The Delegation encouraged the Secretariat to help Member States to effectively use exceptions and limitations to meet policy objectives and to incorporate that into WIPO's technical assistance. The Delegation noted that the technical assistance component could have some elements about how the countries could incorporate exceptions and limitations into their respective national intellectual property strategies. The Delegation also expressed its support for the proposal made by the Delegation of Brazil in document SCP/19/6. It stated that the proposal could be a good basis for a more elaborated work program with respect to exceptions and limitations to patent rights.

AGENDA ITEM 6: QUALITY OF PATENTS, INCLUDING OPPOSITION SYSTEMS

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

73. The Chair recalled the decision of the Committee at the previous session of the SCP concerning agenda item 6 and opened the floor for general statements.

74. The Delegation of Japan, speaking on behalf of Group B, noted difficulties experienced by the IP offices in meeting the increasing demand for patents and reducing backlogs and in that context, the importance of work sharing and collaboration. The Delegation also stressed that work sharing programs facilitated access to the search and examination information of other offices and did not attempt to affect the sovereign rights of participating offices to decide on whether to grant a patent or not. Further, noting that there were some differences among offices concerning, for example, their skills and languages and search databases employed, the Delegation stated that international work sharing and collaboration should be helpful by making the access to such different information easier. The Delegation expressed its hope that the sharing session on work sharing and collaboration would trigger discussion on that issue for the purpose of deepening of understanding and expansion of such collaboration, and that WIPO could serve as a suitable venue to achieve that goal.

75. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, reiterated its great interest in the Committee's discussion on work sharing. The CEBS

Group was well aware that work sharing between patent offices continued to play significant role in the developments of the patent system and in improving its efficiency. The Delegation continued to support the proposal in document SCP/20/11 Rev. The Delegation further stated that CEBS Group supported any improvement of the WIPO webpage on work sharing, efforts towards an increasing awareness of those programs and initiatives and providing up-to-date information. The Delegation was of the view that the annual conferences on the margins of the SCP sessions would be a useful tool for exchanging practical experience and knowledge in that field. Noting the growing number of international cooperation engagements of Member States of the Group, the Delegation stated that they would be able to individually engage in a more intensive manner in the coming sessions. Therefore, the Delegation supported the further development of the Committee's work on work sharing and collaboration, including in the area of opposition systems.

76. The Delegation of Italy, speaking on behalf of the European Union and its Member States, expressed its support for advancing the work of the SCP on the quality of patents. The Delegation stated that it looked forward to the studies to be submitted to the following session of the SCP on inventive step and the sufficiency of disclosure as had been agreed at the twentieth session of the Committee. The Delegation emphasized the importance of fully examining the concept of inventive step in WIPO Member States according to the proposal made by the Delegation of Spain, endorsed by all other Member States of the European Union contained in document SCP/19/5 Rev. The Delegation further expressed its support for the proposal made by the Delegation of Denmark, contained in document SCP/17/7, as well as for the proposal made by the Delegations of the Republic of Korea, the United Kingdom and the United States of America, contained in document SCP/20/11 Rev. In relation to the latter proposal, the Delegation stated that a dedicated webpage on the WIPO website on work sharing and collaborative activities between patent offices would improve awareness of existing initiatives and allow patent offices to collaborate more effectively. In addition, the annual conferences on the margins of the SCP sessions on international work sharing and collaboration would provide opportunities to share experiences on work sharing programs and to improve the usefulness of the programs for IP offices, users of the system and the general public alike. Furthermore, the Delegation expressed its confidence that a sharing session regarding work sharing and collaboration would provide useful insights and provide a good basis for further improvements in that area. Further noting that it would be useful for WIPO to further explore the topic and related challenges, the Delegation proposed that the WIPO Secretariat work with Member States to prepare a study on how different laws and practices limited the potential for work sharing and what measures could be put in place to address problems at the international level. Finally, referring to the issue of opposition systems, the Delegation stated that it would be interested in further looking at administrative revocation and invalidation mechanisms and potential parallel infringement proceedings at court.

77. The Delegation of Iran (Islamic Republic of) wished to restate its concern about the lack of a definition of the concept of patent quality. In particular, the Delegation stated that in the absence of such clarity, the proposals made under that agenda item could not be fully supported by the delegations; therefore, a clear understanding on the definition of that concept was necessary in order to take further steps on that issue. Further, the Delegation stated that while it was important for the SCP to continue discussions in order to come up with a definition of quality of patents, it wished to emphasize that it was against any idea of harmonization with regard to quality of patents. The Delegation was of the view that any work on patent quality should take into account the following elements: (i) the different role and different nature of patent systems in Member States as well as different levels of development in IP offices; (ii) the need for capacity building and training programs for IP offices. The Delegation stated that training programs were to be given due consideration

and developed as a separate and underlying component of patent quality; (iii) any discussion on patent quality should take into account the relevant Development Agenda recommendations with the objective of strengthening the ability of patent offices to grant high quality patents according to their national law; and (iv) the process should be voluntary and be guided by the Member States and not aimed at harmonizing patent laws. Further noting that any work on patent quality should ensure compliance with the requirements of the patentability including the requirement of sufficiency of disclosure, the Delegation stated that it would be important to study and evaluate the role of the requirements of sufficiency of disclosure in the quality of patents. The Delegation was of the view that the proposed initiatives would not achieve those objectives, and would also result in harmonization of practices in the field of patent law, which would be prejudicial to the provisions of flexibility in national legislation on patents of various countries. The Delegation stated further that the concept of quality of patents referred to the ability of patent offices to apply their domestic patent laws and that patentability criteria might be applied differently in different jurisdictions. Finally, the Delegation looked forward to further discussion on opposition systems and other revocation and invalidation mechanisms.

78. The Delegation of India, with respect to work sharing, referred to the following statement made at the previous session of the SCP “[...] work sharing would create a dividing line, i.e., the offices of some countries would forever remain on the receiving side of the dividing line thus depending upon the product delivered by the other countries [...], enhancement of the competence of the offices would thus be a more preferred option. In accordance with the Indian Patents Act, the Examiners are duty bound to conduct their own search and examination. Although they could use the results of the search and examination done by other patent offices, they must use them vis-à-vis the provisions of the Indian Patents Act”. Further, with respect to document SCP/20/11 Rev., the Delegation restated its position that work sharing could not be the ultimate solution for improving the quality of patents. The Delegation noted the following statement of DAG made at the third session of the PCT Working Group in June 2010 (document PCT/WG/3/13): “Member countries of the PCT will always be divided across a line separating those that are international search and examination authorities (ISEA) and those that are not. The former would ideally produce top-notch quality examinations within the PCT system whereas the latter would have little if any capacity for conducting substantive examination of patents, thereby limiting themselves mostly to validating the work of the ISEA. We do not favor this approach that only freezes a divisive situation rather than contributes to the better integration and operation of the overall PCT system”. In relation to the information sharing session regarding experiences on international work sharing and collaboration, the Delegation recalled that the Committee shared the understanding that discussions on work sharing and collaboration did not imply any automatic acceptance of work sharing products and did not prejudice the sovereign rights of Member States in processing patent applications and patents in accordance with the applicable national law. The Delegation further stated that work sharing programs were not compatible with their statute; therefore, it held the same view regarding such programs as in the past sessions. The Delegation further referred to statements made by the following delegations at the eighteenth session of the SCP on that agenda item: (i) the Delegation of Egypt, speaking on behalf of the African Group and (ii) the Delegation of Algeria, speaking on behalf of DAG, stating that a common understanding on the definition of the term “quality of patents” was necessary in order to take further steps on that issue; (iii) the Delegation of Brazil stating that since high quality patents had been paramount to achieving the goals of the patent system, the Committee should engage in a discussion of that important issue looking at the contributions to the improvement of the patent system, including search and examination and evaluation of the workflow; expressing its belief that patents of high quality were crucial to reach the objectives of patent protection stipulated in Article 7 of the TRIPS Agreement; and (iv) the Delegation of Argentina underscoring the fact that defining the

patentability criteria according to national requirements had been a vital tool that countries had had at hand and considering that any endeavor to harmonize the patentability requirements among Member States would affect the flexibility provided under Article 27 of the TRIPS Agreement. Further, the Delegation referred to its statement made at the eighteenth session of SCP where it had pointed out that the search and examination reports on the same intervention, even those prepared by the International Search Authorities were not consistent. Acknowledging the need of quality search and examination, the Delegation reiterated its view expressed at the seventeenth session of the SCP (paragraph 93 of document SCP/17/13) that “[w]ith 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*”. Further, the Delegation referred to its statement made at the nineteenth session of the SCP where it had emphasized that quality of patents had been important not only for the development of any patent system, but also for the technological development of a country. It further stated that India held the same opinion that the full disclosure of the invention including the most relevant prior art and the best mode of performing the invention without any undue further experimentation or know how were most relevant for improving the quality of patents. In that regard, the Delegation continued, Article 29 of the TRIPS Agreement clearly mandated such disclosure, including providing information concerning the applicant’s corresponding foreign applications and grants. The Delegation held the same opinion as it had expressed at the previous sessions of the Committee. Further noting that any agenda of harmonization of patent laws was not a welcome option for India, the Delegation stated that it appeared that such harmonization attempts were being renewed through the proposals made by the Delegations of Denmark (document SCP/17/7), Canada and the United Kingdom (document SCP/17/8) and the United States of America (document SCP/17/10). With respect to the quality metrics, the Delegation was of the view that there was a lack of a universal definition regarding the quality of patents. It noted that a patent office measured its performance with various performance indicators. The Delegation further stated that the most important reason for the patent system was the public interest it served. The quality of the service rendered to the public (not only from the perspective of the patentee or its business rival, but also society) was the ultimate measure of the quality of the patent system. It wished to reiterate that the technological promise embedded in a patent system could only be realized if patent specifications could enable the transformation of technological process without the aid of trade secrets and know-hows. As regards the sharing of search and examination work, as contained in the proposal submitted by the Delegation of the United States of America (document SCP/19/4), the Delegation noted that the work sharing had been proposed in the second session of the PCT Working Group, during which several countries had expressed their reservations against the institutionalization of a work sharing program. In that regard, the Delegation quoted the views expressed by the DAG during the third session of the PCT Working Group (document PCT/WG/3/13): “As a matter of principle, we do not favor the principle of automatic validity of international search and examination reports, nor do we consider that a national patent office is under any obligation to accept automatically any report by another national patent

office". The Delegation in that session had considered that, since a patent had been granted according to the applicable national law, an examiner had remained bound by the national patent law, which had mandated the examiner to carry out search and examination and despite the issue of duplication, the examiner had to perform its statutory duties. However, in its view, a patent examiner had been free to use search and examination reports of other offices, if so desired, as most of the countries had made available their prosecution history, including the search reports. Moreover, the international search and examination reports prepared by the international searching and preliminary examining authorities had also been made available by WIPO and could be used by the examiners. Therefore, the Delegation was of the opinion that such work sharing could be initiated on a voluntary basis. Further, the Delegation referred to its opinion expressed at the twentieth session of the SCP (paragraph 77 of document SCP/20/13 Prov.2): "[...] the quality of the patent system was better understood from the perspective of the degree of technological content of a patent specification and its efficiency as a tool for transfer of technology. The Delegation believed that the quality of a patent could not improve simply by adopting the practice of other patent offices. The Delegation opposed any attempt of harmonization in the name of quality issues. As a matter of principle, the Delegation neither favored the automatic validation of international search and examination reports, nor did it considered that a national patent office was under any obligation to accept automatically any report prepared by another national patent office. In the opinion of the Delegation, work sharing would create a dividing line, i.e., the offices of some countries would forever remain on the receiving side of the dividing line. Thus, those countries would depend upon the product delivered by the other countries. The Delegation therefore considered that the enhancement of the competence of offices would thus be a more preferred option. In accordance with the Indian Patents Act, the Delegation explained that its examiners were duty bound to conduct their own search and examination. Although they could use the results of the search and examination carried out by other patent offices, they must use them *vis-à-vis* the provisions of the Indian Patents Act". The Delegation further stated that it endorsed its views expressed at the earlier sessions and reiterated that India did not subscribe to the view that work sharing in the form of the Collaborative Search and Examination System or PPH would enhance the quality of patents. Noting that a patent was a social product and hence, its quality was linearly proportionate to the policy of the country from the point of view of its socio-economic priorities, the Delegation stated that, therefore, it did not accept the above proposals made regarding the sharing of search and examination work. Further, with respect to the proposal by the Delegation of Spain on the study relating to inventive step, the Delegation stated that such study should not be construed to mean any harmonization of the substantive issues of patent systems. The Delegation continued that, moreover, such study should only be conducted on a factual basis and not with the view of doing an analysis or making a recommendation. Further, the Delegation reiterated its view on that study as expressed in the nineteenth session of the SCP (paragraph 60 of document SCP/19/8). In relation to the studies to be prepared for the twenty-second session of the SCP on inventive step and sufficiency of disclosure, the Delegation reiterated that those studies would be a collection of factual information without analysis or recommendation. It further noted that inventive step and person skilled in the art were not defined in the TRIPS Agreement and, therefore, they were flexibilities. The Delegation noted that as the threshold of the skilled person lowered, the chance of the entry of frivolous inventions became higher. Conversely, higher the level of skill of such person would allow only those inventions which had a higher threshold of inventiveness and therefore, led to technical and industrial development. Noting that the patent system had to promote the progress of useful arts in conformity with public policy objectives, and that with the passage of the time, horizons of inventions were continuously redefined and every day an inventor needed to begin from new vistas, the Delegation stated that the concept of the person skilled in the art were to be judged from that perspective. The

Delegation added, moreover, the perception of the skilled person may not be uniform in the contexts of inventive step and enablement.

79. The Delegation of Pakistan stated that an expeditious patent search and examination system did not necessarily improve quality of patents. The Delegation stated that there was a need to address the real issues that could improve quality of patents, i.e. a robust substantive examination and stricter patentability criteria. The Delegation was of the view that international work sharing, even if it was not mandatory, would increase reliance on other offices' search and examination, which would ultimately result in no substantive examination being carried out at small patent offices. The issue of the deterioration of patent quality was not only because of a lack of infrastructure and delays in the examination process but due to the lowering of the standards of patentability and examination practices. The Delegation continued that in order to achieve public health objectives and to prevent evergreening practices, it was extremely important to grant patents only to those inventions that would meet the strict patentability criteria. In its view, developing countries needed to redefine their patentability criteria to fully benefit from various flexibilities provided under the TRIPS Agreement. The Delegation further stated that, in that regard, evidence showed that countries that had set stricter patentability criteria in their patent laws, like India after introducing Section 3(d) in its Patent Act, and Argentina after issuing patent examination guidelines, had been successful in preventing the grant of invalid patents. The Delegation concluded that developing countries needed to strengthen their substantive examination practices.

80. The Delegation of Kenya, speaking on behalf of the African Group, noted that in discussing the issue of work sharing and collaboration, it needed to have precautions. In particular, the Delegation sought clarification on the question of necessity, feasibility and beneficiaries of work sharing initiatives.

81. The Delegation of Argentina stated that the quality of patents was a fundamental issue for the whole system. Therefore, the application of high standards of patentability requirements in the examination process was important to avoid granting patents for trivial patents that could have a negative impact, for example, on public health. The Delegation further stated that in accordance with Article 1.1 of the TRIPS Agreement, Members were free to determine the appropriate methods of implementing the provisions of the Agreement within their own legal system and practice without granting protection that would actually be more extensive than that required under the Agreement. The Delegation wished to underscore the fact that defining the patentability criteria in accordance with national priorities was a very important tool that developing countries had at their disposal. The way in which those criteria were applied was also important for determining what was in the public domain. The Delegation further stated that any efforts to harmonize the patentability criteria could have an impact on Article 27.1 of the TRIPS Agreement.

82. The Delegation of Egypt reaffirmed its position that it did not support any discussion under agenda item 6 that led to the harmonization of patent laws or patent systems. It further stated that the quality of patents lacked a clear and precise definition at the SCP. In the view of the Delegation, work sharing did not guarantee the quality of patents and that the real factors that could guarantee such quality was the proper application of the patentability criteria. The Delegation continued that the focus should be on improving the quality of patent applications as well as on sufficiency of disclosure.

83. The Representative of ICC noted that the discussions on patent system were particularly useful when focusing on practical issues that helped to ensure that the system worked to support innovation and growth, such as quality of patents and international work

sharing and collaboration between patent authorities. The Representative encouraged the Committee to dedicate significant attention to those topics, which were of great importance, not only for patent authorities, but also for users of the patent system. Further, the Representative emphasized the need for the Committee to carry out studies from different angles as had been suggested at the previous sessions of the SCP. As regards work sharing, the Representative noted that the Committee should: (i) support and strengthen the PCT as the preeminent vehicle for work sharing on international patent applications; (ii) support the work of participating offices in the implementation of the PPH programs; and (iii) encourage patent offices to take positive steps to achieve an earlier comprehensive coordinated search. Regarding the last point, the Representative referred to its paper distributed during the twentieth session of the SCP.

84. The Chair opened the sharing session regarding experiences on international work sharing and collaboration.

85. The Delegation of Australia gave a presentation on the experiences of IP Australia in international work sharing and collaboration. The Delegation stated that work sharing simply meant that a second office looked at the work of another office to ensure the quality and efficiency of its own work. The Delegation emphasized that work sharing was not a substitute for conducting patent search and examination in accordance with the national law of a participating office. Noting that patents were often filed in multiple jurisdictions for the same invention, and the number of patent filings would continue to grow globally, the Delegation stressed that work sharing was a tool necessary to deal with workloads and prevent the patent system from failing. The Delegation further stated that an examiner in its every day work faced the difficult task of searching a big collection of prior art, which typically included the patent documents produced by other offices. The Delegation questioned why examiners should not look at the work of another office that had already looked at the invention, and had searched for relevant documents. The Delegation stated that that did not mean that examiners should accept and validate that application simply because that application had been accepted in other countries. The Delegation explained that, if IP Australia were not carrying out work sharing collaboration with other offices but rather conducting a full international search on every application that came through Australia, the need to hire a significantly large number of patent examiners would arise, resulting in an exorbitantly high cost of patent protection. The Delegation noted further that work sharing allowed examiners to use work products of another office as a head start and to learn from the experiences of other offices in conducting searches. Work sharing also allowed the examiners of IP Australia to focus their efforts on complex cases first filed in Australia. The Delegation recognized the responsibility of IP Australia as an International Searching Authority (ISA) to spend time and effort on the international search so that when such work was used by other countries, it was reliable, high quality and a sound basis to assist other countries in their search and examination according to their national law. The Delegation stressed, however, that IP Australia would not have been able to spend time on such search if it had not been engaged in work sharing and had not used the work results of other offices for all other applications. Further, noting that 90 percent of filings in Australia were of foreign origin, and consequently other offices had likely performed search and examination, the Delegation stated that what examiners in IP Australia would do further was validate and complement foreign work results in order to ensure that that particular application met the requirements of Australian patent law. In that context, the Delegation stated that a process of validation was important to support quality output from its office. The Delegation also informed the Committee about work sharing initiatives that IP Australia had been involved in, such as: the PCT, Vancouver Group, Global Patent Prosecution Highway (Global PPH) and Australia-New Zealand Single Economic Market. In the framework of Single Economic Market, the IP offices of both countries were jointly carrying out a project on a single patent

examination. According to the project, patent applications filed in both Australia and New Zealand would be examined by one examiner located in either country. Examiners would grant or refuse applications under each country's law. The Delegation noted that such integrated patent examination between both countries would eliminate unnecessary duplication of work. The Delegation further highlighted the importance of technical infrastructure allowing offices to access work products of other offices, such as WIPO Patentscope and WIPO Centralized Access to Search and Examination (WIPO CASE). The Delegation explained that WIPO CASE was a platform to share information with regard to search and examination reports among participating intellectual property offices quickly and efficiently. The Delegation noted that in its office, around 99 percent of work sharing was done through WIPO CASE and demonstrated how WIPO CASE worked. Further referring to the discussion on the definition of the term "quality of patents", the Delegation stated that work sharing produced better quality patents because examiners from across the world were working together as a single examination team. The Delegation stressed that work sharing should be looked in that context and not as something demanding, driving or producing acceptance in a second country. In conclusion, the Delegation noted the complexity of prior art search in certain areas of technology and stated that work sharing was an inevitable and necessary tool to ensure the efficiency of the patent system.

86. The Delegation of Ecuador stated that its national patent office was very small. It further stated that it also took advantage of the work products produced by other offices in conducting search and examination of national applications. The Delegation noted that such work sharing was very helpful to its office, in particular, as regards the search for prior art documents.

87. The Delegation of Kenya stated that in order for examiners in developing countries to be able to understand, to analyze search and examination reports and to make valid judgments as to the soundness of the material produced by other offices, capacity building was needed. The Delegation sought further clarification on the question of necessity, feasibility and beneficiaries of work sharing initiatives.

88. The Delegation of Australia, in response to the question on the necessity of work sharing, noted the growing number of patent applications filed around the world and related backlogs. The Delegation stated that work sharing was one way of resolving that problem. As regards the feasibility, the Delegation referred to the possibility of accessing foreign work products electronically as it had displayed during its presentation. The Delegation noted that IP Australia published search strategies used by examiners in carrying out prior art search and encouraged other offices to do the same. Regarding the beneficiaries, the Delegation stated that while the first beneficiary was an applicant, the eventual beneficiary of work sharing was society as a whole, as such programs aimed to ensure that patents were not granted to inventions that did not comply with the patentability requirements of a particular country. In relation to capacity building, the Delegation stated that it was not only relevant for developing countries. IP Australia, like other offices, was also in need of activities related to capacity building to learn from other offices how to better search for prior art documents and be more efficient.

89. The Delegation of Ireland stated that as its patent office was very small with only three examiners processing applications in various fields of technology, the decision on how to allocate resources deserved careful consideration. The Delegation stated that since the ratification of the European Patent Convention (EPC) in 1992, the vast majority of applicants obtained patent protection in Ireland through the EPC. As a result, examiners at the Irish Patents Office had received a few hundred applications a year from very small companies and individual inventors. The Delegation stated that the examiners were processing those

applications by using the work products of other offices, including search reports of the patent offices of the United Kingdom and Germany. The Irish Patents Office was also outsourcing the search to other large offices, as with three examiners, it would not be feasible to reach the required level of quality. The Delegation stated that the Irish Patents Office managed its resources well and the service it provided was fully acceptable by the people it dealt with. The Delegation also reassured that while the examiners of its office used work results of other offices, the national law was being applied.

90. The Delegation of Tanzania, referring to the definition of the term “quality of patents” in the framework of work sharing, stated that there had been a misconception of that term. The Delegation further stated that the presentation given by the Delegation of Australia had addressed that question well. The Delegation noted that work sharing was a tradition of an IP office and was not about harmonizing patent laws. The Delegation stressed that under work sharing the decision on the grant of patents remained with the national patent office according to the patentability criteria prescribed by the applicable national law. The Delegation concurred with the presentation made by the Delegation of Australia and expressed its interest in sharing that presentation with other stakeholders.

91. The Delegation of Paraguay expressed its appreciation for a very informative presentation made by the Delegation of Australia. The Delegation stated that similar to the Irish Patents Office, its Office was very small with three examiners in total. The Delegation stated that its office had also been using work results produced by other offices, which were very useful. Further noting that the question on necessity, feasibility and beneficiaries of work sharing initiatives was very relevant, the Delegation thought further the information regarding capacity building and technical assistance programs provided by the IP Australia was very relevant for Paraguay.

92. The Delegation of Australia stated that its first commitment to capacity building was that it published its search information of every application so that other offices could see it and judge the quality of that work. The Delegation encouraged other offices to be part of WIPO CASE to be able to access and use the search and examination work produced by the IP Australia as it would make use of work produced by other offices. As regards capacity building, the Delegation informed the Committee about the Regional Patent Examiner Training Course in which 15 people from the Asia Pacific Region and Africa were being trained. That course was two years in duration. During the course, participants would be trained, using information technology in their own offices, in terms of searching and evaluating the novelty and inventive step based on real applications. The Delegation explained that two years program was necessary as short term programs would not achieve its results. Further, the Delegation stated that IP Australia had sent two examiners for two weeks to the Chilean Office to assist its examiners in searching complex chemical structures. Noting that due to the limited resources of IP Australia, it could not provide many training programs. The Delegation stated that its office was planning to move its training programs to a broader based model in which the training material would be provided for free on the Internet. The Delegation expressed its hope that such modality would be helpful in training people who would become trainers themselves. The Delegation concluded by stating that that was its commitment to capacity building and to development and thanked WIPO for assisting IP Australia with the funding of training programs.

93. The Delegation of Montenegro posed questions to the Delegation of Australia concerning the validation criteria used in IP Australia as well as regarding the background for the foundation of the Vancouver Group.

94. The Delegation of Australia responded that the Vancouver Group was established between the IP Offices of Australia, Canada and the United Kingdom with the aim to share information and experiences on common issues and areas relevant to managing a mid-sized national IP office. Those Offices had similar backgrounds, challenges and most importantly, were English speaking offices, which facilitated easy interaction among them. The Delegation stated that they kept the Group small, as it would be hard to manage a larger number of offices. As regards the criteria for validation, the Delegation responded that there were no such criteria. While there were some guiding principles, the validation work mainly relied on well-trained professional people who made their own decisions regarding the quality of the work products of other offices. The Delegation stressed that rather than requesting the examiner to follow any validation guideline, the application of critical thinking and analysis skills of the examiner was important in validation process.

95. The Delegation of the United Kingdom gave a presentation on the experiences of the Intellectual Property Office of the United Kingdom (UKIPO) in international work sharing and collaboration. The Delegation stated that one of the challenges that patent offices were facing was that patent application filings had doubled in 15 years, resulting in an estimated four million applications awaiting examination worldwide. Noting that the processing of those applications would require three years of work, the Delegation stated that the problem of backlogs would persist in the future. The Delegation also stated that the complexity of applications in new fields of technology and more prior art in different languages contributed to the backlogs, creating uncertainty for innovators, investors and competitors. The Delegation stated that one of the solutions to that problem was international work sharing. In particular, the Delegation stressed that work sharing reduced duplication and increased the efficiency of the patent system. Further, the Delegation noted that under work sharing initiatives, individual offices applied their own laws in deciding whether to grant a patent; however, with the work product of another office, they could get a “head start”, which could only improve the examination of national applications. Further, the Delegation informed the Committee that the patent law of the United Kingdom had been amended to allow sharing of applications with other patent offices before their publication. Such pre-publication work sharing would require a written agreement with the other office setting out strict rules on confidentiality and data handling. On that point, the Delegation wished to stress that under that framework, the other office would not be required to share their pre-publication information with UKIPO. The Delegation further informed the Committee that UKIPO was working on the details of the implementation of pre-publication work sharing and that the details of all agreements would be published on its website. The Delegation also informed the Committee about the work sharing programs in which its office was participating. In particular, the Delegation stated that the PCT was a successful work sharing initiative allowing offices to benefit from the work undertaken by the international authorities at the international phase of the PCT procedure. Encouraging the offices to make use of the work products produced by the International Authorities, the Delegation stressed that the responsibility for granting patents remained exclusively in the hands of the patent offices of countries where protection was sought. Further, the Delegation stated that under the United Kingdom’s PCT (UK) Fast Track system, patent applicants could request accelerated examination in the United Kingdom national phase if their international application had received a positive International Preliminary Report on Patentability (IPRP), regardless of which Authority had issued that report. The Delegation stated that it also supported improvement of the PCT system generally. In particular, the Delegation referred to a joint proposal made by the United Kingdom and the United States of America entitled “PCT 20/20” at the fifth session of the PCT Working Group, and stated that further work on that proposal was being carried out. The Delegation further stated that UKIPO also actively participated in the PPH pilot and was one of the initial 17 Global PPH members. In addition, it also held a number of other bilateral agreements. Noting further that UKIPO was also a

co-founder of the Vancouver Group, and one of the initial members of WIPO CASE, the Delegation supported expansion of WIPO CASE and linkage to the IP5's One Portal Dossier. In conclusion, the Delegation stated that UKIPO also participated in a wide range of examiners' information exchange with other offices in order to improve search and examination processes, the quality of procedures and to increase the productivity of offices for their mutual benefit.

96. The Delegation of Japan gave a presentation on its experiences in international work sharing and collaboration. The Delegation stated that the Japan Patent Office (JPO) had been working toward expanding the PPH network and enhancing the usability of that framework. The Delegation noted that currently, 33 intellectual property offices participated in the PPH as of October 2014. Further, the total number of requests that had been made worldwide for PPH had exceeded 60,000. The Delegation stated that the PPH was a framework in which an application determined to be patentable in the office of earlier examination was eligible for an accelerated examination in the office of later examination with a simple procedure upon an applicant's request. The Delegation noted that the objectives of the PPH were work sharing and accelerated examination and that it was not aimed at harmonizing substantive examination. The Delegation referred to a Japanese court decision, which had stated that examiners should be considered to be independent of the patent office commissioner in terms of patent examination. Further, the Delegation stated that each examiner had a strong sense of independency. If the PPH were concerned with substantial examination, the JPO examiners would not be able to conduct examinations under the PPH framework. The Delegation noted that the PPH provided three significant benefits to users, which were: (i) accelerated examination process; (ii) cost reduction due to the reduced number of office actions; and (iii) high predictability of the examination outcome. The Delegation stated that firstly, the PPH sped up the examination process. For example, in Japan, the official first action pendency had been an average of 10.4 months, while the first action pendency for PPH applications had been an average of 1.7 months. According to the Delegation, another benefit of the PPH was a decrease in the number of office actions, which may lead to cost reduction in the intermediate process. For example, in Japan, the average number of office actions was 1.12, but for PPH applications, it was 1.08. Thirdly, the Delegation also stated that the PPH had increased the grant rate of applications. The Delegation noted that since PPH applications had already been amended, if necessary, to be patentable in the office of earlier examination, the overall patent grant rate in the office of later examination was higher than that of non-PPH applications. For example in Japan, the patent grant rate for all applications had been 69.8 percent whereas for PPH applications, it had been 74.7 percent. Referring to a graph that showed changes in the number of applications for the PPH and PCT-PPH worldwide, the Delegation stated that the number had continued on an upward trend over the years, which meant users supported the PPH system. In conclusion, the Delegation reiterated that the PPH was a system of an accelerated examination, which however, did not aim to harmonize substantive examination. The Delegation stated that the JPO would like to commit itself to making the PPH a more effective framework.

97. The Delegation of Kenya noted that while work sharing programs increased the amount of information that would be useful to the examiner, such initiatives did not take into account the capacity of offices dealing with those applications, thereby running the risk of eroding the quality of patents. The Delegation stressed that for any work sharing to work well, it was critical to build the capacity of offices and make sure that all offices were of a similar level because the examiner in the second office must have the necessary knowledge and skills to make a valid judgment on a work product produced by another office. In that context, the Delegation stated that Article 51 of the PCT on technical assistance needed to be implemented.

98. The Delegation of Egypt, noting that the patentability criteria in different countries were different, questioned what would be the added value to a developing country to look at the examination made by another country using totally different patentability criteria for granting patents.

99. The Delegation of Australia, in response to some of the comments made by some delegations, stated that the work sharing arrangements, such as the PPH, provided the examiner at the second office with a search and examination results from another office that the examiner could not have accessed otherwise. As regards the different patentability criteria applied by different offices, the Delegation stated that, in practice, the national law provisions relevant to the searching prior art documents for the purposes of determining of novelty or inventive step were not that different. The Delegation continued that for the determination of novelty, any published documents provided by any patent office, whether developing or developed country, would be relevant. The examiner would look at those documents in order to ensure it did not miss the documentary disclosure that had probably been cited by another examiner that well understood the technology. The Delegation emphasized that if a developing country was not involved in the PPH, it might not be getting access to information that would be needed to examine the applications. The Delegation questioned why the office would not use the work product of another office to the extent that it would be appropriate to do so in that country. Another benefit of work sharing the Delegation wished to underline was that the second office would save time conducting its own search because it already had part of the work done by another office.

100. The Delegation of India stated that access to knowledge and technology transfer was important to developing countries. In that regard, the Delegation stated that developing countries needed the support of advanced patent offices. The Delegation stated that if work sharing was a voluntary mechanism, then the Delegation did not have any objection. However, it had concerns regarding the harmonization of examination practices.

101. The Delegation of the United States of America gave a presentation on its experiences in international work sharing and collaboration. Showing a depiction of commerce on a global scale, including international air routes and shipping lanes, the Delegation noted that inventors were marketing their products in multiple jurisdictions and countries, which gave rise to the issue of inventions patented in different countries. The Delegation explained that that was the background of why there were so many patent applications covering very similar or identical inventions filed in different countries. The Delegation stated that a backlog had started to develop in many countries and certainly at the United States Patent and Trademark Office (USPTO). In that regard, the Delegation noted that the USPTO was trying to reduce and eventually eliminate the backlog of unexamined applications. In the 1990s, discussions had begun between the USPTO and other large patent offices in the world on how the problem of backlog could be tackled. One of the solutions had been a work sharing idea. According to the Delegation, the PPH had been developed in 2006, and a pilot program between the JPO and USPTO probably had been the first PPH. The Delegation gave three main reasons for wanting to participate in work sharing. The first of the three reasons was to minimize the duplication of work, since patent applications were filed in multiple jurisdictions, and repeating the search work would be a huge burden on patent offices. The Delegation stated that the second reason was to enhance examination efficiency and quality. The third reason was to deliver real benefits to users of the patent system, which were a broad range of society and patent applicants. The Delegation stated that the main thing work sharing could provide was more efficient and cost effective search and examination. Also, within the framework of the national laws of the country, offices could potentially grant higher quality patents. The Delegation noted that while certain offices might lack specialized capabilities, making those specialized capabilities available to

everybody might be possible with work sharing. Further, the Delegation noted that examiners at the USPTO did not work in certain languages and thus there were some problems utilizing prior art references in certain languages. Therefore, the benefit of the knowledge of certain offices with specialized experience in languages would definitely benefit USPTO examiners. The Delegation noted the same benefits applied with regards to search tools, access to prior art collections, especially national prior art collections, data bases and technical specialization. Noting that the PPH program was not the first work sharing program on which the USPTO had embarked, the Delegation referred to some earlier work sharing programs, including the trilateral program between the JPO, USPTO and EPO, which had evaluated ways to improve the availability and usability of results. The Delegation also noted the JP-First, the Korean Intellectual Property Office (KIPO)-USPTO Share pilot and the UKIPO-USPTO Work Sharing Initiative. The Delegation explained some of the lessons it had learned, including that the timing of the examination had been important. In addition, notification, in terms of how one office would know what was going on in another office, and access to information had also been important logistical or technical factors. The Delegation noted that examiners that had been involved in the program had found it useful to see the examination and search results from other offices, which suggested that a better understanding of offices' practices would improve work sharing and was an important aspect in building trust between the offices. The Delegation stated that one ongoing program within the PCT was collaborative search and examination, the goal of which was to establish a high quality search report for the PCT system. Although that was a pilot program, it was one way for the USPTO and other collaborating offices, initially the EPO and KIPO, to try to see if it was possible to produce a higher quality PCT report. The Delegation further explained the three phases of the collaborative search and examination. With regards to the PPH, the Delegation said that it was essentially a system of work sharing to improve examination efficiency by reducing the duplication of work between different offices where related applications were filed in multiple jurisdictions. The Delegation noted that the benefit to the applicant was that the applicant received fast track processing, which was an acceleration of the examination time line. The Delegation noted that the acceleration was not the goal but was a benefit to the applicant so that they would use the PPH system which, in turn, would make the patent office's work more efficient and cost-effective. The Delegation stated that once an applicant received a positive examination result from a participating office, which could be a national grant of a patent, a positive PCT written opinion or other indication that some of the claims in the application were patentable, then the applicant could file a request for PPH at the USPTO. Once the request was granted, the examination in the USPTO, or other second office, would be accelerated. The Delegation noted that the number of applications that had been processed under that PPH program was over 25,000 applications since 2006 when the PPH program started. The Delegation further noted that since that time, the number of offices with which the USPTO had a PPH program had increased. The Delegation stated that there was a variety in the sizes and backgrounds of offices, from both developed and developing countries, which had been involved in PPH programs with the USPTO. It noted that the average monthly request was 616, which had been increasing every year and that every month the USPTO got more applications compared to the previous year. The Delegation however stated that for the USPTO, the number of applications under the PPH program was a still a small number of total applications processed. It stated that the benefit to the applicant was lower prosecution costs because there were fewer actions per application. The Delegation also noted that timelines had improved, as the application was examined and a decision whether to grant a patent was made faster than if the applicant had not used the PPH program. Additionally, the Delegation said that the patent quality could be potentially higher because by looking at the earlier search report, the USPTO could carry out a search that was at least as good as what had been previously carried out. Therefore, since USPTO examiners still carried out their own search based on the law of the United States of America, the resulting search would

almost every time be better than if the USPTO had conducted the search by itself. The Delegation noted that the first action allowance rate, which meant the number of patents divided by the total number of grants and rejections, was over all about 53 percent, while the allowance rate of the PPH applications went up to about 84 percent. The Delegation explained that that was not because of a reduction in the quality of the examination but due to the fact that the claims presented under the PPH program were fewer and had already been narrowed by the applicant in order to meet the patentability requirements of some other patent offices. Therefore, the Delegation stated that the claims under the PPH program were much closer to what was patentable in the United States of America as opposed to the claims received overall under non-PPH programs. Similarly, with the number of actions *per* application, overall there were three communications from the patent office to which the applicant had to respond. Under the PPH, the number of communications was a little over two. The Delegation noted that since every office action required some work by the applicant and money to be spent, the applicant could expect to save several thousands of dollars per application if they satisfied the requirements of the PPH program. The Delegation noted that on the issue of the quality of granted patent applications under the PPH program, it was in the process of conducting studies. It had looked at 155 first action allowances. The Delegation had found that in all of those cases, the examiner had conducted another search, even though they had had the benefit of the results of a search that had been carried out by another office. In over 84 percent of the cases, the examiners had added new references, and in 40 percent of those cases, the examiner had required some sort of amendment. In its view, that information was the indication that the examiners had examined and searched the PPH application correctly in essentially in the same way that they would have searched and examined any other application. The Delegation elaborated on various PPH Programs under which the USPTO had made agreements with 28 offices. It noted that although USPTO was trying to move to a common PPH program for all the offices, there were essentially three groups of countries with which it collaborated. In this regard, the Delegation mentioned the IP5 PPH with the EPO, JPO, KIPO, State Intellectual Property Office of the People's Republic of China (SIPO) and the USPTO; the Global PPH, which included about 19 offices; and about 12 or 13 bilateral agreements, which were for offices that accepted PPH work products only from the USPTO under that particular agreement and not from other countries that participated in the Global PPH or IP5 PPH. The Delegation then explained various requirements for requesting the PPH with the USPTO, for example, the eligibility of an applicant and the sufficient correspondence of claims between the US application and the earlier examination applications. The Delegation elaborated on the PPH procedures before the USPTO, and stressed that the USPTO did not charge any fee to enter the PPH program. The Delegation noted that it was trying to develop a common request form so that an applicant that entered a PPH in different countries would fill out the same form in order to make the process simpler. Lastly, the Delegation noted that the USPTO website and the JPO website had information, including statistics, on the PPH program.

102. The Delegation of the Republic of Korea thanked the delegations for their presentations during the sharing session regarding experiences on international work sharing and collaboration. The Delegation noted that the presentations had been helpful in understanding the relationship between work sharing and the quality of patents. The Delegation further noted that the KIPO had actively implemented bilateral and multilateral work sharing programs and information sharing platforms, including the PCT-PPH, PCT Collaborative Search and Examination Project, the Joint Prior Art Search Program and the KIPO-USPTO pilot. Noting that the PPH was one of the widely-used work sharing programs, the Delegation stated that at the KIPO, the registration rate and first action allowance rate for applications that were filed through the PPH program had been higher than ordinary patent applications, and that the period required to complete patent examination had been

significantly reduced. Therefore, the Delegation observed that the utilization of search and examination results through work sharing programs such as the PPH had reduced workloads for the patent office and ultimately had secured patent rights for applicants. The Delegation stated that the KIPO had been participating in the PCT Collaborative Search and Examination Project with the USPTO and EPO since 2010. The Delegation informed the Committee concerning the results of the second pilot project. In particular, the Delegation stated that 90 percent of the KIPO examiners that had answered the survey carried out by KIPO responded that the work sharing program had contributed greatly to the increased accuracy of patent examination. Further, over 80 percent had responded that when the results from such collaborative programs had entered the national phase, the international search reports could be relied upon for their accuracy. Accordingly, the Delegation stated that further time was needed only for demonstrative processing and not for supplementary searches. The Delegation noted that the IP5 offices were discussing the implementation of the third PCT Collaborative Search and Examination Pilot Project. The Delegation believed that the pilot could pave the way for improvement of the PCT system. The Delegation further stated that in addition to the ongoing work sharing projects, KIPO was also preparing more advanced-type programs. KIPO had proposed a work sharing program entitled COBOA, which was named from the collaboration before office action, to ensure the utilization of all necessary information from other IP offices before the launch of the first office action on part of the office of early examination. The Delegation further noted that KIPO had also proposed other collaborative programs between the ISAs and national offices in the PCT system. Based upon this positive previous work sharing program, the Delegation expressed its belief that such programs had enhanced the efficiency of the patent system by reducing duplicative work and had also improved the quality of patent examination. The Delegation expressed its hope that studies on the work sharing program could positively contribute to the enhancement of any international collaborative progress.

103. The Delegation of Spain congratulated the Member States who had made statements on the issue of quality of patents because they had helped clarify the issue of work sharing between patent offices. The Delegation noted that it was a pleasure to speak on the issue of work sharing within the framework of quality on patents and to share experiences on using search and examination results and on international collaboration. The Delegation stated that since the beginning of PPH projects, it had been aware of the advantages that PPH projects in bilateral agreements presented for Spanish patent applicants as well as its patent office. By avoiding the duplication of efforts and accelerating the procedures for granting patents, a better service had been provided to patent applicants. The Delegation noted that it had signed bilateral PPH agreements, or had reused the search and examination work, of the patent offices of Canada, China, Colombia, Finland, Israel, Japan, Mexico, Portugal, the Republic of Korea, the Russian Federation and the United States of America. Further, the Delegation was part of the Mottainai pilot program with the patent offices of Australia, Canada, Finland, Japan, the Russian Federation, the United Kingdom and the United States of America. The Delegation stated that under that pilot project, accelerated patent examination using the previous examination results of the office of first examination could be requested, independently of whichever office the patent application had been submitted. The Delegation further said that since January 2014, the Spanish Patent and Trademark Office had participated in the Global PPH pilot program in which patent applicants could ask for an accelerated examination at any of the offices that had been involved in the pilot, if the applicant's claims had been found to be acceptable by any of the other offices involved in the pilot. The Delegation noted that the Global PPH was the natural evolution of those agreements to reuse search and examination work. The Delegation stated that at the previous session of the PCT Working Group, it had supported the proposal by the Delegations of the United States of American and the United Kingdom to incorporate the PCT PPH program through amendment to the Regulations under the PCT. The Delegation

however noted that the use of those programs in Spain had not yet been major. It had only received 9 applications from abroad through those programs, and 29 Spanish applicants had been received accelerated treatment abroad. The Delegation observed that that was consistent with the statistical data provided by the JPO, which had shown that requests within those programs were concentrated in certain offices. The Delegation stated that for those agreements to work properly, the work of patent examiners was very important. The examiners of the second office should make their own assessment of patentability taking into consideration documents from the first office, and should try to complete the search. The Delegation stated that the different levels of inventiveness must also be taken into account and not be influenced by the results from the first office's search. The Delegation stated that if proper quality control was established, and the first office carried out a detailed analysis of the prior art search, then the second office should obtain only positive results from participation in such programs, which in no case entailed a loss of sovereignty of the state on the decision as to whether or not to grant a patent. The Delegation stated that the work sharing programs promoted better quality patents, independent of the level of development of the country or patent office concerned, because of the fact that such programs provided relevant documents on prior art. From its experience with work sharing projects in general, the Delegation considered that the main impediment to the effective use of search and examination results of other offices was the language difference, especially regarding languages very different from the language of the examiner. The Delegation stated that although rapid progress had been made in that field, automatic translation tools did not currently provide the desirable quality. Pending the availability of more advanced automatic translation tools, the Delegation stated that one could not fully use the search and examination results from other patent offices. The Delegation expressed the view that efforts to facilitate the use of work products of other patent offices should focus on two essential points: (i) the development of automatic translation tools; and (ii) facilitating the availability to the public of the prosecution history of published patent applications by national and regional patent offices in order for examiners to easily search and access search and examination results of patent applications belonging to the same patent family. In its opinion, that could be achieved through an extension of WIPO CASE as noted by the Delegation of Australia. In addition, the Delegation recalled that it maintained an intensive program of collaboration and cooperation with Latin American countries in patent review and many cooperation activities with WIPO and the EPO. The Delegation highlighted the Latipat database and the CIBIT training program (Iberoamericana Training on Patent Search), which since its inception in 2002, had enabled patent examiners from many Latin American countries to visit the Spanish Patent and Trademark Office for approximately six months to receive practical training in patent search and examination.

104. The Secretariat presented the WIPO webpage (PCT-PPH) on work sharing initiatives.

105. The Delegation of the United States of America was pleased for the opportunity to share its experiences in international work sharing and collaboration. In its view, work sharing had the potential to significantly increase the efficiency of patent offices and potentially improve the quality of granted patents. The Delegation especially appreciated the statements by the Delegation of Australia regarding its apparently successful attempts to clarify misconceptions about work sharing. The Delegation noted that it would support future seminars on work sharing. As had been indicated in its joint proposal with the Republic of Korea and the United Kingdom in document SCP/20/11 Rev., the Delegation believed that there was a need to increase awareness among patent offices and patent system users of existing work sharing programs and collaborative programs and to keep that information current. The Delegation thanked the Secretariat for the work on updating the PCT work sharing web page. The Delegation felt that was an excellent first step in that regard. However, the Delegation maintained its position that a page on the WIPO web site dedicated

to all work sharing and international collaborative activities between patent offices would be an ideal tool to provide information to those that were interested. In its view, such page should be separate from WIPO's PCT work sharing page so that it could include information on all work sharing regimes, regardless of whether or not they were connected to the PCT. The Delegation stated that it was increasingly apparent that work sharing and international cooperation could be powerful tools to contribute to make the work of patent offices more efficient and effective and could be instrumental in helping offices in granting high quality patents in a more efficient manner. The Delegation further stated that, in many cases, searching the prior art relevant to certain patent applications might be simpler and more efficient for some offices than for others. For example, access to national collections of prior art and the availability of patent examiner who understood foreign languages or with certain technical expertise might not be uniform across all offices. The Delegation recognized that examiners in its office could have difficulties utilizing references in languages other than English or in obtaining prior art which was contained in national collections of other offices. The Delegation stated that it was for those reasons that it participated in work sharing programs with other international offices. The Delegation further stated that sharing search and examination results between offices was likely to result in increased efficiencies, higher quality and lower costs. The Delegation proposed that WIPO conduct a study of whether, under what circumstances and how the implementation of work sharing in international cooperation programs between patent offices could assist the collaborating offices in conducting more efficient searches and examinations and in granting high quality patents by leveraging the work carried out in other offices. The Delegation stated that as was the case for all existing work sharing arrangements, the Secretariat should be mindful to address only arrangements that respected the national sovereignty of the participating offices and where no deference was given to the patentability determinations of other offices. The Delegation stated that for that study, the Secretariat would collect information from the Member States on their experience with work sharing programs. The Secretariat would also find information from available literature on how work sharing had been applied between offices and how it had impacted the search and examination of patent applications in those offices. The Delegation stated that the proposed study would also address the tools that had been used by offices to share information, such as, for example, WIPO CASE, and what shortcomings and benefits the offices had encountered in using those tools. Finally, the Delegation stated that the study would also indicate what type of work product shared between the offices had been found useful by examiners in participating offices and how to best share such work products.

106. The Delegation of Japan, speaking on behalf of Group B, expressed its expectation that the exercise at the sharing session would be a first step that would lead to continued discussion and collaboration at an annual conference on that important subject, as had been suggested by some members of Group B at the twentieth session of the SCP. The Delegation noted that the very fruitful exchange of views at the sharing session would deepen the understanding of the subject matter. The Delegation stated that it strongly expected that continuous work such as the annual conference as proposed in document SCP/20/11 Rev. would be held on that subject matter. The Delegation thanked the Secretariat for its excellent work in updating the PCT PPH website in line with what had been agreed at the twentieth session of the SCP. The Delegation noted that as had been stated by the Delegation of the United States of America, there were other various initiatives that related to the subject matter which were worth being collected and presented to users to increase the usability of the pages. The Delegation stated that the update of the PCT-PHH page was a good first step in that direction. Group B strongly suggested that the further expansion of the portal site of the work sharing initiative, which included various other work sharing initiatives, would be made.

107. The Delegation of the Republic of Korea stated that with regard to the proposal by the Delegations of the Republic of Korea, the United Kingdom and the United States of America contained in document SCP/20/11 Rev., establishing a web page for the work sharing activities on a WIPO website and hosting an annual conference on work sharing were timely and beneficial for any patent related entities.

108. The Delegation of Canada expressed support for the proposal made by the Delegations of the Republic of Korea, the United Kingdom and the United States of America (document SCP/20/11 Rev.). The Delegation noted that as the Canadian Intellectual Property Office had entered into PPH agreements with 18 intellectual property offices worldwide in addition to the Nordic Patent Institute, the Delegation was a firm believer in the value and efficiencies that could be delivered from those types of work sharing arrangements. For the Delegation, the PPH approach provided, under certain conditions, a means of prioritizing the examination of patent applications and accelerating the first examination action. The Delegation noted that it would look forward to the two initiatives that had been mentioned in the proposal, namely the setting up of a dedicated page on WIPO's website regarding work sharing arrangements as well as the organization of annual conferences on the margin of the SCP on the matter.

109. The Delegation of Pakistan noted that the agenda item on quality of patents also included opposition systems, which had not been discussed during the current SCP session. The Delegation of Pakistan believed that opposition systems, both pre-grant and post-grant, were imperative safeguards that ensured quality of patents. The Delegation noted that it was a check on the examination system of the patent offices to ensure that examiners had thoroughly examined an application. The Delegation further noted that opposition systems also ensured that patents were granted only on inventions that met the patentability requirements, as observed in document SCP/18/4. The Delegation requested the Secretariat to study the procedures and modalities of the use of different opposition systems prevailing in various jurisdictions, constraints in using those systems effectively and how such constraints could be removed. The Delegation looked forward to fruitful discussion on that topic in the future.

110. The Delegation of China welcomed discussions on quality of patents and international work sharing collaboration. With regard to quality of patents, the Delegation expressed its belief that the quality of patents was an important theme and the core of the patent system. It also believed, however, that due to different development levels and different problems that had been encountered, countries had different needs and therefore, they had a different appreciation and interpretation in term "quality of patents". The Delegation noted that some countries believed that the efficiency of patent examination and the quality of patent examination was the most important while for others, the most important issue was to raise public awareness about intellectual property and improve the quality of patent applications. The Delegation believed that quality of patents needed a clearer definition, which was indeed very necessary. With regard to work sharing, the Delegation considered that in order to achieve effective work sharing among intellectual property offices, the examination capacity and methodology must reach a certain level. The Delegation noted only on that basis could effective work sharing among intellectual property offices be done. The Delegation noted that during the current SCP session, some delegations had stated that work sharing seemed to be a remote possibility, while delegations from developed countries had stated that work sharing was an important tool and a very useful tool for them to improve their efficiency. Reiterating that capacity building was an important prerequisite for international work sharing, the Delegation expressed its hope that the SCP would do more work on capacity building so as to improve the patent examination capacity of intellectual property offices and thus would lay a good foundation for future international work sharing.

111. The Delegation of Algeria supported the statement made by the Delegation of Kenya on behalf of the African Group. The Delegation stated that in the absence of a clear definition as to the scope of application on the criteria surrounding the concept of quality of patents, it was hesitant regarding more ample work in that area. Regarding work sharing, the Delegation noted it was confused because such discussion should have taken place in the PCT Working Group. In its opinion, there was some overlap and duplication of work in the SCP and the PCT Working Group in that regard. Thus, the Delegation questioned what the added value of a discussion with the SCP was.

112. The Secretariat, with regard to the statement made by the Delegation of Algeria, clarified that while discussions in the PCT Working Group were related to the specific issue of the PPH in the framework of the PCT, the discussion in the SCP went beyond and included work sharing mechanisms not necessarily linked to the PPH programs or PCT PPH. Noting further that around 55 percent of the international patent filings were under the PCT and the remainder was under the Paris route, the Secretariat noted that, in its view, there was no duplication of work and there was substantial room for cooperation between Member States on work sharing that was outside of the PCT system.

AGENDA ITEM 7: PATENTS AND HEALTH

113. Discussions were based on documents SCP/21/8 and SCP/21/9.

114. The Secretariat presented the Study on the Role of Patent Systems in Promoting Innovative Medicines, and in Fostering the Technology Transfer necessary to Make Generic and Patented Medicines Available in Developing Countries and Least Developed Countries (document SCP/21/8).

115. The Delegation of Japan, speaking on behalf of Group B, thanked the Secretariat for the preparation of document SCP/21/8. The Delegation noted that as had been underlined by Group B, innovation was an essential component when discussing the relationship between patents and health, as well as the access aspect. The Delegation stated that if there was a failure to shed enough light on innovation, and a failure to put that issue in the context, the discussion could not be built upon a proper basis and it would just go in the wrong direction far apart from the real world. Further welcoming the document SCP/21/8 prepared by the Secretariat, the Delegation noted that the study stated that patent protection was critical for incentivizing pharmaceutical R&D in general and stimulating R&D. The Delegation also noted that the study recognized literature saying that the same story could not be applied to R&D efforts in treatments for neglected diseases. The Delegation stated the fact that patent protection alone could not solve all the issues of the world by itself and that various elements were related to pharmaceutical innovation. The Delegation stated however that that fact did not deny the critical role of patent protection and pharmaceutical innovation, and it only explained the necessity of other considerations to be built upon patent protection as a prerequisite. Furthermore, the Delegation noted that the whole picture of the structure of R&D in that field had to be looked at without seeing specific situations in a fragmented way separately from the whole picture. The Delegation stated that patent protection directly affected the development of medicines for the potential market but at the same time, it formed the essential basis of R&D, including the resource and environment for medicines that might only have a limited market. The Delegation noted that for R&D in the pharmaceutical field, patent protection was like an essential part of a big machine without which the big machine could not operate at all and could not produce anything. The Delegation noted the study in document SCP/21/8 had reported that some studies had acknowledged that intellectual property protection was a requisite condition for technology

transfer. The Delegation stated that Group B agreed that the existence of the patent system was not a barrier to the transfer of technology. In conclusion, the Delegation underlined that the innovation aspect and the access aspect were inseparable in that field, and it was only evidence-based policy that could bring human beings to the right direction in the long run.

116. The Delegation of Kenya, speaking on behalf of the African Group, thanked the Secretariat for the study contained in document SCP/21/8. The Delegation stated that the study basically gave a mixed picture in terms of the role of patent protection in incentivizing R&D in regard to pharmaceutical products. The Delegation said that if that issue was looked at in a broader context, and based on some of the presentations during the Seminar on Exceptions and Limitations to Patent Rights on the differential penetration rate of generic drugs, especially in the developed countries then it was clear that the issue of R&D per se was not the only driving factor in terms of the availability of generic products in on those markets. The Delegation observed that even where there were very strong provisions for competitive generic drugs, there were situations in which, increasingly, patents were registered for small, incremental changes that did not provide efficacy, and patents protected those drugs from competition. The Delegation considered that the relationship between a strong patent system and incentives for R&D was not conclusive. Therefore, in its view, it was hard to come to any conclusion that patent protection that would necessarily lead to R&D or availability of products, especially for diseases that had affected developing countries. The Delegation considered that strong patent protection was purely driven by search for profit and a want for the exclusive rights over that product for a longer time to increasingly protecting that product with small incremental changes. In that regard, the Delegation noted that further research on those products could be prevented. Noting the limited availability of essential medicines to the public, the Delegation stressed the need to strike a critical balance since innovation per se was not an end in itself. The Delegation stated that while innovation was critical in enabling or serving the public interest, the public had the right to good health and access to the best medicine.

117. The Delegation of Italy, speaking on behalf of the European Union and its Member States, reiterated its understanding of the challenges and concerns certain countries faced with public health problems. In that regard, the Delegation noted that it was supportive of activities that might assist those countries. The Delegation thanked the Secretariat for preparing the study contained in document SCP/21/8. The Delegation positively noted that the study reaffirmed the critical role of patent protection for pharmaceutical innovation. The Delegation also noted that the study rightly made the point based on empirical evidence that non-patent factors also had an influence on innovation in the pharmaceutical sector, and that patent protection alone might not be sufficient to incentivize the development of innovative treatments for neglected diseases. The Delegation further noted that the study confirmed that intellectual property protection was a requisite condition for pharmaceutical technology transfer. The Delegation noted that it had listened with interest to the views of the experts at the Seminar on Exceptions and Limitations to Patent Rights, which had usefully made the point that there were a number of factors that had an influence on access to medicines which were also mentioned in paragraph 15 of document SCP/21/8.

118. The Delegation of the United States of America thanked the Secretariat for producing the study in document SCP/21/8. The Delegation noted that the study in document SCP/21/8 presented a large amount of data derived from different studies and gave a glimpse of that complex topic. The Delegation noted that as had been stated in the study, it was difficult to separate and measure the effect of the patent system from other factors, in particular, from the influence of non-patent based initiatives, laws and policies on innovation and the market for technology. The Delegation stated that with regard to the effect of patent systems on promoting innovation of medicines, it agreed with the conclusion that the patent

system was only one of many factors that affected innovation. The Delegation noted that education level, income level, the size of the market and others were some factors that had a strong influence as well. The Delegation stated that on transfer of technology relative to medications, it agreed that intellectual property protection was a requisite condition for pharmaceutical technology transfer, although it was only one of the components that affected technology transfer. The Delegation noted that the others were, as had been listed in the study, local technical capacity, pharmaceutical regulatory environment and others. The Delegation stated that the study reaffirmed its experience and observations that the publication of patents and patent applications contributed to the transfer of technology. The Delegation noted that patent pools and voluntary licenses that included a technology transfer component also provided an effective channel to promote technology transfer, as had been indicated in the study in document SCP/21/8.

119. The Delegation of Brazil thanked the Secretariat for preparing the interesting study contained in document SCP/21/8. In its view, the study showed that the effect of patent protection for pharmaceutical innovation was not the same in all countries, and it supported the idea that countries should have the necessary autonomy to modify their legislation according to the reality on the ground. The Delegation considered that one good way to measure the efficiency of the patent system was to observe the influence of initiatives, laws and public policies related to innovation or to the technology market that were not directly related to patents. The Delegation stated that through that observation, it could see the complexity of the issue and shy away from making the linkage between enhanced R&D investments and an enhanced intellectual property system. The Delegation noted that the WHO Commission on Intellectual Property Rights, Innovation and Public Health had highlighted the need to differentiate between creative innovation that offered increased effectiveness and also incremental innovation that did not translate into therapeutic benefits. The Delegation of Brazil proposed that further studies be done to examine the relation between the patent system and the availability of medicines in developing countries, especially in LDCs.

120. The Delegation of Egypt thanked the Secretariat for preparing document SCP/21/8 and for the presentation. The Delegation noted that the study had followed a methodology of compiling studies, and it gave impressive and factual information on important studies in that area. Further referring to the indicators for innovation and technology transfer, in particular, the level of R&D expenditures and the quantities of patent granted, the Delegation emphasized that, in paragraph 8 of document SCP/21/8, it was stated that the use of patented activity to measure innovation might pose challenges as well. From that observation, the Delegation understood that that the quantification of patents might not be enough. Further, the Delegation noted that the study observed that the value of pharmaceutical innovation might not be captured by merely counting the patent or patent application. The Delegation also noted that the study observed that as the patentability criteria primarily related to technical advancements from the existing state of the art, the mere grant of a patent did not necessarily reflect the economic value of an innovation or the therapeutic value of pharmaceuticals. The Delegation considered that there was a need for further elaboration on those points.

121. The Secretariat clarified that the fact that a patent was granted because it complied with the patentability criteria did not mean that the particular invention would be a successful pharmaceutical product on the market, since there could be more than the technical advancement necessary such as, for example, effective marketing to consumers to create awareness of the product. Similarly, in relation to the therapeutic value of the pharmaceutical product, the Secretariat clarified that the patentability criteria were independent from the requirements of efficacy and safety of a drug.

122. The Delegation of India expressed its appreciation for the efforts of the Secretariat for document SCP/21/8. The Delegation noted that document SCP/21/8, which was based on relevant literature reviews, admitted that due to complexity and multifaceted nature of the topic, the study might not have exhausted all the relevant issues, which could be subject to further research. The Delegation stated that document SCP/21/8 acknowledged some of the shortcomings associated with the selection of indicators in measuring effect of patent system in relation to the subject, and indicated that there was no universally accepted indicator to measure the role of patent systems in pharmaceutical innovation and transfer of technology. The Delegation also noted that the study showed that a review of empirical literature on the role of patent systems as a whole in pharmaceutical innovation demonstrated that there was no single effect of the patent system on pharmaceutical innovation across all countries. The Delegation noted that the study, Kyle et al. (2012), had found a significant difference between evidence on the association of intellectual property with R&D efforts for global diseases and evidence on the association of intellectual property with R&D efforts for neglected diseases. Referring to that study, the Delegation noted that on the basis of that significant difference, the authors had concluded that patent protection in high income countries had been related to greater R&D investments in diseases that had affected high income countries, but that patent protection in developing countries and LDCs had not stimulated greater R&D efforts in treatments for neglected diseases. The Delegation observed that patent thickets were undoubtedly a great barrier to the generic entry. Referring to a European Commission Report on the pharmaceutical sector which had reported that patent thickets had been common practice and that generic pharmaceutical companies had increasingly perceived them as an obstacle to market entry, the Delegation stated that unless there was sufficient opportunity for the entry of generics, the availability of medicines to the common public could not be realized. Therefore, in its view, the European Commission Report at least implicitly admitted that the present patent system in the post-TRIPS Agreement regime was not very successful in promoting innovative medicines. The Delegation noted that the exorbitant price of the patented anti-cancer medicines in India was an example that did not support the role of patents in innovative medicines in developing countries and LDCs. The Delegation stated that "Multinationals and Monopolies Pharmaceutical Industry in India after TRIPS", Economic & Political Weekly, March 24, 2012, No 46, page 12, by Sudip Chaudhuri, which had not been cited in the study, gave an example of the tremendous price of patented anticancer drugs in India, which showed the impact of product patenting in the post-TRIPS era. Referring to the third part of the study in document SCP/21/8 concerning the role of patent systems in fostering technology transfer, the Delegation stated that that part of the study had failed to reach any conclusion regarding the technology transfer to make generic and patented medicines available in developing countries and LDCs. Considering that some observations were noteworthy, the Delegation noted that empirical studies examining the relationship between patent systems and technology transfer to make medicines available in developing countries and LDCs were very scarce. The Delegation further noted that since a patent application was not a recipe for manufacturing a commercially viable product, as had been indicated in the trilateral study prepared by the WHO, WIPO and WTO, one of the fundamental questions that had been raised with respect to the role of disclosure requirement was to what extent a patentee must disclose his invention in order to contribute to the transfer of technology and further innovation. In that context, the Delegation observed that for example, Markush claims covering a vast number of compounds that had not been assessed by an applicant and supported by the disclosure in specification should not be allowed. Additionally, the Delegation referred to a WHO publication that had reported that the identification of the patent status of the particular pharmaceutical might prove difficult for a number of reasons and as a result, specific expertise may be required to assess the patent status of medicines. The Delegation noted that the WHO publication had indicated examples such as a

multiplicity of patents covering a pharmaceutical product; lack of a reference to the INN in a patent application; and the technical language of the specification, among others. The Delegation considered that the study acknowledged the incompleteness of the sufficiency of disclosure requirement in the context of transfer of technology and also acknowledged the view expressed by some scholars about the uncertainty brought by the patent disclosures of Markush formulae. The Delegation reiterated that for the sake of transfer of technology, the disclosure of INN in patent specifications should be made mandatory. Further, the Delegation agreed that compulsory licenses might be most effective when the technology was already known and only access to it was required. In its view, indicators like Disability-Adjusted Life Year (DALY), availability and affordability of the medicines vis-à-vis the per capita incomes also might be used in conjunction with patenting activity in a specific jurisdiction. The Delegation stated that in essence, further studies could only reveal the real picture in developing countries and LDCs. The Delegation was of the view that a study focused upon the real impediments that the health care systems faced in the wake of the product patent systems would be helpful. The Delegation noted that from experience, and as had been admitted in the Doha Declaration, in the post-TRIPS regime, patented products were being sold at exorbitantly high price in certain areas of health care, thereby making them unaffordable for ordinary people. The Delegation considered that the study would therefore provide an opportunity to discuss how developing countries could utilize the patent system for the improvement of their public health care systems.

123. The Delegation of Algeria thanked the Secretariat for preparing the study contained in document SCP/21/8, which had shed light on the role of patent system in promoting innovative medicines and fostering transfer of technology for making generic and patented medicine available in developing countries and LDCs. The Delegation stated that in the study it was indicated that the level of pharmaceutical R&D expenditures could be an indicator of innovation. However, the study noted that a lack of reliable data may restrict research on and analysis of the role of intellectual property rights on pharmaceutical R&D and technology transfer. Further, noting that the study in document SCP/21/8 also stated that patent data or patent activity was an indicator of pharmaceutical innovation, the Delegation, however, pointed out that most of the granted patents were not actually promoting real innovation. The Delegation stated that there were some studies that had reviewed 15 fundamental medical and pharmaceutical discoveries in innovation listed in the British Medical Journal that had found that only 2 of those 15 innovations had been patented. The Delegation further stated that those studies had reviewed a list of top 10 public health achievements in the twentieth century, which had been compiled by the United States of America Centers for Disease Control and Prevention, and had found that none of those top 10 achievements had been patented. The Delegation of Algeria stated that, in its view that suggested that the patent system had not played such an important role in incentivizing the most significant medical and pharmaceutical innovation known to human kind. The Delegation stated that the study in document SCP/21/8 observed that although the industry had argued for strict protection of intellectual property rights in view of the high costs of R&D, statistical studies had shown a mixed effect with regard to the effects of strengthened patent protection in developing countries, or with regard to pharmaceuticals needed for the treatment of diseases predominantly prevalent in developing countries and LDCs. The Delegation stated that it was clear from extensive investigation undertaken by the WHO that strong patent protection did not facilitate R&D in developing countries, particularly for diseases that affect developing countries and more. The Delegation asked whether, on that particular subject, the Secretariat had reviewed WHO-established processes and studies that had already been done on the relation between innovation and intellectual property and whether a correlation between R&D and the facilitation of access to medicines in developing countries had been found. Further, the Delegation reiterated that the WHO, which the Delegation considered was the organization primarily targeted for access to medicines, had

stated that R&D was not really facilitated by strong patent protection. In that regard, the Delegation sought more clarification from the Secretariat.

124. The Secretariat clarified that it had strictly interpreted the scope of document SCP/21/8 as having two parts: the first on the role of the patent system in promoting innovative medicine, and the second part on fostering the technology transfer necessary to make medicines available in developing countries and LDCs. The Secretariat noted that the issue of access to medicines could go beyond technology transfer, since technology transfer such as local production, was not the only way to facilitate access. The Secretariat further noted that while the topic of intellectual property, R&D, trade and access to medicines was well covered by the trilateral study prepared by the WHO, WIPO and WTO, literature analyzing the role of patent systems in fostering technology transfer to make medicines available was scarce compared to literature on the role of the patent system in innovation. In that regard, the Secretariat noted that that might be an area that could be further developed by scholars and academics.

125. The Delegation of Cameroon congratulated the Secretariat for its work on document SCP/21/8. The Delegation observed that a patent system was a passive system in the sense that an invention became part of the system only when it was declared by the inventor, i.e. a patent application was filed. The Delegation considered that other non-declared works, even if it assisted R&D, would not be known through the patent system. The Delegation, therefore, asked WIPO to assist those whose work was “made in the shadow”.

126. The Delegation of Algeria asked whether the Secretariat had worked with the WHO since a WHO working group in charge of financing R&D had recommended that the WHO Member States look more broadly at that issue and had stated that there was some room for work to be done internationally.

127. The Secretariat noted that as the research methodology for document SCP/21/8 comprised searching publicly available databases for relevant literature for the purposes of drawing up that study, the WHO or any other organization was not contacted. The Secretariat clarified that a conclusion that had been presented in the report was that patent protection did not necessarily always positively impact R&D and innovation of medicines, but rather, the findings on that issue were mixed, as had also been indicated by some delegations.

128. The Representative of the WHO stated that the issue of to what extent the patent system triggered innovation for certain disease was a longstanding issue debated in the WHO by Member States for a long time. Further, the Representative stated that the Report of the Commission on Intellectual Property Rights, Innovation and Public Health that had been published in 2006 had pointed out that the patent system had not delivered the innovation needed in areas where the diseases were concentrated in countries and populations that were poor because the lack of buying power was not delivering the incentive to pharmaceutical companies to research on the development of new drugs or vaccines against those diseases. The Representative noted that WHO Member States in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property had highlighted the lack of research needed for the diseases prevalent in developing countries and LDCs. The Representative further noted that the mobilization of resources was needed to deal with those diseases, for example, the current Ebola crisis which was a prime example of a disease that had not attracted investment as that was not an interesting market for companies. The Representative observed that the trilateral study prepared by the WHO, WIPO and WTO in 2012 pointed out in page 56 that empirical studies had found evidence of both positive and negative effects of patents on innovation, and that inconclusive

evidence on the role of the patent system in encouraging R&D and technology transfer made it difficult to draw any clear cut conclusions about the effectiveness of the patent system for economic development. The Representative further stated that the question of the extent to which pharmaceutical innovation was triggered by the patent system was an incredibly complex question to answer.

129. The Secretariat presented the Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents (document SCP/21/9).

130. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, expressed its thanks to the Secretariat for documents SCP/21/8 and 9. The Delegation stated it recognized the importance of the protection of public health and activities that could help developing countries and LDCs in addressing their public health concerns and finding adequate solutions. Further, the Delegation also recognized the complexity of that topic. The Delegation expressed its belief that the study in document SCP/21/8, based on review of numerous empirical and statistical studies, in particular on the impact of patents on pharmaceutical innovation or examining the relationships between the patent systems and the transfer or dissemination of pharmaceutical technology, would contribute to an increased awareness of all relevant elements in those areas. The Delegation noted that the CEBS Group was convinced that patents provided a significant incentive for innovation in pharmaceutical field and contributed effectively to the field's further development. The Delegation stated that it continued to share the opinion that any discussion on patents and health within the Committee should be balanced, taking into account interests of all patent users, various aspects and factors. The Delegation stated that as regards document SCP/21/9, the CEBS Group appreciated the Secretariat's collaboration with the WTO and WHO, in particular with respect to the functioning of the INN system. The Delegation further stated that information that had been provided in the study describing the INN system and the particularity of searching pharmaceutical substances disclosed in patent documents, exploring the current and future possibilities of patent search for medicine, had gathered interest within the CEBS Group. The Delegation therefore noted that all of the information, including provisional findings contained in document SCP/21/9 should be carefully considered.

131. The Delegation of Italy, speaking on behalf of the European Union and its Member States, thanked the Secretariat for the preparation of document SCP/21/9. The Delegation noted that, according to the preliminary findings, it was impossible to disclose at the time of filing of the application the future corresponding, and yet to be published, INN in patent applications filed before the publication of the recommended INN. The Delegation stated that in that scenario, the preliminary findings pointed to a major challenge of how to retroactively link the corresponding INN information to such applications without unduly burdening applications and patent offices. The Delegation stated that while the study had not been able to conclude on the potential benefits and costs, it had found that the mere indication of the INN in patent applications was not sufficient to find out, with one click, what a patent searcher was looking for. The Delegation noted that, at the same time, the feasibility study pointed to the fact that patent searchers had developed methodologies to search patents for a medicine primarily using publicly available databases. The Delegation further referred to the description in the study that the increasing sophistication of IT tools might significantly contribute to a simple and more cost efficient patent search in the field of chemistry and pharmacology. The Delegation stated that against that background, it appeared that on the basis of the information that had been assessed and provided in the study, the case for the disclosure requirement of INN had not been made. In closing, the Delegation emphasized that any further work in the area of patents and health should reflect a balanced approach taking into account the various interfaces and factors of relevance and drawing inspiration from the proposal of the Delegation of the United States of America.

132. The Delegation of Japan, speaking on behalf of Group B, thanked the Secretariat for document SCP/21/9. The Delegation stated that Member States had to keep in mind the principle of the patent system that the patent rights were given to the patent holder by virtue of disclosure of the invention in a way that a person skilled in the art could carry it out, which struck a balance between the exclusive rights and the disclosure obligation to form the basis for further R&D based on the disclosed invention. The Delegation stated that patentability requirements, substantive or procedural, had to be justified in relation to that principle, and the mere fact that the disclosure of some information in a patent application might have some potential value for some specific people could not justify the introduction of the additional requirement, which had nothing to do with the aforementioned principle. The Delegation stated that the disclosure of INN had no relationship with the sufficiency of disclosure requirement, which enabled those skilled in the art to make the invention. The Delegation further stated that attention must be paid to the fact that the patent application was filed before the publication of the corresponding INN in many cases, and the requirement to disclose such INN would impose a serious burden on applicants and intellectual property offices. The Delegation also stated that the burden on applicants in monitoring the INN process and following up applications was difficult to capture in the literature, and therefore, it could not be well reflected in the factual study by the Secretariat. The Delegation stated however that obviously, that did not mean that that aspect could be underscored. The Delegation explained that the burden on intellectual property offices to incorporate information submitted after the filing of an application into their database was also higher than what was described in document SCP/21/9. Due to those shortcomings, the Delegation considered that the potential increase of searchability should be pursued through the alternative solutions noted in the document, including the development of methodologies for searching patents, rather than INN disclosure in patent applications or patents.

133. The Delegation of Kenya, speaking on behalf of the African Group, thanked the Secretariat for document SCP/21/9. The African Group noted that while the study showed that at times, it was not possible to provide information on INN in patent applications, it was also true that some patent applications could be filed with a description of the existing INN. Noting that there was a tendency to file patent applications for incremental changes on existing substances or chemicals for which the INN was available, the Delegation stated that it was important for the INN to be disclosed for such follow up applications when it existed. Observing that there was no burden on the applicant or the patent system from disclosing the corresponding INN, and noting that the WHO already maintained a database on INN, the Delegation stated that INN should be made available where it existed. The Delegation believed that the Committee should have further discussions on that study to improve the patent system by INN disclosure in patent applications. The Delegation stated that it did not want a situation in which access to essential medicines was prohibited due to the grant of patents to small or incremental changes that had been made to those medicines. The Delegation further stated that, at that time, it could not make a judgment as to whether the feasibility study had proved that the INN was not important or useful. The Delegation reiterated that it maintained its view that the INN should be indicated in patent applications since, where it existed, it did not cost anything to the patent system.

134. The Delegation of the United States of America thanked the Secretariat for preparing document SCP/21/9. The Delegation stated that the feasibility study pointed out a few of the many difficulties and costs associated with making available the INN in conjunction with patents and patent applications related to chemical and pharmaceutical inventions. Referring to paragraphs 12 and 13 of the feasibility study, the Delegation stated that the requirement to provide the INN after filing a patent application once the INN became available would be excessively burdensome to both patent offices and applicants. The

Delegation stated that patent offices would be forced to develop and implement new procedures for handling the INN disclosed either later in the patent prosecution process or after the grant of the patent. Further, the Delegation stated that most likely, those procedures would be resource intensive and difficult to enforce. In addition, the Delegation pointed out that national laws might not provide a mechanism for reopening the prosecution of patents already granted based on INN disclosure or lack thereof. The Delegation noted that the accuracy and timeliness of an applicant's disclosure of an INN would have to be verified, and patent examiners would have to be trained on the INN system and procedures. In that regard, the Delegation stated that that would place a high burden on the offices in part due to the significant differences between patent processes and INN processes. In the Delegation's view, the time as well as financial and human resources that were needed to implement and enforce those procedures would be much better spent by patent offices for other uses, such as increasing the quality of granted patents, reducing the backlog that many offices faced. The Delegation expressed its agreement with the part of the feasibility study that stated that using the INN to search chemical and pharmaceutical inventions would not be sufficient to find all relevant prior art even if INN disclosure was mandatory. The Delegation stated that even if the relevant INN was provided, an INN search would not be sufficient and would still have to be supplemented with the structure and or chemical name search, as indicated in paragraph 35 of document SCP/21/9. The Delegation further agreed with the feasibility study's observation that the search on chemicals in pharmaceutical inventions could presently be carried out with existing tools and databases, although at some cost and with specialized knowledge. The Delegation noted with interest paragraph 57 of the feasibility study, which indicated that some websites hosted free databases that enabled users to conduct a patent search with various query variations, including chemical structure search. The Delegation further noted that the study went on to suggest that, while at present, the content, coverage and functionalities of those sites were limited, further developments in the future might make such free sites a more practical option for patent searching. In its view, the INN would not be necessary to make use of such a site, and that the INN could be just one option among others for pharmaceutical, chemical nomenclature or description, such as the IUPAC name, molecular structure, CAS registry number, or any other name that had been used in literature. Recognizing the challenges faced by offices with more limited search resources, the Delegation stated that it was very interested in a related finding of the feasibility study that a system capable of translating a query with an INN into a query with a corresponding chemical or molecular name structure, CAS registry number and other information could potentially enable the searching of pharmaceutical and chemical inventions in a more efficient manner. The Delegation considered that the best way to address the stated difficulties in searching and examining chemical and pharmaceutical inventions was the approach that had been implicitly suggested in paragraph 57 of the feasibility study, wherein a software-based system should be developed for carrying out the automatic identification, extraction and indexing of chemical data from patent documents. The Delegation stated that that would provide a simple and cost effective way of searching those inventions using, for example, a known INN or other chemical identifier. The Delegation expressed its belief that WIPO was well suited to oversee the development of the tools and database necessary to implement the system. The Delegation thus proposed that the SCP evaluate how best to develop and implement a system for the automatic identification, extraction and indexing of data from patent documents using, for example, chemical and natural language, and to provide tools that would be accessible to everyone for searching chemical and pharmaceutical patents more cost effectively. The Delegation expressed its belief that such a system would provide an efficient way of resolving other problems outlined in the feasibility study. Further, the Delegation proposed that once the SCP had identified a way forward on how to develop such a software-based system, WIPO implement the system with the ultimate goal of making such a capability freely available. The Delegation further stated that the feasibility study indicated that some

patent offices seeking to search chemical and pharmaceutical inventions might experience difficulties due to the complexity and expense involved in finding prior patents relevant to those inventions. The Delegation stated that the study also indicated that many patent offices were already able to search and examine chemical and pharmaceutical inventions using the tools and databases that were presently at their disposal. The Delegation stated that, as an example, the USPTO would routinely examine patent applications in those technical fields without the need to utilize any information that had not been normally already provided by the inventor in its patent application. The Delegation observed that the same situation existed in a number of other offices that routinely searched and examined patent applications with respect to chemical and pharmaceutical inventions. The Delegation thus proposed that the SCP carry out a study to determine how work sharing and international cooperation between various patent offices could be used to facilitate the search and examination of chemical pharmaceutical patents by offices that might have encountered difficulties in doing so. The Delegation stated that the study would be carried out with the consideration that the arrangements evaluated, like existing work sharing arrangements, would operate without infringing on any country's national sovereignty and without requiring an office to abide by another office's patentability decisions. Further, the Delegation stated that every national office would continue to handle and examine all patent applications according to its own national laws, but would be able to do so with the benefit of search results from other offices. The Delegation expressed its belief that work sharing could provide a more efficient and effective way to assist offices in accessing information needed to search and examine the type of inventions that had been discussed in the feasibility study. In conclusion, the Delegation proposed that the SCP, as part of that new study, gather information on how the various offices currently searched and examined chemical and pharmaceutical patent applications, what kind of work products that were relevant to those types of patent applications would be generated and how and under what circumstances that information could be utilized by other offices to simplify their own search and examination of that category of patent applications.

135. The Delegation of Japan thanked the Secretariat for the preparation of the documents. The Delegation noted that it supported the statements of Group B and of the Delegation of the United States of America. Noting that developing new medicines required a large amount of time and resources, the Delegation expressed its belief that there was a need to give certain incentives to inventors so that they could develop new medicines. Further, the Delegation stated that the existing patent system was well balanced and that any work of the Committee should not destroy that balance. With regard to the issue of INN disclosure in patent applications or patents, the Delegation stated that it would like to know what effect the disclosure of INN would have on the patent system itself, and what the results would be if the INN were included in patent applications. The Delegation considered that those questions should be examined before making any conclusion, taking into account the increased burden on the applicants.

136. The Delegation of India appreciated the efforts of the Secretariat for document SCP/21/9 for discussion in the current session of the SCP. The Delegation stated that in document SCP/21/9, certain positive views that were very much useful from the perspective of developing countries were reflected. The Delegation noted that the feasibility study acknowledged that the increased searchability of patent documents concerning pharmaceutical substances through the use of INN keyword search might potentially benefit all stakeholders. Additionally, the Delegation noted that the feasibility study stated that although with respect to patent applications filed before the publication of the corresponding INN, it was impossible to indicate, at the time of filing, the corresponding INN in the patent applications, for patent applications filed after the publication of the corresponding INN, if the INN was known to the applicants, it was possible to indicate, at the time of filing, the

corresponding INN. The Delegation stated that on the basis of studies conducted by WIPO on the patent landscape of two anti-retroviral drugs, atazanavir and ritonavir, it was shown that the peak of the number of patent families filed per priority year appeared after the publication of the relevant INN. The Delegation therefore concluded that in most of the cases, it was not impossible for the applicant to include INN in an application at the time of filing. Further, the Delegation concluded from the feasibility study that the supply of the INN at post-grant stage was possible by way of amendments made to the application through the available legislative means. The Delegation also concluded from the study that it was immaterial in which part of the specification the INN needed to be disclosed, as most patent searching authorities employed a text-based search. The Delegation noted that regarding the potential benefits and costs, the feasibility study admittedly disowned any responsibility for any empirical study, but acknowledged the usefulness or potential of an INN search. The Delegation also noted that although INN disclosure was not a matter of compulsion under primary legislation anywhere in the world, secondary legislation, such as administrative guidelines, could at least indirectly indicate that the INN disclosure could be incorporated in the patent specification. The Delegation stated that therefore there was ample room for further discussion. The Delegation observed that there were certain elements in the feasibility study that needed close attention and scrutiny, and suggested further amendment of the document to be presented at the forthcoming SCP session. In that regard, the Delegation stated that the feasibility study showed some negative bias with respect to the burden on the applicant for submitting the INN, which should be contradicted. Additionally, the Delegation stated that although the feasibility study mentioned that it was possible to disclose the INN in patent applications, it evaded the question of usefulness or the advantage of mandatory disclosure of the INN in the patent specification when the applicant was fully aware of said INN. The Delegation also stated that although the feasibility study referred to the Markush structure, it failed to acknowledge the tremendous hardship that an examiner or any third party would face when the compound was buried in a Markush structure, even though the compound could be easily recognized had it been identified by its INN. The Delegation noted that such situations were frequently encountered in the field of pharmaceutical chemistry. The Delegation stated that the feasibility study referred to a patent landscape study of ritonavir conducted by WIPO in which it had been pointed out that 119 records had been found on the basis of the structure-based search, which had not been included in 841 records identified by a text-based search. Although the feasibility study did not mention how many of those 119 records had been filed before the INN establishment, the Delegation stated that from Figure 3 of the feasibility study, it appeared that some, or perhaps many of those 119 patent applications, might have been filed after the establishment of the INN of ritonavir. The Delegation stated that if the INN had been mentioned in the applications, one needed not waste resources on a costly structure-based search. The Delegation noted that, therefore, the feasibility study could be improved with the inclusion of factors such as the cost and benefit of INN disclosure, particularly when an important pharmaceutical compound remained buried within the billions of compounds covered by Markush structure. The Delegation also noted that the lack of information on INN not only made the task of examiners more difficult, it also increased the burden of any person potentially interested in filing pre- or post- grant oppositions, since they would be forced to monitor and research a large number of applications in order to identify those that might deserve to be opposed. Further, with respect to Markush claims, the Delegation noted that they posited a big riddle before stakeholders and examiners, not only of developing countries, but also of developed countries as well. The Delegation referred to the 2007 Federal Register, which stated that “[a]pplicants sometimes use Markush or other alternative formats to claim multiple inventions and/or to reside hundreds, if not thousands of alternative embodiments of a single invention in one claim. Proper search of such complex claims [...], often consume a disproportionate amount of office resources as compared to other types of claims”. The Delegation observed that apart from the resource burden, Markush claims

posed several constraints surrounding different issues of patent law. In its view, also from the perspective of public health, Markush claims created severe hurdles to the availability of essential medicines. The Delegation noted that, as had been stated in the World Patent Information, Markush structures were a paradox of the patent system, and that some critics had rightly designated them as a figment of imagination rather than matters of chemistry and law. The Delegation pointed out that Adam Sussman, in his article that had been published in 2013 in the John Marshall Review of Intellectual Property Law, had cited an example of a claim of a patent on quinazoline derivatives exemplified by a Markush structure. According to Adam Sussman, the entire range of compound covered in the single Markush claim had exceeded 1,024 different permutations. The Delegation therefore considered that it was unlikely that most of the compounds had at all been invented, tried or tested by the applicant or the inventor. The Delegation stated that a Markush structure posed a burden of examination for the patent office and for third parties, and that it was a huge mysterious barrier that blocked the entry of an interested person in the specific field of pharmaceutical to which the Markush compounds related. The Delegation stated that the Committee may therefore undertake a study related to Markush formulae and the impediment that they created in the healthcare industry by creating mysterious cobwebs of unreal compounds to be discovered in the future, thus stifling innovations in that field of technology. In its opinion, the situation had reached a stage where even an expert examiner or a skilled patent searcher failed to recognize the real compounds of interest of the applicants that had been buried within the nested riddle of Markush structures. The Delegation stated that the questions to be studied could be broadly divided into two vistas, one relating to the basic issues of patent law, and the other, a set of questions that arose from the barriers which Markush structures created in respect of the availability of essential medicines to the public. The Delegation enumerated the following questions: (i) on the issue of actual enablement of compounds covered in a Markush formula, did Markush structures meet the requirements of sufficiency and support; (ii) did all compounds under the coverage of such a broad Markush claim meet the requirement of usefulness or industrial applicability; (iii) what were the actual scopes of such claims; (iv) and to what extent Markush structures helped develop essential medicines. The Delegation expressed its interest in taking part in any future discussion surrounding those issues.

137. The Delegation of the Russian Federation thanked the Secretariat for the study contained in document SCP/21/9. The Delegation stated that while the provisions of the legislation and administrative regulations did not provide for the mandatory disclosure requirements of the corresponding INN in the patent application, in practice, as a rule, applicants did indicate the INN in applications where they were known either in the title of the invention, the description, claims or abstract. The Delegation noted that an indication of the INN, in particular, in the title or description could greatly facilitate a prior art search, since not every information database could be searched by chemical structural formula or a Markush grouping, which was also confirmed in the example of ritonavir in the study. Therefore, the introduction of disclosure requirements of INN in patent applications and/or patents for the purposes of prior art search might play a positive role in processing the application. The Delegation continued that, moreover, an indication of the INN in patent applications or patents would contribute to a more complete disclosure of the invention. The Delegation noted further that, when considering the requirement of INN disclosure, the interests of right holders and manufacturers of medicines as well as society at large should be taken into account. The Delegation stated that there remained a number of issues related to the disclosure of INN in patent applications and/or patents remained, such as: (i) the lack of national/regional patent laws that required the determination of pharmaceutical substances by INN in patent applications and patents; (ii) the lack of clear guidelines regarding the extent of the requirement on the disclosure of the INN in patent applications and/or patents; (iii) the differing timing of the INN procedures and the patenting procedures required a

solution to a situation in which a patent application was filed when the corresponding INN was not yet known, and required clarification as to whether it would be possible to require the applicant to notify the patent office once such INN was made available.

138. The Delegation of Spain expressed its support for the statement made by the Delegation of Italy on behalf of the European Union and its Member States. It thanked the Secretariat for the work on the feasibility of the disclosure of INN in patent applications and/or patents. The Delegation noted that the proposal by the Delegation of South Africa on behalf of the African Group and the DAG on patents and health, which included studies on technical issues related to patents, such as a study on the disclosure of INN in patent applications, fit perfectly within the mandate of the Committee. The Delegation expressed its thanks for the clear exposition of the advantages that the disclosure of INN would have on the health sector as well as the difficulties that were involved in associating the INN to patent documents. The Delegation believed that it would be interesting to indicate in patent applications the INN of the active pharmaceutical ingredients because it would allow access to all documents in relation to that product. The Delegation however noted that there were a number of difficulties that made it complicated or impossible. The long pharmaceutical research process together with the patent law system induced pharmaceutical companies to rush to file patent applications at a very early stage of research. Therefore, pharmaceutical companies had a very general outline of the chemical structure embodied in a structural formula with many substitutes that covered an enormous number of elements, which were called Markush structures. The Delegation noted that at the time of filing a patent application with respect to a new pharmaceutical compound, there was no corresponding INN because INN would be granted by the WHO after a product had been authorized for commercial sale, for example, 10 to 12 years from the filing date. The Delegation however noted that for many derivative products of a known compound, an INN might be available. The Delegation stated that when the INN was published, usually the first patent application relating to that compound had already been published and usually a patent had been granted. The Delegation explained that under its legislation, it would be very difficult to modify a patent document once the administrative procedure was finished, and that neither its present patent law, nor an amendment to the patent law to be discussed in the Parliament, allowed substantive changes to applications. The Delegation considered that if a patent application was filed after the INN had been known, for example, when the application was related to an improved formula for manufacturing a pharmaceutical substance, the applicant could indicate the INN in the written description, abstract or title. The Delegation observed that offices with expert examiners that had access to specialized databases as well as large pharmaceutical companies had no difficulty searching patents that did not include the INN. However, those who were less technically equipped would have to use the technology services that had been established by patent offices or other information providers in order to minimize the risk of making a medicine already covered by a patent right. The Delegation stated that the Orange Book system in the United States of America did not exist in European countries, in which drug approval authorities, for example the European Medicines Agency, did not establish a relationship between drug authorization and industrial property rights. The Delegation stated further that supplementary protection certificates (SPC) would be an important source of information on the relationship between patents and the INN, since the SPC applications usually contained the INN of the protected product. In conclusion, the Delegation stated that one possible solution to the issue would be that once the information technology was sufficiently developed, it would be sufficient to put the information into a search engine to produce the INN.

139. The Delegation of Egypt thanked the Secretariat for the study. The Delegation was of the view that the objective behind the feasibility study was to explore the feasibility of the disclosure of INN in patent applications to assist patent examiners to consider whether the

patent application was for an absolutely novel pharmaceutical substance or whether it was for a new form of a known substance. The Delegation noted that the feasibility study stated, in paragraph 27, that an INN was usually requested by a drug developer at the beginning of the clinical trial stage, while a patent application might be filed at the earlier stage of the discovery of a compound or derivative that might have a medical indication. While the Delegation recognized that an INN might not be available at the time of the filing of the patent application, that did not mean that the INN would not be available for a subsequent patent application claiming an improvement over patented medicine. The Delegation noted that according to the example of atazanavir given in the study, a founder patent application had been filed in 1995, whereas the INN had been established in 2003, which was almost eight years after the founder patent application had been filed. However, if near the end of the patent term in 2015, an applicant filed another patent application claiming an improvement over that medicine, then the INN atazanavir certainly would have been available and its disclosure would have assisted patent examiners. The Delegation stated that another point that had been emphasized by some delegations, particularly by the Delegation of India, was that the lack of information on the INN would increase the burden of anyone who was interested in filing a pre- or post-grant opposition. The Delegation stated that while there were some doubts about the cost, burden and effectiveness of the INN requirement, in its view, the requirement was a simple transparency measure that entailed no cost or disadvantage to the applicant. The Delegation stated that the fact that such requirement might not achieve a thorough prior art search did not diminish the value of the information about the INN, especially for those who were interested in knowing what new applications had been made. In its view, the lack of such information might put at risk the availability of medicines at affordable prices.

140. The Representative of the WHO thanked the Secretariat for consulting with the WHO on the study. The Representative expressed its appreciation for the excellent collaboration, and stated that it had been glad to provide the Secretariat with input on the WHO INN program. He stated that the Head of the WHO INN program was present in the room to take any questions that delegations might have in relation to the INN.

141. The Representative of the WTO expressed its appreciation for the opportunity that had been given to the WTO to provide comments on the feasibility study. In his opinion, that was an expression of the continuation of close collaboration between the three organizations, which certainly had been very much welcome. He further stated that collaboration among the three agencies was supported at the head of agency level. He underlined the usefulness of working in a complimentary manner, which made best use of each organization's expertise in its areas of competence. The Representative stated that the feasibility study was, for the WTO, a continuation of the trilateral study prepared by the WHO, WIPO and WTO, as demonstrated by multiple references to the trilateral study. The Representative noted that the trilateral study deserved further elaboration on specific issues since there was only a brief mention on the issue of INN in the trilateral study. Further, he believed that the feasibility study was a building block in efforts to further enhance the provision of factual information by the three organizations. While noting that the scope of the feasibility study should be limited to the feasibility of the disclosure of INN in patent applications and/or patents, the Representative noted that in a number of notifications that had been made to the WTO on legislation that implemented the so-called Paragraph 6 system that allowed countries to issue compulsory licenses for the purposes of exporting medicines, a number of those laws also required the applicant for a compulsory license to disclose the INN where available.

142. The Representative of IFPMA noted that IFPMA represented innovative biopharmaceutical companies and associations around the world, including local

manufacturers in developing countries. The Representative stated that it was widely recognized that pharmaceutical R&D was a lengthy, costly and complex process for which success was never guaranteed. The Representative explained that it was therefore essential for the industry to obtain high quality patents that could protect its innovations during the long process of drug development. She stated that patent offices must be able to properly examine applications and to grant patents with a high presumption of validity. Further, the Representative clarified that it was certainly not a benefit to its industry to obtain a weak patent that could not withstand the process of enforcement. The Representative stated that she did not believe that mandatory INN disclosure was an effective or efficient way to increase the overall quality of examination, and it was likely to have negative consequences on patent applicants and offices. Since some of the IFPMA's companies routinely filed applications in up to 180 countries, the Representative noted that it would be unreasonable to suggest that after a patent was granted, a patentee should return to each office in order to submit information about a newly issued INN. She said that it was even more unreasonable to suggest that 180 patent offices should then be required to link the INN to a patent that had been previously issued. The Representative stated that inclusion of an INN would harm unsuspecting searchers who might believe that an INN keyword search would reveal all relevant information. She stated that the feasibility study made clear that prior art search using only the INN would produce an incomplete record. The Representative noted that the suggestion that the INN would benefit patent examiners or others was flawed. In response to comments regarding the two products exemplified in the study, the Representative pointed out that the study also admitted that those were limited examples and that they did not provide conclusive evidence in support of INN disclosure. Further, noting that a number of delegations had proposed work sharing programs between various national patent offices, she stated that those types of information sharing systems could greatly improve patent offices' access to relevant information and could ultimately increase the quality of patent examination. In particular, she noted that work sharing between patent offices ensured that the most relevant and robust information was available to assess the patentability of a given invention. In her view, if an examiner was to search information about compounds, formulations or uses, the INN would be of no benefit. She further noted that the fact that the costs and risks associated with biopharmaceutical research were high was often best understood when one could see and experience it for oneself. Therefore, she invited delegations who wished to better understand the R&D process in the pharmaceutical sector to visit one of the sites of an IFPMA member.

143. The Representative of KEI congratulated the Chair and thanked the Secretariat for preparing the study. The Representative highlighted paragraph 48 of that study, which stated that “[M]inistries of Health, procurement agencies and humanitarian organizations may be interested in knowing the patent status of medicines in order to check the validity of patents, negotiate price or license with the patent holder or to consider the possible use of compulsory licenses or governmental use. A comprehensive INN keyword search function would facilitate a search for relevant patents and their legal status without the need for specialized skills for searching pharmaceutical substances”. The Representative stated that since the disclosure of INN would be useful, it believed that the Committee should move forward in continuing that work.

144. The Chair stated that the floor was open for discussions of a potential of a study on the implementation of flexibilities concerning different types of exhaustion of rights in Member States.

145. The Delegation of Japan, speaking on behalf of Group B, noted that factual information on exhaustion of rights had been gathered in document SCP/21/7 and was presented to the Committee during the Seminar on Exceptions and Limitations to Patent Rights. In addition,

in that Seminar, Ms. Kyle had mentioned about possible or ongoing studies focusing on developing countries being carried out outside of WIPO. Taking those elements into account, Group B could not see the merit and the justification for conducting a further study at that point in the SCP on the same subject matter. The Delegation therefore stated that Group B could not observe any added value in conducting a further study.

146. The Delegation of Kenya, speaking on behalf of the African Group, stated that the study by the Secretariat was a factual compilation of the policies and laws regarding that particular area, and that there had been no analysis with respect to the effects of exhaustion regimes on making medicines available in developing countries. The Delegation noted that the presentation given during the Seminar had shown that the effects of different types of exhaustion of rights on pricing and accessibility of medicines were mixed. Referring to the presentation during which it had been mentioned that Canadian pharmacies had experienced a drug shortage due to cross-border purchases from the United States of America, the Delegation stated that the exhaustion of patent rights was a very complicated issue that required a clear analysis in terms of the accessibility and price of medicines. Further, the Delegation noted that as different quality certifications were issued depending on the market in which drugs were distributed, the issue should be also analyzed from the point of quality. The Delegation stressed the importance of moving the issue forward. The Delegation reiterated its appreciation for the factual information provided in the SCP and the presentation that had highlighted some of the challenges that needed to be further addressed.

147. The Delegation of Brazil sought clarification from the Delegation of Japan, speaking on behalf of Group B, on whether Group B had objected to any study on exhaustion of rights in general or it would be possible to have a more focused study. Referring to the presentation made by Ms. Kyle, the Delegation noted that there was a lack of data on the effect of the exhaustion of rights in developing countries. Consequently, the Delegation considered that that could be one area for a further study.

148. The Delegation of Japan, speaking on behalf of Group B, stated that Ms. Kyle had mentioned about an ongoing or possible further study outside of WIPO that focused on developing countries. At the same time, she had explained the relationship between exhaustion and price of goods, including pharmaceutical issues. Therefore, the Delegation maintained its position that there would be no room for further study on the topic to be pursued in the SCP at that point in time.

149. The Delegation of Tanzania stated that document SCP/21/7 was an overall survey, which did not include detailed information on particular situations in which different exhaustion principles had been applied. To adopt a best practice, the Delegation considered that an appropriate exhaustion principle might be different from one country to another depending on national conditions. Therefore, the Delegation stated that there was a need to conduct a further deeper, analytical assessment of the exhaustion principles, such as their application and limitations.

150. The Delegation of Paraguay, speaking on behalf of GRULAC, stated that it would be interesting to have a document with an analysis that could look at the issue of exhaustion of rights with some analysis. The Delegation noted that the framework and principle for such analysis could be decided later, taking into account of the interest of all Member States.

151. The Delegation of Italy, speaking on behalf of European Union and its Member States, supported the statement made by the Delegation of Japan on behalf of Group B in light of

the fact that the subject matter was the subject of ongoing studies outside of WIPO. The Delegation stated that it did not agree with duplicating the work done elsewhere.

152. The Delegation of Iran (Islamic Republic of) supported the statement made by the Delegation of Kenya on behalf of the African Group. The Delegation expressed its belief that any kind of a study on the subject should not focus on one side, i.e., either the positive or negative role of a patent system. The Delegation considered that following the outcome of studies and information exchange, Member States should be in a position to fully utilize the flexibilities accorded to them under international agreements. The Delegation said that WIPO should give advice to Member States on the basis of those findings in order for Member States to make appropriate revisions in their national law. In its view, the studies should not be conclusive about the role of patent systems in promoting innovation in the pharmaceutical sector, and should provide an assessment and analysis on the impacts of a patent system on the availability of medicines.

153. The Chair noted that those delegations that had proposed a new study on the topic might present a concrete proposal that clarified additional points not addressed in the documents already prepared so that there would be no repetition of studying issues that had been already captured elsewhere. The Chair then invited any comments on the overall item of patents and health.

154. The Delegation of Pakistan expressed its appreciation for the discussions on that agenda item, which was especially important for resource-constrained developing countries and LDCs. The Delegation stated that the agenda item of patents and health had a close link with the preceding agenda items, namely, exceptions and limitations to patent rights and quality of patents. In its view, while all developing countries should benefit from the flexibilities in international agreements, in reality, the problem was that many developing countries had little capacity to practically implement and benefit from those flexibilities. The Delegation therefore requested the Secretariat to provide technical assistance to developing countries and LDCs in order to enable them to amend and modify their patent laws using flexibilities. The Delegation considered that that was in line with Article 4 of the Agreement between WIPO and the WTO regarding technical assistance on IP-related matters, which gave WIPO a mandate to offer technical assistance on the issues related to the TRIPS Agreement. Further, the Delegation stated that there was a need of studies to be undertaken on the impediments to the practical implementation of public health-related flexibilities in developing country and LDC Member States from technical and legal points of view. The Delegation observed that although many countries had incorporated health-related flexibilities in their national patent legislation, they failed to practically enforce and benefit from them. The Delegation considered that public health was a serious concern of developing countries and LDCs, which should be given utmost importance. The Delegation noted that the grant of bogus patents impeded the public health objectives of developing countries. The Delegation quoted the International Journal of Medical Marketing (2003) in which an example of the successful use of evergreening strategies to obtain extended protection had been provided (the case of paroxetine in which the compound patent had expired in late 1990s, while ancillary patents covering new forms, tablets, uses and processes would not expire until 2018). The Delegation stated that thousands of patents were granted per year on incremental innovations often trivial to a person skilled in pharmaceutical research and production. The Delegation observed that such patents could be used strategically to block generic competition and access to affordable medicines. In its view, public health objectives could not be achieved unless the quality of patents was improved and developing countries could fully benefit from the flexibilities available under the TRIPS Agreement through technical and legal assistance from WIPO. In relation to document SCP/21/8, the Delegation stated that various studies had pointed out that most of

the granted patents were not promoting the real innovation, and that statistical evidence had showed that many patents relating to pharmaceuticals had brought no significant advancement in healthcare. The Delegation referred to a survey published by *La Revue Prescrire* (2005), which had concluded that 68 percent of 3,096 new products approved in France between 1981 and 2004 had brought nothing new over previously available preparations. The Delegation further noted that, similarly, the *British Medical Journal* (2005) had published an article stating that 5 percent of all newly patented drugs in Canada were breakthroughs. Furthermore, according to the National Institute for Healthcare Management Research and Educational Foundation in Washington, D.C. (2002), a breakdown of 1,000 new drugs approved by the United States of America Food and Drug Administration between 1989 and 2000 had revealed that over three quarters had had no therapeutic benefit over existing products. The Delegation further noted that by reviewing a list of ten public health achievements in the twentieth century compiled by the US Centers for Disease Control and Prevention, Baldwin and Revine had found that none of those inventions had been patented. In the view of the Delegation, that suggested that the patent system had not played a role or had a little role in incentivizing the most significant medical and pharmaceutical inventions known by humankind, which was also confirmed by the cases with respect to the treatment of the Ebola virus in Africa. The Delegation further stated that that did not explain whether the increase in pharmaceutical R&D was because of strengthened patent protection. The Delegation, referring to the Commission on Intellectual Property Rights, Innovation and Public Health, stated that where the market had very limited purchasing power, as in the case for diseases affecting millions of poor people in developing countries, patents were not a relevant factor or effective in stimulating R&D and bringing new products to the market. The Delegation considered that overall, the study was inconclusive about the role of the patent system in promoting innovation in the pharmaceutical sector, and ignored the problem of the failure of the patent system in incentivizing R&D on neglected diseases that disproportionately affected patients in developing countries. With respect to document SCP/21/9, the Delegation was of the view that the objective of exploring the feasibility of disclosure of INN was to assist patent examiners in considering whether patent applications were for an absolutely novel pharmaceutical substance or for a new form of a known substance. The Delegation stated that a patent search was an expensive task, which many governmental organizations in a developing country could not afford. The Delegation therefore considered that asking patent owners to disclose and list all relevant information relating to their patents should be the right thing to do. The Delegation noted that, where an INN was not made available at the time of filing a patent application, relevant INN information could be requested at the beginning of the clinical trial stage. The listing and linking information could be submitted later once such INN was known. In its view, that would be similar to other reporting, such as assignment, licensing status and patent renewal. The Delegation indicated that the disclosure of INN could play a significant role in preventing evergreening practices, facilitating third parties in identifying patents that should be opposed, and assisting a search for relevant patents and their legal status without any need for specialized skills in searching pharmaceutical substances. Consequently, the Delegation was of the view that the mandatory disclosure of INN would bring transparency in patent data, as researchers would know how many relevant and irrelevant patents were filed to cover drugs. The Delegation underscored that a mandatory requirement of INN disclosure, if the INN was known, neither violated any international rule nor constituted any burden or cost for patentees. Therefore, in its view, INN or INN/M, whenever recommended by the WHO, should be communicated to patent offices in order to achieve the objective of patent quality and promoting access to health.

155. The Delegation of Kenya, speaking on behalf of the African Group, reemphasized its proposal on patents and health, which had been jointly made by the DAG during the sixteenth session of the SCP. Recalling that its proposal had three elements: (i) studies;

(ii) information exchange; and (iii) technical assistance, the Delegation considered that the Committee needed to further reflect on those studies and finalize those that had not been undertaken. The Delegation noted that while some issues had been touched upon in the SCP, information that was available at that moment was not sufficient to enable the Delegation to move to the next level of its proposal that would ultimately lead to technical assistance. To reach that goal, which would allow Member States to make use of the flexibilities on exceptions and limitations available to them within their national jurisdiction, the Delegation was of the view that further studies were necessary. The Delegation stated that it did not want to have patents that did not really involve novelty, merely indicated new forms or use of the same substance or involved only a small incremental improvement, as in the long run, they would impede access to medicines or further research. Recalling its proposal to invite the UN Special Rapporteur to the Right to Health to come and shed light on some of the issues, the Delegation noted that that proposal was based on its understanding that health was a basic human right. In its view, even if innovation helped mankind, if it ended up segregating people based on their ability to pay, it failed to meet the duty of caring for each other as humanity. The Delegation reiterated its wish that its proposal be implemented in full and that studies be focused in view of the goal of its proposal.

156. The Delegation of Iran (Islamic Republic of) expressed its belief that the issues of public health and patents and having access to medicines at affordable prices were important issues for all countries, particularly developing countries. The Delegation stated that according to the UN Special Rapporteur to the Human Rights Council, nearly two billion people lacked access to essential medicines due partly to high costs. Further, the Delegation stated that according to the Rapporteur, IP law had an impact on the right to health, and patented products could create absolute monopolies, as they could prevent others from the use of those products. Given that the Delegation's expectations of the inclusion of that agenda item in the work of the Committee was to recognize practical ways to respond to the challenges resulting from the patent system in the field of health, the Delegation noted that the full use of flexibilities accorded under international agreements and their ineffectiveness was under issue. The Delegation therefore was of the view that the Committee should explore practical ways to respond to existing challenges, including the use of flexibilities under international agreements. The Delegation supported the proposal jointly submitted by the African Group and the DAG (document SCP/16/7), and expressed its belief that WIPO as specialized agency of the United Nations had the mandate to address the subject of patents and public health. The Delegation further stated that the proposal would not lead to any duplication with any other work within WIPO. In its view, the proposal covered a work program that would enhance the capacity of Member States, in particular, developing countries and LDCs, to adapt their patent regimes to make full use of the flexibilities and the ability of their national patent systems to promote their policies on public health. The Delegation considered that any work program on health and patents should be balanced and based on a long-term approach. Further, the Delegation was of the view that the work program of the SCP should also provide the possibility of analyzing potential impediments and obstacles created by the patent system in accessing medicines, such as legal and structural impediments, capacity constraints faced by developing countries and LDCs in making full use of the flexibilities and how those constraints could be removed. On the issue of the interrelation between patents and the right to health, the Delegation stated that WIPO's cooperation and contribution to work of the WHO should be reported to and discussed by the SCP. The Delegation reiterated that WIPO should represent the consensus views of its Member States in providing information to a norm setting process.

157. The Delegation of Argentina made comments on document SCP/21/9. The Delegation expressed its thanks to the Secretariat for preparing the document on INN. The Delegation

considered that disclosure of INN supported the notification of inventions to the society, facilitated a better understanding of the scope of the invention and increased the possibility of seeking prior art. Further, the Delegation stated its understanding that the disclosure of INN would assist the transfer of technology because pharmaceutical companies that produced generic medicines were mainly interested in the contents and the legal status of patents relating to medicines that had already been successfully marketed. In its view, for such companies, the possibility of identifying those patents via a search using the INN as a keyword would be extremely useful.

158. The Delegation of China expressed its belief that, under the leadership of the Chair, discussions concerning public health and exhaustion of patent rights would be carried out effectively. The Delegation expressed its appreciation to the Secretariat for the complete documents, which had laid down a very good basis for further discussions. The Delegation considered that while those documents were a very complete analysis allowing Member States to understand the situation on those issues, the Committee had not reached any conclusive results. In view of the practices of the Member States and the reports from the WHO, WTO and WIPO, the Delegation observed that there were still problems to be resolved in the future. The Delegation considered that WIPO should play a leadership role in further discussing and considering what kind of role patent systems should play in public health so as to promote the health of the mankind. The Delegation therefore supported other delegations that requested the Secretariat to conduct further research on that issue. With respect to the exhaustion of rights, the Delegation expressed its appreciation to the Secretariat for the study and to the experts for their presentations during the Seminar. The Delegation pointed out that the Committee was still in short a conclusive view with respect to what the Committee should do to promote the benefits for society. The Delegation expressed its hope that the Secretariat would not avoid the issue and would carry out further research and consideration on the issue.

159. The Representative of KEI noted that the reason why there was a conflict in the Committee was because patents were typically implemented as an exclusive right, and the monopoly led to very high prices. In his view, that was particularly true in the area of cancer, in which new drug prices were often more than \$100,000 per year and sometimes more than twice that price. The Representative observed that, in the past five years, there had been an explosion of news reports and academic journal articles detailing one outrage after another as regards high prices for life saving drugs, including not only cancer, but also autoimmune diseases, hepatitis C, and a host of other diseases and conditions. The Representative considered that while one response to those high prices was to avoid granting patents that extended and broadened monopolies, or to grant compulsory licenses when prices were unreasonable or unaffordable, another approach was to delink the patent from the notion of an exclusive right, and make the patent a mechanism to establish a claim on innovation inducement prizes given as a reward for innovation – as a substitute for the grant of a monopoly. In his opinion, that approach allowed the patent system to play a constructive role without being in conflict with access to drugs, as the patent would be used to establish the ownership of the innovation inducement prizes. The Representative noted that the US Senate and the US National Academies had proposed a study of delinkage as an alternative to drug monopolies. In September 2014, the US White House had issued a statement asking to explore delinkage in the context of antibiotic drug development, an approach endorsed by some of the leading European R&D focused drug companies. The WHO was also experimenting with delinkage drug development models for a wide range of diseases for which market failures existed. The Representative therefore suggested that the SCP undertake a review or ask for a study of the provisions in national patent laws that would enable the full delinkage of drug prices and R&D costs, noting that document SCP/12/5 identified alternative models for innovation as a part of the non-exhaustive list of issues for

consideration by the Committee. Further, the Representative underscored his support for the proposal by the African Group and the DAG on patents and health (document SCP/16/7), in particular paragraph 14 of that document. The Representative recalled that, at the General Assembly in 2014, the Delegation of the United States of America had objected to the development of the technical assistance module, as they had viewed that that had been beyond the mandate of WIPO. In that regard, the Representative recalled Article 4 of the Agreement between WIPO and the WTO which explicitly provided WIPO with the mandate to provide legal technical assistance relating to the TRIPS Agreement.

160. The Representative of JIPA noted that JIPA, which had about 900 major Japanese companies as members, was a private user organization established in Japan in 1938 for the purpose of promoting intellectual property protection. The Representative noted that his statement had been prepared in cooperation with the Japanese Pharmaceutical Manufacturers Association (JPMA), which comprised 72 research-oriented pharmaceutical companies. The Representative expressed the view of JIPA and JPMA that it was important to reach an agreement in the SCP that providing excellent pharmaceuticals for patients all over the world was a mission for governments and businesses of both developed and developing countries. Further, the Representative considered that it was necessary to discuss the method and the means for realizing that mission based on an analysis of facts on existing problems. The Representative stated that pharmaceutical and biotechnology companies in Japan responded to requests to license their patents, negotiated licensing terms and licensed their patents or transferred their technology accordingly. The Representative considered that it was essential to protect pharmaceutical technology with patents in developing countries as an incentive for the R&D of new medicines, which required a huge amount of money and effort. Additionally, the Representative expressed his belief that it was necessary to promote the R&D of innovative pharmaceuticals for patients suffering from neglected diseases in developing countries and set policies and take actions to make new drugs available to the patients. The Representative noted that pharmaceutical companies in Japan were making efforts to provide new drugs to patients in developing countries by various actions that were shown on the website of JPMA, for example, participation in the WIPO Re:Search.

161. The Representative of IFPMA noted that pharmaceutical R&D was an extremely expensive process with a high rate of failure: only one new chemical compound out of 10,000 studied in the laboratory ultimately became a marketed medicine and the time needed to market was frequently over ten years. Given that reality, the Representative stated that it was not surprising that the mean cost of bringing a new medicine to market, including regulatory processes to ensure the safety and efficacy of the medicine, was consistently estimated at over \$1 billion. The Representative explained that, despite those odds, research-based pharmaceutical firms reinvested double digit percentages of sales to R&D, which was more than any other industry, in order to invent, develop and market new medicines. The Representative noted that the reason for such a high percentage of reinvestment was because the future of medicines depended on it. Despite some of the comments made during the previous days, the Representative stated that most of the medical breakthroughs of the last century had owed their existence to innovative pharmaceutical industry: aspirin, antibiotics, anti-retroviral and all the recent breakthroughs in relation to cancers had come from the R&D of pharmaceutical companies. The Representative stressed that the ability to keep the innovation going depended on the existence of adequate incentives to help offset the high risks and the high costs inherent in the R&D process and to allow the companies to recoup such costs. The Representative explained that in pharmaceutical industry, such incentive came primarily in the form of intellectual property, particularly patents, which provided the industry with a limited period of market exclusivity that in turn provided the market with the opportunity to generate the

returns that funded the next round of R&D, leading to the next generation of life-saving or life-enhancing innovative medicines. The Representative stated that she recognized the critical role that generic medicines played in helping lower healthcare costs and in increasing access to medicine, as generic companies were able to produce lower-cost versions of medicines by avoiding the costs and risks associated with R&D and by copying the successful outcome of the R&D that had been carried out by innovators. In her view, while in the short term, IP might temporarily postpone the introduction of generic medicines, generic and lower-cost medicines could not exist without the original R&D cycle. The Representative observed that since IP made lower-cost generics possible, nothing was more paramount than global respect for IP and certainty that such respect enabled pharmaceutical companies to continue to invest in the innovative R&D cycle. The Representative therefore supported the TRIPS Agreement and the standards for IP protection that Member States had agreed upon. The Representative expressed her belief that, properly interpreted in the context and the spirit in which it had been signed, the TRIPS Agreement struck an appropriate balance between IP protection necessary to incentivize innovation of new medicines and the limited circumstances of extreme urgency in which increased access to essential treatments was required.

162. The Delegation of South Africa aligned itself with the statement made by the Delegation of Kenya on behalf of the African Group. Further, the Delegation expressed its support for the full implementation of the proposal submitted by the African Group and the DAG on patents and health, which in its view would benefit the Committee, and for a study on exhaustion of rights.

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

163. The Seminar on Confidentiality of Advice from Patent Advisors (see document SCP/21/INF/3) was chaired by Mrs. Bucura Ionescu, *ad hoc* Vice Chair of the Committee.

164. The Secretariat introduced the background of the Seminar, and presented a webpage that contained the information on the topic in a more accessible and user-friendly format.

165. Four speakers presented practical experiences of patent advisors with respect to how the confidentiality of their advice affected the quality of their professional advice. Those presentations were made on behalf of the associations of which they were members, i.e., AIPPI, AIPLA and FICPI. Mr. Pravin Anand, Anand and Anand, gave a presentation on the features of client-attorney privilege under common law. He explained the uncertainties relating to the coverage of such privilege, and discussed the needs for the privilege for patent agents.

166. Mr. Jeffrey Lewis, Patterson, Belknap, Webb & Tyler, presented the attorney-client privilege in the United States of America and its applicability to national and foreign patent agents. He also explained the particularities of legislative and judicial systems under United States federal law.

167. Mr. Wouter Pors, Bird & Bird, presented a civil law approach to confidentiality of advice received from IP advisors. He explained the professional secrecy obligation of IP advisors, including its scope, coverage and limitations as well as the aspects relating to in-house counsel and cross-border disputes.

168. Mr. Steven Garland, Smart & Biggar/Fetherstonhaugh, summarized the issue of protecting confidential client-IP advisor communications from forced disclosure on a global scale. He highlighted the needs of the recognition of foreign privilege at the international level, and presented the AIPPI/FICPI/AIPLA Joint Proposal for multilateral agreement.

169. At the second part of the Seminar, the *ad hoc* Vice Chair introduced the two speakers who would address the issues from the perspective of clients who relied on professional advice of patent attorneys and sought reliable advice from them.

170. Mr. Hans Bloechle, Head of the Intellectual Property in the Schindler Group, based on his experiences in foreign courts, stressed the importance of concluding an international agreement in this area. He also noted that in-house advisors, who are generally closely involved in multinational conflicts, should be also covered by the privilege.

171. Mrs. Manisha Desai, Assistant General Patent Counsel, Eli Lilly, presented the necessity of including advice from non-lawyer IP professionals, as well as in-house counsel, in the scope of privilege. Since companies did business and partnered with institutions around the world, she emphasized the importance of privilege for both domestic and cross-border communications.

172. At the last part of the Seminar, the *ad hoc* Vice Chair invited Member States to present their perspectives on the issue.

173. The Delegation of Switzerland explained the situation surrounding the confidentiality of advice by patent advisors in its country prior to the enactment of the Swiss Patent Attorney Code in 2011 as well as subsequent to the amendment of the Civil Procedure Code, which explicitly exempted lawyers and patent attorneys from producing information that flowed between them and their clients. The Delegation however noted the uncertainty surrounding cross-border litigation in foreign courts, and stressed that those who were mostly affected were inventors and patent holders who had to bear the risk of unwanted disclosure and the cost of avoiding that risk. The Delegation stated that since any solution within the SCP had to strike the balance between maximum legal certainty and flexibilities in view of a multinational and political backdrop, the option of a non-binding soft law approach had a number of advantages. The Delegation considered that a WIPO recommendation on cross-border aspects of client-patent advisor privilege might be a promising next step for the Committee, and volunteered to draft such a proposal with the participation of any interested delegations.

174. The Delegation of the United Kingdom expressed its appreciation to all the speakers who had provided a wealth of information on the subject. Expressing its support for the next steps outlined by the Delegation of Switzerland, the Delegation stated that the soft law approach was the appropriate methodology to be taken by the Committee.

175. The Delegation of Australia stated that in recognition of the importance of confidentiality of communication between clients and patent advisors, it had recently introduced legislation clarifying that the privilege extended to communication between clients and their patent advisors. According to the Australian legislation, in order to be covered under the privilege, an individual must be authorized to do patents work in Australia or under a law of another country or region, and communication must be made for the dominate purpose of providing intellectual property advice to a client. The Delegation observed that it afforded inventors privilege for communications with their patent agents when seeking protection in Australia. In the absence of similar rights in foreign jurisdictions, the Delegation noted that Australian clients could not be assured that communications even with local attorneys in Australia would be protected against disclosure in foreign court proceedings. In

its view, such a situation could potentially affect inventors in all Member States, whether they were developed, developing or LDCs. Accordingly, the Delegation expressed its belief that those cross-border aspects required a solution at the international level, and therefore, the Committee should move forward on the issue.

176. The Delegation of Germany stated that under German law, a patent attorney admitted to the bar was obliged to keep confidential any confidential communication gathered within the attorney's professional activity. The patent attorney had also the right to refuse to testify before a court. The Delegation observed that such connection between the obligation to maintain confidentiality and the corresponding right to refuse to testify created so-called client-attorney privilege for German patent attorneys who were admitted to the bar. The Delegation clarified that the privilege did not apply to patent advisors who were not admitted to the bar. Further, the Delegation noted that the privilege established under the German law also applied to any foreign patent attorney or advisor who, under the jurisdiction of its place of business, was obliged to keep communications confidential and had the right to refuse the testimony. Therefore, within its territory and purely domestic perspective, the Delegation considered that an international instrument did not appear very necessary. However, as legal frameworks were different in other countries, the Delegation understood that there was a general interest in international harmonization in that area. Nevertheless, the Delegation stressed two issues which were very important to consider when discussing international harmonization. First, the Delegation noted that patent attorneys and attorneys in other fields of law should enjoy an equal legal privilege, since there was no justification for such differentiation. The Delegation considered that as the discovery rules were unknown in most continental European states, focusing on patent attorneys alone might be problematic. As the second point, the Delegation observed that a possible legal instrument should leave enough flexibility with regard to different legal frameworks, especially with regard to the legal framework concerning in-house counsels. In its opinion, it should be left to Member States to decide on the applicable regime.

177. The Delegation of Denmark expressed its thanks to the speakers for their brilliant presentations. The Delegation stressed the importance of cross-border issues. The Delegation noted that it was an actual challenge that companies and users in its country met in their everyday work, and that companies and users had to find ways to work around the challenge when doing business internationally, especially with those countries that had discovery procedures. The Delegation therefore welcomed the proposal that the Delegation of Switzerland had put forward. In its view, that would assist the Committee in having better understanding of the issue and taking the question further to a stage where the Committee could take an action.

178. The Delegation of India reaffirmed its stand on the issue as taken at the previous sessions of the SCP. The Delegation explained that there was no provision on client-attorney privilege in India's Patents Act with respect to patent agents who were required to be science graduates. It further reiterated that neither the Paris Convention nor the TRIPS Agreement provided for any such privilege. Therefore, in its view, the issue was of substantive nature governed by national laws, and the work on that issue in the Committee should be discontinued. The Delegation considered that harmonizing client-attorney privilege implied harmonizing the exceptions to the disclosure. The Delegation noted that, in the Indian patent system, persons who graduated in science or engineering were qualified to practice as patent agents after passing the Indian Patent Agents examination, even without having a law degree. The Indian Evidence Act provided protection for lawyers from discovery proceedings. A patent agent, being a person of scientific background, did not fall under such protection. The Delegation observed that, since such disclosure might help the courts in the final determination of substantive issues such as novelty, inventive step,

industrial applicability and sufficiency of disclosure, such privilege might be detrimental to the patent system. Therefore, The Delegation stated that any attempt for the cross-border harmonization of the issue was not compatible with its perspective and thus, the Delegation had opposed and continued to oppose it. The Delegation noted that, during the last session of the SCP, the African Group had stated that the issue of client-attorney privilege had been a matter that had fallen within the purview of private law and the regulations of professional services and hence, had fallen outside of the mandate of WIPO. The African Group had also expressed its view that it should be up to each Member State to decide how to handle the issue within its national law. While the Delegation thanked the speakers for sharing their views at the Seminar, the Delegation shared its understanding that discussions on the confidentiality of advice from patent advisors did not imply any automatic acceptance of the privilege and did not prejudice the sovereign rights of Member States in processing patent applications and patents in accordance with the applicable national law. The Delegation expressed its concern over the manner in which the matter had been progressing in the Committee towards a soft law approach harmonizing client-patent advisor privilege.

179. The Delegation of Guatemala stated that although the intellectual property legislation in Guatemala did not set a standard regarding confidentiality of communication between a client and its patent attorney, within the legislative framework corresponding to the code of professional ethics, Article 5 of the code stipulated the obligation of attorneys to maintain confidentiality and to preserve professional secrecy before judges and other authorities, even after the termination of their service. The Delegation expressed its interest in entering into a discussion on the theme of confidentiality.

180. The Delegation of Kenya, speaking on behalf of the African Group, recalled its previous statement in regard to the topic, and reiterate that the issue was a matter of national law. The Delegation therefore stated that it did not support any norm setting activity in that area, whether soft law or an instrument of non-binding nature.

181. The Delegation of the Republic of Korea expressed its appreciation to the speakers for their presentations. The Delegation noted that, as a civil law country, it recognized importance of the client-patent attorney privilege, especially in relation to cross-border lawsuits. The Delegation therefore considered that a multilateral agreement regarding the client-patent attorney privilege should be established because the multilateral agreement would offer the maximum predictability for all countries and fulfil users' needs. The Delegation was of the view that in establishing such an agreement, the Committee should take time to consider and discuss the details, such as the qualification requirements for intellectual property advisors and types of communication that should be covered by the privilege. Further, the Delegation stated that, in order to resolve the national issue pertaining to the client-patent attorney privilege as well as to pave the way for cross-border collaboration in that area, the Government of the Republic of Korea was in the process of amending its Patent Attorney Act in the near future. While there was no provision in the Patent Attorney Act that stipulated the protection of confidential communication between clients and their intellectual property advisors, the amendment would introduce the right to refuse the disclosure of confidential communications between a client and its patent attorney if such disclosure was ordered by authorities, such as a court.

182. The Delegation of Sweden echoed what had been stated by the Delegations of the United Kingdom and Denmark.

183. The Delegation of Iran (Islamic Republic of) thanked the speakers for their presentations. The Delegation stated that the issue of client-attorney privilege was a matter of procedure that fell outside the scope of the application of patent laws and that it was not treated similarly within different national laws. Therefore, it was not clear to the Delegation

how the mandate of the SCP and WIPO could be extended to encompass such issue. The Delegation expressed its strong belief that it was premature to discuss that issue before having an agreement on the extension of the mandate of WIPO in general and the SCP in particular.

184. The Delegation of the United States of America expressed its appreciation to the speakers for their interesting and informative presentations. The Delegation expressed its belief that confidentiality of communication between clients and patent advisors was very important and its discussion was timely. The Delegation noted that in a global economy where applicants filed patent applications in various jurisdictions, the treatment of confidential information and a risk of divulgence of such information in proceedings in different jurisdictions was of significant concern. The Delegation supported further discussions among Member States regarding best practices, national experiences and solutions to the problems arising under that important topic, which could eventually be adopted on a voluntary basis by Member States.

185. The Delegation of Pakistan reiterated its position expressed during the last session of the SCP. In its view, the issue of confidentiality of communication between clients and their patent advisors fell within the purview of private international law and the regulation of professional services in many countries, including Pakistan. The Delegation considered that the issue was not a substantive patent law matter, but rather the subject of the law of evidence. The Delegation therefore stated that it did not support any norm setting in that field, and that the matter should be left to national preferences.

186. The Delegation of the Czech Republic noted that, while all speakers had touched upon the cross-border aspect of the client-patent attorney privilege and some of them had referred to the possibility of an international instrument or a convention, it might not be a possible way forward at the multilateral level at that stage. The Delegation considered that a soft law approach should be explored as a possible way forward. However, noting the discussions having been held in the SCP, the Delegation asked the speakers what the biggest benefits, and possible pitfalls, of such an approach could be.

187. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, welcomed the Seminar and expressed its belief that it was a valuable, substantive contribution to the Committee's discussions. The Delegation reiterated the importance it attached to confidentiality of communications between clients and patent advisors in relation to the cross-border aspects. The Delegation therefore supported further work on that issue which was relevant to all countries. The CEBS Group also reaffirmed its position that, in order to address the issue, non-binding principles or non-binding recommendations would be an appropriate way forward and could be considered as a possible solution acceptable to all, regardless of the status of each country. In its view, that would enable Member States to avoid amending national legislation or changing their systems, if they did not wish to do so. The Delegation encouraged Member States to engage in further work in that manner and to put specific proposals forward.

188. The Delegation of Japan, speaking on behalf of Group B, thanked the speakers for bringing voices from the real world and for speaking about problems to be addressed at the international level. Reflecting on the real world concerns that had been heard and future work at WIPO, the Delegation stated that it was not convinced by the points made by some delegations that had stated that the issue was a national matter that did not require discussions at the international level. In its view, legal uncertainty regarding the cross-border effects of foreign privilege and secrecy obligation was a concern that could only be addressed at the international level. Under the circumstances in which business was

conducted across the border, the Delegation considered that the Committee should not stop seeking a solution at the international level, paying due attention to differences among national legal systems. The Delegation stated that Group B continued to support further work on that issue in the SCP, as the issue was strongly related to the procedures to obtain patent rights in that it had a significant impact on how patent applications were filed and how communications under those procedures were handled. In its opinion, a soft law approach based on non-binding minimum standards should be pursued as a possible solution, which could be taken into account in national policy making. As for the future work under the agenda item for the next session, the Delegation looked forward to future discussions as suggested by the Delegation of Switzerland. The Delegation proposed that the Secretariat study problems that limit or prevent the implementation of client-patent advisor privilege.

189. The Delegation of Italy, speaking on behalf of the European Union and its Member States, remained convinced that the convergence of existing diverse systems in the area of confidentiality of communications between clients and patent advisors among Member States would be beneficial for users of the patent system irrespective of the level of development of each country. In its view, the time was ripe to consider a concrete mechanism to address the recognition of foreign patent advisor's privilege. Without prejudice to existing national legislation and in order to ensure optimal flexibility, the Delegation considered that a soft law approach should be considered, aiming at offering, under applicable national law, the same protection to communications between a client and its foreign patent advisors and to communications between a client and its national patent advisors.

190. The Delegation of Poland supported the statements made by the Delegation of Italy on behalf of the European Union and its Member States and by the Delegation of the Czech Republic on behalf of the CEBS Group. The Delegation noted that it had been extremely interesting to hear and learn how the issue was seen from the perspectives of patent advisors and clients. The Delegation observed that the information provided in the presentations clearly demonstrated how important the issue of confidentiality was, how a variety of regulations on privilege existed and how unclear regulations or the lack of regulations in some countries could be detrimental to the interest of patent holders who wanted to market their products in other countries. The Delegation considered that the issue was especially important in relation to multinational conflicts and litigation in different jurisdictions. The Delegation therefore was of the view that an international instrument on the privilege was needed in order to overcome those problems. The Delegation strongly supported continuing the work in the Committee with the aim of developing at least a soft law instrument that would protect confidential communications between a patent advisor and a client.

191. The Delegation of China stated that confidentiality of communications between a client and its patent advisor was of utmost importance for the quality of patents. In its view, there was no difference between confidentiality of communications between clients and patent advisors and confidentiality of communications between clients and lawyers, as they were both related to evidence law. The Delegation considered that, since delegates participating in the SCP were specialized in patent law but not in evidence law, whether the SCP was an appropriate forum to discuss the issue should be further clarified. While the Delegation welcomed the discussions held in the Committee, it raised the concern about the appropriateness of elaborating international norms in that regard within the SCP.

192. The Delegation of Japan noted that the issue of attorney-client privilege had been discussed last year in conjunction with the revision of the Japanese Patent Attorney Act, particularly within the Patent Attorney System Committee. The Delegation stated that, as a

result of the discussions, it had been agreed that discussions at the international level were necessary to advance the issue. It considered that since domestic measures taken by individual countries did not have a binding effect in countries that categorically denied the confidentiality of advice by patent advisors, adopting an international legal framework was more desirable so that attorney-client privilege on communications between clients and their patent advisors would most certainly be recognized by judicial authorities in every country. Recognizing the fact that some countries had difficulties adopting any binding international agreement, the Delegation was of the view that adopting an agreement based on non-binding soft law was a practical option. Finally, in order to deepen the discussions in the Committee, the Delegation suggested that the Secretariat conduct a questionnaire survey on the issue. For example, such a survey might include the following questions: (i) are there any obstacles to expanding the types of professionals covered by the privilege; and (ii) are there any obstacles or differences when it came to domestic and foreign advisors.

193. The Representative of the EAPO pointed out the aspects in relation to a regional patent system in which applicants were involved in procedures before a regional patent office as well as the national procedures of its Member States in which the regulations on confidentiality of advice by patent advisors might vary. In the Representative's view, it would be better to prepare an international agreement that could be either binding or non-binding. The Representative noted that the issue of confidentiality was closely linked to technology transfer. In view of the fact that some countries considered that the issue was not in the purview of the SCP, the Representative observed that the Committee might pursue an agreement which would be available for those who wished to adhere to such an agreement; in other words, it would simply serve countries that considered it useful.

194. In response to the question raised by the Delegation of the Czech Republic, Mr. Garland, speaking on behalf of the AIPPI, stated that a soft law approach would not be seen by the AIPPI as the preferred approach. He noted some downsides to it: for example, it would lack certainty in the sense that whether it would be enforceable or followed, applied or recognized by a court in a particular jurisdiction in cases of cross-border scenarios. In his view, the SCP had been looking at the issue for a few years, and had done very good work in looking at the problems that existed in various jurisdictions. In order to move forward, he considered that exploring other possible solutions was a very good idea. The Representative stated that if the Committee at that time thought that a soft law approach was a preferred option, then it would be a positive step forward that should be encouraged. Further, he considered that a questionnaire suggested by the Delegation of Japan was a very good idea. To conclude, he stated that while AIPPI did not view the soft law approach as a preferred approach, it considered that if the SCP was prepared to consider solutions including a soft law solution, then that was an encouraging step forward. In addition, he clarified that the issue of confidentiality of advice of patent advisors was a specific issue related to patent law and to intellectual property, as certain jurisdictions had dealt with the issue within their patent laws. He stated that the client-patent advisor privilege led to better advice in respect of intellectual property rights and to better and stronger IP systems.

195. The Representative of the TWN stated that one of the fundamental principles of patent law was the disclosure of information on technology: non-disclosure or partial disclosure was a ground for refusing patent grant or revocation of a patent. The Representative was of the view that extension of client-attorney privilege to patent advisors went against the fundamental principle of disclosure. The Representative noted that the patent specification, a public document, as well as any related records used in the preparation of patent specifications, should be made available to public scrutiny in order to find or verify the truth about the claims in the specification. The Representative observed that there were wide-ranging public policy concerns associated with patent law, and consequently, absolute

transparency around granting of patents was particularly important. The Representative considered that society could not afford another layer of opaqueness around patent specifications. In the opinion of the Representative, the extension of client-attorney privilege to patent advisors would compromise the transparency requirement in the administration of patents, which included patent prosecution procedures as well as litigation of patents. Further, the Representative remarked that the extension of client-attorney privilege to cover patent advisors would incapacitate patent offices and courts in developing countries from safeguarding public interest following the grant of patents. The Representative expressed her concerns about the unintended consequence of such extension, such as its effect on patent applications, TRIPS flexibilities, patent opposition systems and the transparency of patent procedures. In addition, the Representative noted that a seminar on attorney-client privilege should have addressed all the different concerns associated to the issue, and that the concerns in relation to misuse of attorney-client privilege had not been explored at all during the Seminar.

196. The Representative of the ICC expressed its thanks for the half day Seminar on the Confidentiality of Advice from Patent Advisors. He stated that the presentations had clearly demonstrated the international character of the issue and the importance of finding a cross-border solution. The Representative said that given the increasingly international nature of transactions involving intellectual property rights, including patent rights, the ICC had consistently emphasized that finding a solution was important for both holders of patent rights as well as for those who were confronted by the patent rights of others. The Representative noted that businesses, whether large or small and whether operating locally or in export markets, required advice from professional patent advisors in order to understand how they could act within the limits of their own patent rights and how they could act when confronted with the patent rights of others. The Representative further noted that for such advice to be frank, both patent advisors and their clients needed the assurance that advice would remain confidential. He explained that while advice from professionally qualified lawyers in most countries was protected by confidentiality and thus was not accessible to other parties in a court case, such was not the case in many countries for communications from professionally qualified patent advisors who did not have a professional legal qualification. The Representative said that at the international level, even if the communications between a client and its professional patent advisor were considered confidential in the national context, that confidentiality might not be respected in the cross-border context. In other words, advice that had been protected as confidential in one country might not be protected in another country and could be, for example, disclosed to other parties upon order of the court. The Representative therefore stressed the importance of the cross-border aspect of confidentiality of communications between clients and their patent professional advisors. In his view, the lack of confidentiality across-borders obviously impacted the quality of advice given to businesses by local advisers around the world. Emphasizing the public interest implications of the issue, the Representative stated that confidentiality of communications between the client and its patent professional advisor helped to ensure respect for local laws by helping clients understand the scope of patent protection and to achieve just and efficient outcomes for all parties, including holders of rights as well as those confronted by the rights of others. The Representative noted that some delegations had expressed concerns that client-patent privilege would have a negative impact on patent scope and conceal prior art from patent examiners. The Representative said that had demonstrated a total misunderstanding of the concept. He explained that confidentiality applied only to advice that had been given by the professional advisor to the client and it did not cover publicly available information, such as prior art or technical and other information that related to the patent rights in question. The Representative further stated that protecting the confidentiality of advice by patent advisors therefore had no bearing on issues relating to the substance of a patent, such as scope of protection and

disclosure of prior art. He stressed that it would not affect the work of patent offices or examiners, and that it only related to the type of evidence that could be used in litigation in a specific case. The ICC believed that the work in the Committee over the last several years, notably the half day Seminar on the Confidentiality of Advice from Patent Advisors and the various documents prepared by the Secretariat, had brought the topic significantly forward. The Representative urged all Delegations to continue work towards a cross-border solution.

197. The Representative of FICPI noted that the effects of the disclosure of communications between a client and attorney during a discovery procedure had been discussed during the half day Seminar. The Representative noted that a FICPI presentation explaining the process and the influence of client-attorney privilege was available in order to give Delegations proper insight in the process that was involved in drafting and processing patent applications. The Representative said that about 30 years ago, as a Brazilian industrial property agent, he had handled patent application in Brazil on behalf of a client from the United States of America about which an examiner had issued a negative opinion. He had written to the client expressing his opinion that the examiner had appeared to be correct concerning the fact that the claimed invention was obvious in the face of the prior art. The client had thereafter asked the Representative to never again send letters that expressed such a negative opinion. The Representative said that the client had explained two things. First, in the client's opinion, the invention had not been obvious. Second, if letters such as the one the Representative had sent to the client were reviewed during a discovery procedure in the United States of America, then that would jeopardize the client's efforts to prove the invention had been patentable. The Representative believed that it was not in the best interest of clients, the patent office nor the public that he had not been able to write to clients in a completely frank manner. The Representative noted that where a client wished to have the Representative's opinion regarding whether a client's product infringed a patent, he would try to avoid giving a direct opinion due to the uncertainty surrounding the confidentiality of the communication. The Representative further noted that he had tried to counterbalance the negative aspects with possible defenses against infringement. As a result, the Representative said his client would not receive the frankest possible opinion, and therefore the client might decide to launch its product in the Brazilian market and might suffer an infringement action. In his view, that was bad for the client and for the public, because the product might need to be withdrawn from the market. If it was an industrial machine, a judge could even order the machine to be sealed or seized, and the person who had acquired the machine would suffer losses. The Representative also said it was bad for the judiciary system because the court action could have been avoided by a completely frank communication between the attorney and his client. The Representative stressed that the adoption of an attorney-client privilege would not reduce the level of available information concerning an invention. The Representative noted that it did not affect the disclosure of the invention in any way because patent laws around the world required that a patent application disclose an invention in a manner sufficient for a person skilled in the art to put it in to practice and any prior art cited during an examination by a patent office would also continue to be available.

198. The Representative of JPAA noted that the issue was very important for patent holders and not only for patent attorneys. The Representative stated that it was patent holders who held the right to protect the secrecy of communications between patent advisors and clients. Therefore, the Representative stated that the issue had to be considered from the viewpoint of a user-friendly patent system. The Representative also noted that since the privilege of secrecy of communications between clients and foreign patent attorneys was not present in every country, there was a clear gap and inconsistency among countries. As a result, he observed that a patent holder had big concerns when infringement lawsuits were filed in foreign countries, especially those with discovery procedures. JPAA strongly hoped that at

least certain guidelines or recommendations on the issue would be established in the SCP for patent holders.

199. The Representative of APAA expressed its thanks to the Chair for his leadership and to the Secretariat for its preparation of the half day Seminar on the Confidentiality of Advice from Patent Advisors. The Representative noted that the APAA was an association of patent attorneys in private practice in the Asian region. She further stated that the APAA had adopted a resolution at its fifty-fifth Council Meeting in Singapore in 2008, urging an international consensus on setting minimum international standards of client privilege against the forced disclosure of confidential communications between clients and qualified intellectual property professionals. She noted that intellectual property disputes were raised in multinational jurisdictions, and that the parties needed to have full and frank communications not only with domestically qualified intellectual property advisors but also with qualified intellectual property advisors in other countries. The Representative stated that the disclosure of confidential communications between clients and qualified intellectual property advisors protected in one country was sometimes forced during litigation. She also stated that the increase in international litigation had exposed clients to a higher risk of forced disclosure, which had potentially undermined a client's ability to obtain legal advice on intellectual property-related matters. The APAA believed that discussions on the confidentiality of communication between clients and their patent advisors did not have any substantial influence on discussions on the harmonization of substance to a patent law, about which some Member States had expressed concern. The Representative said it would benefit companies in all Member States, which could be the parties to a potential patent dispute, since it would give an opportunity for them to obtain suitable legal advice from a patent advisor without fear of forced disclosure of their confidential communication during litigation in the future. Therefore, the APAA expressed its strong support for the proposals of the Delegations of Switzerland and Japan, as well as the joint proposal made by AIPPI, FICPI and AIPLA for further discussion to take steps for a minimum international norm regarding the mutual recognition of confidentiality of communication between clients and their patent advisors.

200. The Representative of AIPPI stated that AIPPI was more than a hundred years old and it grouped together 100 national groups, many among which were from developing countries or LDCs. The Representative said AIPPI had groups that were extremely active, including national groups representing countries that had intervened during the current SCP session, such as India, Egypt, Brazil and Argentina. AIPPI had considered a few years ago that it was very important to take up the issue of client privilege because it was an international question that concerned all countries. Consequently, AIPPI had set up a Committee, presided over by Steven Garland, who had given a presentation during the half day Seminar. The Representative stated that when a question was asked in AIPPI Congress on whether the issue should be included on the agenda, all countries, developed, developing and LDCs, had endorsed the idea. Accordingly the Representative noted that AIPPI would continue to work on the issue, taking into account discussions during the half day Seminar. He stressed the importance of arriving at a satisfactory solution for developed countries, developing countries and LDCs.

AGENDA ITEM 9: TRANSFER OF TECHNOLOGY

201. Discussions were based on document SCP/21/10.

202. The Delegation of Japan, speaking on behalf of Group B, expressed its appreciation to the Secretariat for the preparation of document SCP/21/10. The Delegation stated that the

fact that almost all comments from Member States had addressed the incentives to technology transfer reflected the reality of the subject matter. The Delegation observed that various initiatives and measures described in document SCP/21/10 encouraged promoting technology transfer in the framework of the existing patent system. The Delegation noted that the importance attached to technology transfer and Member States' sincere attitudes toward it could be observed in the document. The Delegation stated that the examples of patent-related impediments to transfer of technology found in the document were issues that could be taken into account in the patent system, and were not necessarily patent-related impediments. It further noted that while the examples of patent-related impediments submitted by the observer were cases in which licensing negotiations might have prevented transfer of technology, obviously, not all licensing negotiations went well and they might fail because of various reasons. The Delegation however highlighted that inventors could not even sit at the negotiating table to transfer technology without patent protection for their inventions. The Delegation clarified that, without appropriate patent protection, inventors would hide their inventions so as not to let others imitate them, which would prevent transfer of technology. Accordingly, in its view, patent protection was an essential component and prerequisite for technology transfer. In addition, technology transfer could be further enhanced by the initiatives under the existing patent systems, as included in the working document. In that context, the Delegation considered that legal certainty and predictability of patent rights were critical to technology transfer. The Delegation was of the view that the problem mentioned in the document relating to the licensing of a patent, which ultimately did not satisfy the enablement disclosure requirement and which could not be reduced to practice based on its specifications, could be interpreted as a problem associated with the quality of the given patent. The Delegation stated that the SCP could deal with such factors, among others, which had a direct relationship to its core mandate. Further, referring to the CDIP project "Intellectual Property and Technology Transfer: Common Challenges – Building Solutions", including a high-level expert forum scheduled in January 2015, the Delegation considered that the CDIP was the adequate forum to hold discussions on transfer of technology. Consequently, the Delegation expressed its belief that the SCP should not consider further work related to technology transfer in general, and that the Committee should consider whether there still remained any other concrete issues that should be dealt with at the SCP, taking into account of the mandate of the SCP. In its view, in order to avoid duplication among the committees, further work on the issue should be considered in the SCP only after the completion of the discussions at the CDIP.

203. The Delegation of Italy, speaking on behalf of the European Union and its Member States, thanked the Secretariat for preparing document SCP/21/10 providing further practical examples and experiences on patents and transfer of technology. The Delegation regretted the fact that none of the LDCs had submitted information regarding their examples and experiences. The Delegation recalled the findings in documents SCP/21/10 and SCP/18/8 that high quality patents, such as those with sufficient disclosure in patent applications, an adequate scope of patent claims and a well-functioning PCT system were essential elements for a patent system to fulfill its objectives in terms of innovation and transfer of technology. The Delegation noted that document SCP/20/10 in particular highlighted that better awareness of the patent system and the encouragement of the private sector also played an important role in assisting technology transfer. Further, referring to the CDIP project "Intellectual Property and Technology Transfer: Common Challenges – Building Solutions", the Delegation reiterated that until the completion of that Project and its follow up analysis, the European Union and its Member States were not in favor of launching new initiatives on transfer of technology within the SCP.

204. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, thanked the Secretariat for preparing document SCP/21/10. The Delegation noted that the

practical experience and examples of several members of the CEBS Group had also been included in the document, and that there was also no doubt that transfer of technology was affected by various factors. The CEBS Group considered that the further information contained in document SCP/21/10 confirmed the previous findings in documents SCP/18/8 and SCP/20/10: in particular, the finding that quality of patents and the well-functioning PCT system were important elements for the patent system to fulfil its objectives in terms of supporting innovation and transfer of technology. The Delegation further noted that practical examples and experiences were also helpful in increasing the Committee's understanding of the role of the patent system in technology transfer. The Delegation emphasized that any duplication of work with other WIPO bodies such as the CDIP, which dealt with the Project on Intellectual Property and Technology Transfer: Common Challenges – Building Solutions and others, must be avoided. Further, the Delegation shared the view of other delegations that until the completion and analysis of that Project, any new work on the topic should not be developed within the SCP.

205. The Delegation of Pakistan expressed its appreciation to the Secretariat for the preparation of document SCP/21/10. The Delegation referred to some empirical studies regarding impediments to transfer of technology arising from the patent system, in particular Kim (2002), Kumar (2001), Nicolson (2002) and a study by Glass, found in paragraphs 23 to 26 of document SCP/21/10. The Delegation requested that the Secretariat set up an independent commission and that further studies be conducted on the issue of technology transfer to analyze failures in technology transfer arising due to impediments from the patent system. The Delegation explained that the objective of those activities should be to: (i) identify flexibilities/measures available in the TRIPS Agreement under technology transfer; (ii) improve understanding of developing country policy makers of the role of IPRs in technology transfer and learning from experiences of developed countries in acquiring technology; (iii) building technological base, collating information on R&D policies of developed countries and identifying appropriate policies that could be implemented by developed country governments and entities to facilitate technology transfer to entities in developing countries; (iv) analyzing the extent to which developed countries have fulfilled their commitments under Article 66.2 of the TRIPS Agreement. Further the Delegation proposed that, at the twenty-second session of the SCP, the Secretariat provide information on the involvement of the WIPO Secretariat in discussions on transfer of technology in the post-2015 Development Agenda in line with Goal 9 of the Sustainable Development Goals in the UN, which listed as a goal to build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation.

206. The Delegation of Ecuador stressed the importance of the subject of the disclosure, dissemination and transfer of technology, which were key elements for development. The Delegation expressed its belief that the topic should be kept in the agenda of the SCP, as discussions on different national experiences would facilitate a better and deeper understanding of transfer of technology. From the point of view of public interest, the Delegation considered that technology transfer was the central element of the patent system, and that protection and respect for intellectual property rights should contribute to technological innovation and dissemination of technology, so that intellectual property rights would benefit the producers as well as the users of the technology. In its view, an important issue to discuss was sufficiency of disclosure that would lead to real technology transfer: a patent should include all information necessary to transfer technological knowledge. Further, the Delegation stressed the importance of technical assistance provided by WIPO, particularly with respect to better use of information available in the patent system in developing countries and LDCs. The Delegation supported the proposal by the DAG to set up an independent committee of experts to look at issues on transfer of technology and patents. The Delegation considered that the study by the Secretariat should be revised in

order to include concrete examples of the refusal of transfer of technology to developing countries. The Delegation therefore supported a compilation of information on regulations, guidelines, national and regional jurisprudence with regard to voluntary licenses, including practice of anti-competitive licenses, as the Delegation had encountered competition issues with regard to transfer of technology.

207. The Delegation of Japan thanked the Secretariat for its preparation of the document. The Delegation expressed its firm belief that the existing intellectual property system did not constitute a barrier to technology transfer, but rather it provided a stable foundation that induced direct investment and technology transfer. Referring to the WIPO GREEN initiative, in which the Japanese industry had been actively involved, the Delegation stated that it was a good example of technology transfer utilizing the patent system. The Delegation stated that such activities should be further enhanced.

208. The Delegation of Tajikistan expressed its appreciation to the Secretariat for the document compiling various contributions from Member States, and thanked those Member States that had contributed. The Delegation expressed its support for activities that would enable Member States to improve the use of patent systems and intellectual property. The Delegation stated that Tajikistan had a plan of action that ran from 2013 to 2020 that contained various intellectual property mechanisms that contributed to development and innovation. The Delegation explained that innovation had been the subject of several initiatives included in the reports of its country. At that time, its country was working on legislation that would facilitate receiving technology and opening up a market for absorption of technology, which would play an important role in commercializing and marketing new technology in Tajikistan.

209. The Delegation of India expressed its compliments to the Secretariat for preparing the document. The Delegation reiterated its view expressed at the twentieth session of the SCP: “from the viewpoint of public interest, transfer of technology has been the central theme of the patent system. The protection and enforcement of the patent rights should contribute to the promotion of technological innovation and the dissemination of technology, retaining the mutual advantage of producers and users of technological knowledge and in a manner conducive to the social and economic welfare and to a balance of rights and obligations”. The Delegation stated that since the twelfth session of the SCP, India and other developing countries had been consistently pressing for a discussion on the issue of sufficiency of disclosure and transfer of technology. In its view, in order to transform the patented invention into a working reality, if a skilled person in a country where a patent application had been filed or a patent had been granted required the help of other secret technologies that were outside the coverage of the patent, and consequently the skilled person was not able to transform the invention into a working reality using the patent as a stand-alone reference, it meant that the basic purpose of the patent system was not fulfilled. The Delegation stated that such inability to transform the invention into working reality posed a serious challenge to the very purpose of the patent system. The Delegation considered that the role of the patent system as a stand-alone system, in which the transfer of technology was enabled independent of any know-how or show-how, had not yet been firmly established, as could be seen from the practical examples in document SCP/21/10. The Delegation observed that under an ideal situation, a patent as a stand-alone document should contain all necessary information for the transfer of specific technological knowledge: it should disclose the invention fully and completely, including its operation or use and the method by which it was to be performed along with the best method known to the applicant of performing the invention. With respect to practical examples, the Delegation noted that the example of efavirenz in Brazil, in particular, showed the shortcomings of the patent system in transferring technology in emergency situations in the area of public health. The Delegation

further stated that the rise of litigations in the context of standard essential patents (SEPs) and their effects on technology transfer in information and communication technology (ICT) was a matter of concern and worry in the field of emerging electronic technologies, as many companies were losing their corporate legs in the minefields of submarine patents in ICT. The Delegation was of the view that the entirely rosy picture of the transfer of technology riding on the vehicle of the patent system was only a fairy tale. Therefore, the Delegation stated that the document needed to do something more than compiling data from different stakeholders. The Delegation suggested that eminent economists be asked by the Committee to conduct a thorough study on the impact of the patent system on transfer of technology.

210. The Delegation of Kenya, speaking on behalf of the African Group, thanked the Secretariat for the document. The Delegation reiterated that the patent system was not working in a manner which was designed to promote dissemination and transfer of technology. The Delegation considered that the fact that no LDCs had contributed good examples could be a testimony that there had been no meaningful example of technology transfer carried out in those countries. The Delegation was of the view that the Committee had an important role to play in practically facilitating transfer of technology, as the patent system as designed was a key in transferring technology. The Delegation therefore stated that the work that could be carried out in other committees, in particular, the CDIP, should not be an excuse not to undertake work in the committee that dealt with patents. In its view, the work in the CDIP should proceed independently of the work in SCP. Consequently, the Delegation requested the Secretariat to continue working in that area and to maintain the issue in the agenda. In its view, the information available at that moment was not sufficient in indicating and isolating the issues which impeded transfer of technology, and a more systematic approach to the issue was necessary.

211. The Delegation of Brazil thanked the Secretariat for preparing the document. It noted that the expression "transfer of technology" could be understood in at least two different ways: first, a national transfer of technology among universities, other research institutions and firms, and second, the international obligations expressed in Article 66.2 of the TRIPS Agreement. The Delegation further noted that a similar understanding aiming at bridging the technological divide was also part of Cluster C of the WIPO Development Agenda. The Delegation touched upon its national public policies aimed at the transfer of technology, stating that since the adoption of the Innovation Act in 2004, all universities and research institutes in Brazil had been mandated to establish technological innovation centers (NITs in Brazil, but regularly referred in international practice as TTOs). In accordance with the Innovation Act, they were responsible for safeguarding policies related to fostering creations, licensing, innovation and transfer of technology, evaluating and classifying the results obtained from research activities and projects developed by the institution, assessing and promoting the protection of the inventions developed by the institution and monitoring the processing of applications and the maintenance of the intellectual property rights of the institution. The Delegation further explained that national fora, such as Fortec, had gathered managers who dealt with innovation and technology transfer, and that the NITs, which were responsible for managing the partnerships with the institution and the private sector, had an important role in raising awareness regarding how to innovate and protect inventions. One of such initiatives was to display inventions available for licensing to promote public-private partnerships. The Delegation noted that after 10 years, while facing some challenges, they were changing the way universities and research institutes worked in Brazil. In 2012, 176 institutions had participated in the assessment of the implementation of the Innovation Act, the results of which had been very positive. 160 institutions had completed the establishment of their TTOs and 49 were still in the process of implementing them. The

Delegation observed that since the establishment of TTOs, patent applications submitted by TTOs had been increasing both in Brazil and abroad.

212. The Delegation of Chile thanked the Secretariat for preparing the document which contained important information about different initiatives in various countries in the area of technology transfer. The Delegation underscored the importance of technology transfer for small and medium sized enterprises, in particular, the importance of special tools and platforms that enabled exchange of technologies through better use of intellectual property rights. The Delegation noted that since transfer of technology was very important for all communities having a relation with intellectual property, the Committee should continue working on that subject.

213. The Delegation of Argentina expressed its appreciation to the Secretariat for preparing the document. The Delegation noted that since technology transfer was fundamental for balanced patent system, it was of paramount importance to further elaborate the study. In relation to the analysis of technology transfer, the Delegation considered that the capacity of countries to absorb new technology and to introduce it needed to be taken into account, and that the patent system had a very important role to play in that context. The Delegation observed that the fact that patent applicants did not always provide all the techniques necessary for applying the new technology often led to an unbalanced patent system. In its view, in conformity with Article 7 of the TRIPS Agreement, the protection of and respect for intellectual property rights must encourage the use, dissemination and transfer of new technologies in the mutual interest of both parties. The Delegation considered that the full disclosure of innovations was one of the most important preconditions in the area of patents. Referring to paragraph 32 of document SCP/21/10, the Delegation noted that, for the preconditions for sufficient disclosure, a country might demand a description of the manufacturing process in order for an applicant to obtain the patent, or it could also request the patent to be properly adapted to the situation in the receiving country. The Delegation highlighted the need to have a holistic approach to intellectual property, and pointed out a close link between dissemination of information and transfer of technology.

214. The Delegation of Tanzania stated that while transfer of technology was very important especially for LDCs, it was not without some complexities in transferring appropriate technology to the LDCs. The Delegation noted that as LDCs had been struggling with improving their environment with full use of the flexibilities given under the TRIPS Agreement, there had been issues regarding the establishment of legal and institutional frameworks that were conducive to transfer of technology. In its view, more engagement between the producer of technology and its recipient as well as enhancement of the capacity of the recipient to engage fully in the technology transfer arrangements, either bilaterally, regionally or internationally, were needed. Further highlighting sectorial challenges and other issues such as infrastructure, including IP infrastructure in LDCs, the Delegation stated that, despite those challenges, LDCs were willing to fully engage in transfer of technology.

215. Following the request by the Chair, the Secretariat presented the status of the CDIP Project on Intellectual Property and Technology Transfer: Common Challenges – Building Solutions

216. The Delegation of the Czech Republic requested the Secretariat to elaborate more on the expected outcomes and possible evaluation of the Project after the conclusion of the Project in the beginning of 2015.

217. The Secretariat stated that a number of thoughts, which would be an outcome of the High Level Expert Forum, would then be fed back into the CDIP for Member States' approval.

Eventually, Member States would decide on whether any of those thoughts were agreeable to all the membership of the CDIP. If that was the case, those thoughts might be incorporated into the work of the Organization. In the opposite case, only the least common denominator elements agreeable to all the membership of the CDIP would be incorporated.

218. The Delegation of Pakistan asked whether the Secretariat could share any preliminary outcomes or findings of that Project.

219. The Secretariat explained that the main deliverables so far consisted of the convening of the five regional consultations in the five regions and the six technology transfer studies that had been commissioned and completed by technology transfer experts and peer reviewed by international experts. In addition, a concept paper had been prepared, incorporating all the comments received from Member States, IGOs, NGOs, professional associations and selected experts.

220. The Delegation of the Czech Republic stated its understanding that there would be a possible or rather a probable continuation of work on that Project within the CDIP.

221. The Delegation of Japan stated its understanding that while the Project was coming into the final phase, at that point, it could not be foreseen what kind of tools would emerge from the discussion at the High Level Forum and what would be taken up at the subsequent CDIP session. Therefore, the Delegation was of the view that the outcome of the Project could not be foreseen even at the very latest stage of the Project, and consequently, overlaps of the work between the CDIP and SCP could not be evaluated for some time. The Delegation therefore reiterated that it was dangerous to launch a new project within the SCP before being able to assess what would emerge from the CDIP Project.

222. The Delegation of South Africa dismissed those comments that had linked the agenda item in the SCP with the CDIP Project. In its view, they were two different issues that should not be linked. The Delegation pointed out that when the Project had been agreed at the CDIP, the SCP had already undertaken the work on transfer of technology. The Delegation considered that the SCP and CDIP could discuss issues on transfer of technology based on the mandate of each committee.

223. The Delegation of Kenya noted the differences in approaches between the SCP and CDIP: while the CDIP took a project approach with a specific timeframe, the SCP approach was one of continuous work.

224. The Delegation of India supported the statement made by the Delegations of South Africa and Kenya. The Delegation noted that the SCP should take advantage of the studies prepared by the experts and to be discussed at the CDIP so that the SCP could advance its work in the area of transfer of technology. The Delegation stated that the agenda of transfer of technology should be maintained in the SCP permanently, and should further enhance the Committee's understanding on the patent system and technology transfer.

225. The Delegation of Brazil stated that it welcomed not only the report of the CDIP project but also regular reports on the activities of WIPO GREEN, WIPO Re:Search or any other projects. The Delegation supported those delegations that had stated that the discussions under the SCP and the CDIP Project were of different natures. In its view, both types of dialogues should be continued. The Delegation noted that although the Project would end at one point in time, the subject of transfer of technology and innovation would not leave the Organization.

226. The Delegation of Pakistan stated that each committee had a different mandate. In its view, as the SCP had a mandate to work on the issues of patents, the Committee had been working on the issue of transfer of technology from a patent perspective. The Delegation considered that there would be no duplication of work, since the CDIP Project would finish in the near future.

227. The Delegation of El Salvador expressed its appreciation to the Secretariat for presenting the document, which informed the Committee about various technology transfer initiatives being carried out in different countries. The Delegation expressed its belief that the Committee could discuss issues relating to transfer of technology which was of extreme interest to developing countries such as El Salvador.

228. The Delegation of Paraguay stressed that all delegations that had spoken had expressed their greatest interest in continuing the debates on technology transfer both in the CDIP and SCP.

229. The Representative of TWN stated that any discussion on technology transfer should not and must not ignore the need to better understand patent-related impediments to technology transfer. The Representative noted that its submission on that subject focused on practices and experiences in which patents were a barrier to technology transfer with the right holder adding a price premium and imposing unreasonable conditions for the use of the patent-protected technologies or simply refusing to license out the technology with a fear of competition with the licensee. The Representative observed that the cases had revealed that technology transfer was also hindered by the restrictive terms and conditions required in licensing agreements by the patent holder. The Representative requested that its full submission be circulated to all Member States. Further, the Representative considered that it was within the mandate of the SCP to unpack the issue of technology transfer. In view of the Representative, the Committee needed to understand the kinds of impediments to technology transfer, the issues surrounding technology transfer and measures that should be undertaken for facilitating technology transfer. The Representative stated that the SCP should have in-depth discussions in relation to patent-related impediments to technology transfer. The Representative was of the view that there was no overlap with the CDIP Project, which was a time specific project with specific components.

AGENDA ITEM 10: FUTURE WORK

230. The Delegation of Japan, speaking on behalf of Group B, underlined that the official work program had to be in line with the core mandate and the objective of the Committee and should enable technical discussions on issues of substantive patent law. It believed that the package, which consisted of five items, should be maintained for the next session taking into account the remaining work under those agenda items. The Delegation stated that the expansion of the package could be considered at a later stage, taking into account a balance of the elements to be included. With respect to the quality of patents, the Delegation was pleased to see a good exchange of views and clarifications at the Sharing Session in order to deepen the understanding of that issue. The Delegation noted that that was a good first step, and that it could lead to continuous discussions and collaboration on that subject so as to continue to establish a common ground for further work and an annual conference at the margins of the SCP as proposed in document SCP/20/11 Rev. The Delegation said that it shared the feeling that improving the capacity of intellectual property offices in developing countries was one of the important components for successful and mutually beneficial work sharing and collaboration and noted that such component could also be discussed in the context of annual conferences. The Delegation further stated that a WIPO webpage

dedicated to work sharing and collaborative activities, as proposed in document SCP/20/11 Rev., should be a part of the future work program. In its view, the webpage, which would include PPH work sharing initiatives in addition to other work sharing initiatives all over the world, could serve as a one-stop portal for applicants to get the information necessary to benefit from such initiatives. The Delegation noted that that contribution could only be achieved in a multilateral context. The Delegation stated that work sharing should be helpful since differences among intellectual property offices, including examiners' language skills and technological knowledge as well as available databases, could lead to different search results. For that reason, the Delegation said that a Secretariat study on those differences and how those differences could be overcome, as proposed by the Delegation of the United States of America, could form the basis of discussion at annual conferences and feed into the information to be posted onto the webpage that would be dedicated to work sharing initiatives. The Delegation stated that the inclusion of that element in the future work program could produce a synergistic effect. With regards to the questionnaire proposed by the Delegations of Canada, Denmark and the United Kingdom (document SCP/18/9), Group B believed that it should be part of the SCP's work program. At the current SCP session, the Delegation had heard different interpretations of quality of patents in addition to views that the definition was unclear and should be discussed within the Committee. The questionnaire proposed in document SCP/18/9 could feed into such discussions. The Delegation explained that the objective of that questionnaire included capacity building of patent offices at varying stages of development and the improved provision of technical assistance to patent offices as needed. With respect to the study on inventive step agreed upon at the twentieth session of the SCP, the Delegation looked forward to discussing the outcome at the twenty-second session of the SCP. Additionally, the discussion at the twenty-second session of the SCP could form the basis of future work on that subject matter at a future Committee. The Delegation also attached importance to the future work on the confidentiality of communications between clients and patent advisors. The Delegation said that the Committee should take substantive steps to concrete mechanisms that addressed the communication of foreign patent advisors privilege based on a soft law approach. The Delegation supported the proposal by the Delegation of Australia at the twentieth session for a Secretariat study on problems that limit or prevent the implementation of attorney privilege and the proposal by the Delegation of Japan at the current session that the Secretariat conduct a questionnaire survey on the attorney-client privilege in every country, including obstacles to the expansion of the privilege to other professionals. The Delegation looked forward to the proposal by the Delegation of Switzerland to be introduced at the twenty-second session. With respect to patents and health, the Delegation said that the Committee had to bear in mind that there were two aspects on the relationship between patents and health, namely access and innovation. The Delegation noted that patents were directly linked with the innovation aspect and indirectly linked with the access aspect. The future work program should take into account that relationship and should avoid a one-sided focus. The Delegation stated that a patent search in the pharmaceutical field was significantly different from other fields. For example, a chemical structure search or nucleotide sequence search was often required and the prior art was often found in non-patent literatures. That difference sometimes led to divergent sources of information for respective offices to access. The Delegation noted that given the nature of the field, work sharing could make more sense because the necessary prior art references could be collected in cooperation. The Delegation further noted that at the same time, it would allow respective patent offices to make their own proper decisions based on sovereignty. The Delegation therefore considered that the Secretariat study proposed by the Delegation of the United States of America during the current session was the right way forward. Further, the Delegation said that the studies in document SCP/17/11 as proposed by the Delegation of the United States of America could also serve to better the understanding of the matter. With respect to exceptions and limitations, the Delegation stressed the importance of not dealing with that

issue in a manner isolated from patent protection. In its opinion, the Committee should avoid sending the message that implementation of exceptions and limitations was unconditionally encouraged for development. The Delegation said that although the necessity of limited and specific exceptions were justified, a Secretariat evaluation of exceptions and limitations and the preparation of a manual under the name of WIPO were not the right way forward, given the aforementioned perspective. The Delegation considered that WIPO was not the right forum to discuss how exceptions and limitations under the TRIPS Agreement could be interpreted. With respect to technology transfer, the Delegation noted that future work should be considered only when the whole picture was clearly presented after the completion of work by the CDIP. The Delegation further stated that it maintained its concern regarding the duplication of work of the CDIP after hearing the Secretariat's explanation.

231. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, expressed its belief that the Committee could put together an SCP program that would advance the Committee's work and possibly take it to the next level and would give a clear signal to the users. The Delegation wanted to focus on elements that could be achieved. The Delegation stated that as far as the quality of patents was concerned, the CEBS Group saw it as the core of the SCP agenda. It believed that in order to go forward, the work of the Committee should move towards substantive patent law issues. The Delegation noted within the debates in the CEBS Group, it was pointed out that while studies and discussions were highly valued as a means to increase mutual understanding in different areas, it was work on concrete steps to be taken that would increase the quality of patents in the global context. The Delegation stated that the Committee had several proposals at its disposal, especially in the area of information sharing, work sharing and collaboration, which had been perfected over the years and which were ripe to be acted upon. The Delegation expressed support for the proposal on a questionnaire contained in document SCP/18/9 and the elements proposed in document SCP/20/11 Rev. With regards to the elements proposed in document SCP/20/11 Rev., which included annual conferences, the Delegation said that the growing number of international cooperation engagements led the CEBS Group to foresee more intensive involvement of its members in such conferences if given the chance. With regards to the area of confidentiality of communications between clients and patent advisors, the Delegation noted that it had listened very intently to the half day Seminar on the Confidentiality of Advice from Patent Advisors. While many interesting elements had been mentioned, in its view, one common message communicated to the Committee was the importance of, and the need for, solutions to the cross-border element for both users and holders of intellectual property rights and also for their advisors. The Delegation said that it was aware of the view that that issue was closely related to substantive aspects of patent law, as disclosure of information concerning new technical solutions was extremely sensitive. The CEBS Group expressed the opinion that the issue could only be resolved through international cooperation fully in line with the mandate of the SCP and WIPO. The CEBS Group had been supporting a soft law approach, which it saw as a reasonable and doable way forward. The Delegation proposed that the Secretariat conduct a study to describe and evaluate various types of soft law approaches feasible in that area with the aim to move forward. The Delegation clarified that with respect to all of the items on the agenda of the current SCP session, it did not and would not dismiss outright any proposal put forward by other delegations, and was ready to discuss them. However, the Delegation requested that all delegations take due account of the CEBS Group's proposals, which it had carefully selected with the aim to be pragmatic.

232. The Delegation of Italy, speaking on behalf of the European Union and its Member States, emphasized that in discussing future work, the work program should be balanced. Regarding the quality of patents, the Delegation stated that a work program should be established based on the proposals made by the Delegation of Denmark (document

SCP/17/7), the Delegations of Canada and United Kingdom (document SCP/17/8), the Delegation of the United States of America (document SCP/17/10) and by the Delegation of Spain and other Member States of the European Union (document SCP/19/5 Rev.). The Delegation stated that it remained in favor of launching a questionnaire containing the elements of all the proposals by the Delegations of Canada, the United Kingdom, Denmark and the United States of America. It reiterated the importance of further examining the inventive step concept as well as the method of evaluating inventive step in WIPO Member States. The Delegation was therefore looking forward to the study to be submitted to twenty-second session of the SCP on inventive step. With respect to opposition systems, the Delegation stated that the elaboration of a compilation of models of opposition systems and other administrative and revocation mechanisms in a non-exhaustive manner should be considered. On work sharing programs, the Delegation stated that a WIPO webpage dedicated to work sharing activities would improve awareness of existing initiatives and enable offices to collaborate more effectively. The Delegation further said that annual conferences on the margins of SCP sessions would allow for the sharing of experiences on work sharing programs and the exploration of ways to make those programs useful for intellectual property offices, to users of the intellectual property system and to the general public. A study by the Secretariat on how different laws and practices limited the potential for work sharing and what voluntary measures could be put in place to address any problems at the international level could assist in identifying areas where the efficiencies of the patent system could be improved. The Delegation noted that given the optional nature of the work sharing schemes, any national endeavors to improve the quality and efficiency of the patent system would not be hindered. In relation to the confidentiality of communications between clients and patent advisors, the Delegation stated that the time was ripe to consider a concrete mechanism to address the recognition of foreign patent advisor privilege. Without prejudice to existing national legislation and in order to ensure optimal flexibility, in its view, a soft law approach should be considered, aiming at conferring in Member States the same protection for communications between a client and its foreign patent advisor as for communications between a client and its national patent advisor. The Delegation stated that in relation to patents and health, while it understood the concern of developing countries and the LDCs, the Delegation emphasized that the mere existence of intellectual property rights on a product was not a barrier to, nor its absence a guarantee of, access to that product. The Delegation stated that any further work in that area should reflect a balanced approach, taking into account the various interfaces and factors of relevance to patents and health, and drawing, for instance, inspiration from the proposal by the Delegation of the United States of America (document SCP/17/11). On the topic of transfer of technology, referring to the Project on Intellectual Property and Technology Transfer: Common Challenges – Building Solutions reported to the thirteenth session of the Committee on Development and Intellectual Property, the Delegation said it was not in favor of launching new initiatives in the SCP until the completion of that project and a thorough follow-up analysis. Finally, as regards exceptions and limitations, the Delegation believed that although specific exceptions and limitations were justified, an evaluation of their impact on development by the Secretariat, and the preparation of a manual under the name of WIPO, was not the right way forward. The Delegation looked forward to a constructive discussion and remained committed to participating in establishing well-balanced work program.

233. The Delegation of Pakistan, speaking on behalf of the Asian Group, stated that it had carefully analyzed and discussed all the different proposals. It supported continuing discussions on all topics under discussion in the SCP. In general, the Asian Group agreed to carry forward the work on exceptions and limitations. The Asian Group expressed support for the analysis of the effectiveness of exceptions and limitations to address development issues and also the analysis of the questionnaire that had been compiled for the current SCP, which could lead to a possible manual. Regarding the quality of patents, the Asian Group

supported having further discussions in order to reach a definition that was agreeable to all. The Delegation also supported continuing discussions on technical assistance and capacity building of Member States to allow them to reach a competitive level in which they would be at the level to benefit from any exchange of knowledge and best practices. The Delegation stated that patents and health was a subject that the Asian Group held to be of essential importance, especially in resource-constrained countries. The Asian Group stated that it supported activities consisting of studies, information exchange and technical assistance in order to make full use of flexibilities. The Delegation also said that it supported a study on the relationship between patent systems and availability of essential medicines in developing countries and LDCs. Further, the Delegation was in support of continuing discussions among Member States on different proposals regarding confidentiality of communications between clients and patent advisors. Regarding transfer of technology, the Asian Group supported further studies on the failures of technology transfer arising from the patent system. The Delegation said that the exchange of ideas and the discussions in the current SCP session had been very fruitful and productive. It had allowed the Committee to have a better understanding of different points of views, which the Delegation believed would take the Committee forward toward arriving at a mutually agreeable decision on a number of topics taking into account the disparity in the development status of Member States. The Delegation said that it looked forward to contributing both in its national capacity and as a coordinator for the Asian Group.

234. The Delegation of Kenya, speaking on behalf of the African Group, noted that it had followed the deliberations during the current SCP session with interest. At the beginning of the current SCP session, the African Group noted that its understanding was that the discussions under various agenda items were purely for the sharing of experiences, and the Committee was not to make any recommendations of a norm-setting nature. The Delegation noted that despite that understanding, discussions under some agenda items had begun to take a norm-setting direction, which the African Group did not accept. The African Group was of the firm belief that discussions of attorney-client privilege were issues for national law and could not be the subject of norm-setting at the international level. The Delegation therefore did not support any norm-setting work in that area, whether soft law or a binding norm. On quality of patents, the Delegation said that it continued to question the relationship between work sharing and quality of patents, especially in the absence of a clear definition on the quality of patents. The Delegation therefore considered that the next SCP session should focus on the definition of quality of patents, given that the Committee already had an agreed work program in that area. On exceptions and limitations, the African Group said that it would like to build upon the work undertaken so far in the Committee and safeguard all the information by creating a dedicated webpage on all the studies and experiences that had been shared. In addition, the Delegation suggested that the Secretariat carry out technical assistance programs for developing countries, taking into account all exceptions and limitations practiced by all Member States. The Delegation also supported further work in that area based on the proposal by the Delegation of Brazil. Regarding patents and health, the Delegation suggested that the Committee adopt the proposal submitted by the Delegation of South Africa on behalf of the African Group and the DAG and implement it in full. In its opinion, that should be the starting point of the Committee's discussions on patent and health. In addition, the Delegation requested a revision of the study on the role of patents in promoting innovative medicines and facilitating transfer of technology, based on the comments made by Member States, especially those that were related to the work on R&D and access to medicine. Further, the Delegation requested an in-depth study on the disclosure of INN and a study on the impact of the exhaustion of patent rights in relation to the accessibility, quality and price of medicine. On transfer of technology, the Delegation believed that the SCP was the right forum for discussion on issues of transfer of technology,

and supported further studies on the failures in technology transfer arising from the patent system.

235. The Delegation of Paraguay, speaking on behalf of GRULAC, noted the importance of an inclusive and academic approach, which would allow the SCP to move forward with a fair and balanced agenda. The Delegation stated that as regards exceptions and limitations to patent rights, GRULAC would like to have an analysis of exceptions and limitations that had been proven effective in addressing development concerns, as well as the elaboration of an exceptions and limitations manual to serve as a reference for WIPO Member States. In addition, the Delegation stated that GRULAC had proposed the revision of the WIPO Model Law for Developing Countries on Inventions since it had not been revised since 1979. In view of the Delegation, such revision could include updates regarding, for example, the role of exceptions and limitations in implementation of public policies based on the discussions that had been held at the current SCP session. Regarding the issue of quality of patents, the Delegation stated that that it was necessary to move forward on that issue. It further noted two studies under that agenda item, namely a study on inventive step and a study on sufficiency of disclosure, which would be carried out for the following session of the SCP. The Delegation further expressed its support for carrying out capacity building and technical assistance activities to analyze the challenges faced by patent offices in developing countries. On the topic of patents and health, the Delegation stated that that GRULAC supported the idea of preparing a study on the effect of the patent system in the availability of medicines in developing countries and LDCs. GRULAC was also in favor of maintaining the issue of transfer of technology in the agenda of the Committee because that was an item that was part of the non-exhaustive list of issues to be considered for the work program of the SCP.

236. The Delegation of Peru supported the statement made by the Delegation of Paraguay on behalf of GRULAC. The Delegation further underlined the importance of having flexibility and a balanced agenda so that an agreement could be reached to guarantee the continuity of the work of the Committee. The Delegation noted that that for its Group, it was important that the future work included the revision of the WIPO Model Law for Developing Countries on Inventions of 1979. In the view of the Delegation, such revision should include, among others, issues such as transfer of technology and patents and health.

237. The Delegation of Egypt stated that that as regards the issue of exceptions and limitations to the rights, it endorsed the statement made by the Delegation of Kenya on behalf of the African Group. The Delegation further proposed creating a webpage that would include all the studies and seminars conducted on the issue of exceptions and limitations to the rights. In addition, the Delegation requested the Secretariat to include those exceptions and limitations in technical assistance programs in order to raise awareness about them. The Delegation further expressed its support for the proposal by the Delegation of Brazil regarding exceptions and limitations to patent rights, in particular, regarding the elaboration of a manual. With respect to the patents and health, the Delegation requested the full implementation of the African Group proposal contained in documents SCP/16/7 and SCP/16/7 Corr. Moreover, the Delegation looked forward to a further in-depth discussion on the issue of feasibility of INN disclosure in patent applications and/or patents. In particular, in that regard, the Delegation proposed to prepare a study on the best practices on how patent offices could search prior art using the INN. Further, regarding the issue of transfer of technology, the Delegation noted that that issue was included in the non-exhaustive list of issues to be considered by the Committee. Concerning the quality of patents, the Delegation wished to endorse the views of those delegations that considered that there was a lack of clarity regarding the relationship between the work sharing and the quality of patents, especially in the absence of a clear definition of the term "quality of patents". The

Delegation further proposed a thorough discussion on that definition to be held before moving forward on specific proposals on that agenda item. In conclusion, the Delegation stated that that it looked forward to constructive discussions on the two studies to be presented at the following session of the SCP, namely a study on inventive steps and a study on sufficiency of disclosure.

238. The Delegation of India supported the statement made by the Delegation of Pakistan on behalf of the Asian Group. In addition, the Delegation emphasized that on the issue of exceptions and limitations to the rights, it supported the proposal by the Delegation of Brazil. Regarding the quality of patents, the Delegation was of the view that work sharing programs should be discussed in the PCT Working Group, since discussions on that topic within the SCP constituted a duplication of work. Further, the Delegation stated that that it would like some work to be carried out in relation to opposition systems. In addition, the Delegation supported the views suggesting that the Committee should define the term “quality of patents” and discuss technical assistance and capacity building activities with respect to patent search and examination in developing countries. Moreover, the Delegation supported work on sufficiency of disclosure. With regard to the patents and health, the Delegation referred to the following sentence in document SCP/21/8 “[d]ue to the complexity and multifaceted nature of the topic, the study may not exhaust all relevant issues, which could be subject to further research”, and requested such further research to be carried out. In particular, the Delegation stressed that such further study should focus on the real impediments that the health care system faced under the product-patent regime. In addition, that study should also come to a conclusion regarding the role of patent systems in fostering the technology transfer necessary to make generic and patented medicines available in developing countries and LDCs. With regard to document SCP/21/9, the Delegation proposed a further study examining the question of the usefulness or advantage of a mandatory disclosure of INN when the applicant was fully aware of such INN. In addition, the Delegation insisted that that study should include a cost and benefit analysis of INN disclosure, particularly when important pharmaceutical compound was covered by Markush claims. Further, as regards Markush claims, the Delegation stated that the study should analyze: (i) barriers created with respect to availability of essential medicines to the public and whether the actual enablement of the compounds covered in Markush claims should be met in order to comply with the requirement of sufficiency of disclosure; and (ii) whether the compounds covered by Markush claims met the requirement of the industrial applicability or usefulness and what the actual scope of such claims should be. On transfer of technology, the Delegation reiterated its support for the study on the sufficiency of disclosure requirement. In its opinion, both the quality of patents and technology transfer were closely related to the sufficiency of disclosure requirement, and therefore, patent documents should serve as a stand-alone document for the seamless transfer of technology.

239. The Delegation of Pakistan stated that WIPO’s technical and legal assistance to countries should incorporate the issue of the exceptions and limitations to patent rights in order to raise awareness about their modalities. The Delegation expressed its strong support for the proposal made by the Delegation of Brazil to evaluate the responses to the questionnaire on exceptions and limitations. The Delegation stated that WIPO should conduct a study on the implementation of exceptions and limitations to address development concerns, including structural and practical difficulties in using exceptions and limitations. Regarding the quality of patents, the Delegation stated that a robust substantive examination, stricter patentability criteria and an effective opposition system improved quality of patents, and that the Secretariat should provide technical and legal assistance in that regard. The Delegation further requested the Secretariat to study the procedures and modalities of the use of different opposition systems prevailing in various jurisdictions, constraints in using those systems effectively and how to remove such constraints. On patents and health, the

Delegation supported the proposal submitted by the Delegation of South Africa on behalf of the African Group and the DAG contained in documents SCP/16/7 and SCP/16/7 Corr. The Delegation requested the Secretariat to provide technical assistance to developing countries and LDCs in order to enable them to amend and modify their patent laws in order to use public health related flexibilities. In its opinion, that was in line with Article 4 of the Cooperation Agreement between WIPO and the WTO, which clearly mandated WIPO to offer technical assistance on IP related matters. In the view of the Delegation, there was also a need of study on the impediments to the practical implementation of public health related flexibilities in developing countries and LDCs from technical and legal point of view. Regarding the issue of transfer of technology, the Delegation requested the Secretariat to set up an independent commission to further analyze failures in technology transfer due to patent-related impediments. The Delegation stated that the objective of those activities should be to: (i) identify flexibilities and measures available in the TRIPS Agreement on technology transfer; (ii) improve the understanding of policy makers of developing countries on the role of IPRs in technology transfer and experiences of developed countries in acquiring technology; (iii) build technological base, collating information on R&D policies of developed countries and identify appropriate policies that could be implemented by governments of developed countries and entities to facilitate technology transfer to entities in developing countries; and (iv) analyze the extent to which developed countries had fulfilled their commitments under Article 66.2 of the TRIPS Agreement. The Secretariat was also requested to provide information at the twenty-second session of the SCP on the involvement of the WIPO Secretariat in discussions on transfer of technology in the post-2015 Development Agenda in line with Goal 9 of the United Nations Sustainable Development Goals, which affirmed to build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation. In conclusion, the Delegation stated that while discussions should continue on confidentiality of communication between clients and their patent advisors, it did not support any norm-setting on that issue as it was a matter of national preference.

240. The Delegation of Iran (Islamic Republic of) supported the statement made by the Delegation of Pakistan on behalf of the Asian Group. In relation to exceptions and limitations to the rights, patents and health and transfer of technology, the Delegation supported the statements made by the Delegations of Kenya on behalf of the African Group, Egypt, India and Pakistan in its national capacity. Regarding the issue of quality of patents, the Delegation reiterated that the Committee still had no common ground regarding the term "quality of patents". In the view of the Delegation, a common understanding on the definition of that term was necessary in order to take further steps on the issue and before discussing a detailed work plan. Further, in relation to work sharing, the Delegation noted that work sharing was a unilaterally initiated activity and was not a substantive matter; it was a procedural matter, which fell outside the mandate of the SCP. As regards the confidentiality of communication between clients and their patent advisors, the Delegation was of the view that it was a matter of procedural law that fell outside the scope of the application of the patent law and outside of the mandate of the SCP and WIPO. Therefore, the Delegation did not support any norm-setting activities on that issue.

241. The Delegation of Montenegro associated itself with the statement made by the Delegation of the Czech Republic on behalf of the CEBS Group. Further, the Delegation stated that that quality of patents was an essential item on the agenda of the SCP and therefore, the Committee should move towards discussion of substantive patent law issues. As regards work sharing initiatives, the Delegation stated that that Montenegro had a small patent office, which did not carry out substantive examination; however, it fully supported the information sharing to improve patent quality that would be of benefit to both offices and applicants. In relation to the confidentiality of communication between clients and their

patent advisors, the Delegation stated that since the issue was deeply rooted in many countries' tradition, it supported a soft law approach.

242. The Delegation of the United States of America supported the statement made by the Delegation of Japan on behalf of Group B. Regarding document SCP/21/9 related to the feasibility of INN disclosure in patent applications and/or patents, in its opinion, the best way to address the difficulties in searching and examining chemical and pharmaceutical inventions was what was implicitly suggested in paragraph 57 of that study. The Delegation considered that a software-based system should be developed for carrying out the automatic identification, extraction and indexing of chemical data from patent documents. The Delegation was of the view that that would provide a simple and cost efficient way of searching those inventions using, for example, a non-INN or other chemical identifier. The Delegation observed that WIPO was well suited to oversee the development of the tools and databases necessary to implement such system. Therefore, the Delegation proposed that the SCP evaluate how best to develop and implement a system for the automatic identification, extraction and indexing of data from patent documents using, for example, chemical natural language and to provide tools that were accessible to everyone for searching chemical and pharmaceutical patents cost effectively. The Delegation suggested that once the proposed study identified a way forward on how to develop such software-based system, WIPO would implement it with the ultimate goal of making it freely available.

243. The Delegation of Brazil supported the statement made by the Delegation of Paraguay on behalf of GRULAC, and supported proposals to have further discussions on exceptions and limitations to the rights, patents and health and transfer of technology. As regards the quality of patents, the Delegation stated that a common definition of the term "quality of patents" was necessary to have a clear understanding on what the Committee was aiming at in discussing that issue.

244. The Delegation of India, in response to the statements made by some delegations on the possibility of developing software for automatic identification, extraction and indexing of chemical data from patent documents instead of the INN disclosure in patent applications, stated that while the development of such software would be useful, it questioned whether there would be any negative effect of indicating the INN in patent documents when it was available to the applicant at the time of filing.

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

246. During discussions on the future work of the SCP, some Delegations proposed changes to the Chairs' suggestions. Some Delegations noted they had exercised flexibility to the maximum extent possible. Some Delegations noted they could take into consideration changes to the suggested future work program proposed by some other Delegations.

247. The Delegation of Kenya expressed its concern regarding the balance of the future work program.

248. The Delegation of Japan, speaking on behalf of Group B, thanked the Chair, *ad hoc* Vice Chairs and Secretariat for their hard work in preparing the suggested future work program. Noting that striking a balance was always difficult, the Delegation said that the whole package was not a good balance for Group B, but that it was necessary for the Committee to have concrete items to continue work for the next session. From that spirit, the Delegation expressed that it had seriously and faithfully worked on the proposal that had been presented at the informal consultation instead of its own proposal. The Delegation

noted that although it had at first asked for many amendments, it had made a decision to go along with the Chair's proposal in order to let the Committee work for the next session and to continue to let WIPO conduct its work in line with its objectives.

249. The Delegation of Paraguay, speaking on behalf of GRULAC, thanked the Chair for his work. GRULAC noted that it had followed the Chair's instructions regarding an innovative approach to dealing with the issue of the program for future work. The Delegation noted that it, and all Delegations, had tried to work constructively. The Delegation stated that although there was some good work, it believed that GRULAC was prejudiced and was most affected by the proposal since its proposal to revise the 1979 WIPO Model Law for Developing Countries on Inventions as well as other proposals had not been examined by Member States. The Delegation felt that the proposed work program was unbalanced, as there were several aspects dealing with the quality of patents, including two studies the Committee had asked the Secretariat to prepare for the twenty-second session of the SCP in addition to a seminar on the definition of quality of patents and another on work sharing. The Delegation noted that with regards to exceptions and limitations, the future work program contained a compilation of experiences of Member States and case studies, which the Delegation thought was very little work. The Delegation remarked on the extreme importance of the Committee and of WIPO and expressed the need to reach a solution. The Delegation stated that the time had come to reach an agreement in the Committee in order to give a positive signal for the future.

250. The Delegation of Belarus, speaking on behalf of CACEEC, thanked the Chair for his hard work in providing the suggested future work program. The Delegation noted that it was not entirely happy with the suggested future work program, because in its view, more work should have been done on confidentiality, for example, to achieve a more balanced work program. The Delegation expressed its impression that the trouble of the Organization was that Member States were all obsessed with pursuing their own perception of balance. Since the Delegation said it was not inclined to follow that path, it endorsed the suggested future work program as it stood on behalf of CACEEC.

251. The Delegation of Pakistan, speaking on behalf of the Asian Group, expressed its appreciation for the hard work of the Chair, *ad hoc* Vice Chairs and the Secretariat. The Delegation joined other Delegations in stating that it was not ecstatic about the suggested future work program, but as a general impression, the Asian Group could live with it. The Delegation noted that members of the Asian Group had reservations about the suggested future work program, especially regarding balance including the number of seminars to be held.

252. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, expressed its thanks to the Chair for not giving up on a substantive work program. The Delegation noted it had eyed a substantive work program for the future work of the Committee, and to that end, the CEBS Group had worked hard during informal consultations and the plenary sessions on substantive items and future work. As for the word "balanced", mentioned by many delegations, the Delegation said that Member States should reflect on what it meant. For the sake of the Committee and the Organization, the Delegation stated that it endorsed the suggested future work program. It further noted that it had not coordinated with the CEBS Group members on the text of the suggested future work program, and that they could intervene in their national capacity. The Delegation stated that although it was not happy about the suggested future work programs as other delegations had said, that might be a good sign showing a significant element of compromise that contained something in common that Member States could live with.

253. The Delegation of Brazil thanked the Chair, the *ad hoc* Vice Chairs and the Secretariat for their hard work. The Delegation stated that it could not disagree with the statements of the Delegations of Paraguay on behalf of GRULAC and Kenya on behalf of the African Group that the suggested future work program was not balanced because of the heavy work on quality of patents, including opposition systems, and little progress on exceptions and limitations to patent rights. The Delegation noted that at the twentieth session of the SCP, the Committee had agreed to include a seminar on exceptions and limitations for the current SCP session. The Delegation further noted that, at the twentieth session of the SCP, the Committee had addressed the imbalance and had conducted discussions on all subjects. The Delegation believed that it was possible to reach a balance regarding the suggested future work program.

254. The Delegation of Iran (Islamic Republic of) thanked the Chair for his hard work in presenting the suggested future work program. The Delegation noted that it had some concerns regarding the suggested future work program.

255. The Delegation of Chile thanked the Chair and the *ad hoc* Vice Chairs for their work. The Delegation noted that the suggested future work program was a basis on which it could work. The Delegation further noted that there were a number of activities in the suggested future work program under the agenda item on quality of patents, including opposition systems. The Delegation expressed its interest in the elements in the suggested future work program on patents and health and transfer of technology.

256. The Chair submitted his revised suggestions on the future work of the SCP in writing, which were discussed by the Committee.

257. The Delegation of Paraguay expressed support for the revised suggested future work program and stated that it thought that the revised suggested future work program was a last-ditch attempt. The Delegation hoped that other delegations could show a last morsel of flexibility.

258. The Delegation of Japan stated that although some Delegations had noted that there were numerous activities under the agenda item on quality of patents, including opposition systems, in comparison to activities under other agenda items, the studies on inventive step and sufficiency of disclosure had been agreed upon at the twentieth session of the SCP. Further, the Delegation noted that the modification of a seminar on work sharing to discussions on work sharing had substantially narrowed the activities under that agenda item. The Delegation said that the purpose of the Committee was not negotiation for the sake of negotiation and that the Committee had a responsibility to do substantive work. The Delegation further noted that the Committee should not repeat what it had experienced two or three years ago. In its view, the revised suggested future work program had decreased in the amount of work compared to the previous suggestion, which was the second instance of a decrease in ambition and its interests. The Delegation stated that in order to save the bigger interests of WIPO, the Delegation had decided to accept the revised suggested future work program as a whole.

259. The Delegation of Pakistan, speaking on behalf of the Asian Group, noted that the meaning of balance was very relative for all Member States and within regions. The Delegation said that in the spirit of compromise and flexibility, the Asian Group would be able to live with the revised suggested future work program.

260. The Delegation of the Czech Republic, speaking on behalf of the CEBS Group, stated that the revised suggested future work program was as much of a compromise as it could

get. The Delegation noted that the revised suggested future work program was a landing point rather than a landing zone. Further, the Delegation noted that although it preferred a seminar on work sharing and collaboration, rather than discussions because it had found both seminars held during the current SCP session to be informative, it was willing to show extra flexibility and accept the revised suggested future work program.

261. The Delegation of Belarus, speaking on behalf of CACEEC, expressed appreciation for the relentless efforts of the Chair and Vice Chairs in steering the Committee toward a positive result. The Delegation expressed its readiness to extend flexibility one step further and join other regional groups in accepting the revised suggested future work program.

262. The Delegation of Kenya, speaking on behalf of the African Group, thanked the Chair and Vice Chairs for their tireless efforts in leading discussions so that the Committee could progress. The Delegation noted that the Committee had worked tirelessly, had conducted consultations in various configurations and had put forth a proposal from the three largest groups in the organization: the African Group, Asian Group and GRULAC. The Delegation further noted that it had offered a package that showed a lot of flexibility and good intentions to move the Committee's work ahead, which had been dismissed without further reflection. The Delegation felt that the revised suggested future work program was very imbalanced. The Delegation stated that although it took into account the fact that the studies on inventive step and sufficiency of disclosure had already been agreed by the Committee at its twentieth session, in order for the African Group to be comfortable, it needed an equivalent reflection of studies in other areas in which it had an interest. The Delegation noted that it had asked for a study on exhaustion and a study on Markush claims to make sure that there would be a balance. The Delegation stated that those had become red lines. The Delegation said that the African Group was disappointed because the Committee did not seem to be taking into account the seriousness of the health concerns and health disasters that had been happening in Africa, noting that the continuing Ebola disaster was a health issue. Observing that the disaster was a failure of the patent system, the Delegation stated that thousands were dying, yet the patent system and the Organization, which was supposed to cater to the African Group's interest, did not seem to care. The Delegation expressed its disappointment that although lives were being lost and people had to walk around with masks to bury their loved ones and could not touch the sick, the Committee had said that to strike a balance it could not have studies on serious issues of health. The Delegation noted that its people were dying, and if the patent system could not help its people live normal lives and enjoy what everyone was enjoying in other parts of the world, and that when advisories were issued stating those coming from Africa could not get a visa because there was Ebola in Africa, then the Committee should be concerned. The Delegation stated that although the African Group would like to show flexibility for the sake of moving forward, it could not show flexibility when its people were dying and nobody seemed to care. The Delegation expressed the opinion that if the patent system and the pharmaceutical industry could not work for all of the Member States, then the Committee should not pretend and use the word "balance". The Delegation stated that there was no balance when over 4,000 people had died, when there was a continuing disaster in Africa on public health and when Member States were afraid of shaking other people's hands. The Delegation also stated that there was no balance when the health system was ravished and health care workers were dead. In conclusion, the Delegation said that the African Group was not ready to accept the revised suggested future work program. The Delegation said the Committee needed to see flexibility to ensure that normal lives could be led and that the patent system did not become a hindrance to the survival of Africa. The Delegation noted the Committee needed to be serious. The Delegation said it did not see how one could sleep when other people were in distress. The Delegation expressed its thought that the world had become unequal and unbearable when people died and there was no feeling. The Delegation noted that even if it

was said that the African Group had become a problem, it was ready to be blamed for the sake of its people. The Delegation expressed its belief that the Committee should move forward taking into account what it faced in reality.

263. The Chair noted the support and solidarity of the international community with respect to the Ebola crisis. The Chair submitted further suggestions on the future work of the SCP under the agenda item on patents and health.

264. The Delegation of Kenya, speaking on behalf of the African Group, noted that the Proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group (documents SCP/16/7 and SCP/16/7 Corr.) contained an in-depth analysis involving INN and a study on Markush claims. The Delegation said that if the Committee could move forward in those two areas, it could begin to open the issue of health and to demystify the issue of medicine and the evergreening of patents. The Delegation expressed its impression that patents were granted with respect to small adjustments and information available to the public, for example, the INN provided by the WHO was not taken into account. Noting that small adjustments were made to create new drugs, the Delegation considered that INN provided as mandatory in patent applications for new drugs would assist in the ascertainment of whether the compound was new or not. Accordingly, in its view, it would unclog the system of evergreening of patents and would open research for new drugs. The Delegation reiterated that the African Group had asked for two studies in the area of public health, one on a further in depth analysis of INN and one on Markush claims. The Delegation stated that if that would be accepted by the Committee, the Delegation could live with the revised suggested future work program.

265. The Chair noted that the revised suggested future work program provided that the study on INN (document SCP/21/9) would be discussed at the twenty-second session of the SCP. The Chair raised the possibility of a discussion regarding a potential study on Markush claims at the twenty-second session of the SCP.

266. The Secretariat noted that since patent applications concerning pharmaceutical products sometimes contained Markush claims, they were referenced in document SCP/21/9 on a few occasions. The Secretariat said that it fully shared the interests of the SCP that the Committee addressed substantive patent issues that were of interest to all Member States. The Secretariat further noted that one of the challenges, particularly for developing countries, was to absorb the amount of information put on the table in an effective manner; it was not just a matter of asking the Secretariat to produce as many studies as possible. The Secretariat further noted its limited human resources to deliver all those studies of the quality the Committee deserved. The Secretariat said that, in its view, document SCP/21/9 was a thorough analysis of INN that would assist the needs of developing countries. While the Secretariat noted an option of adding more studies in the work program of the next session of the SCP, it expressed its doubt about delivering the two studies that had been agreed upon at the twentieth session of the SCP, plus the two studies requested by the Delegation of Kenya on behalf of the African Group, in the quality the Committee deserved. The Secretariat noted that the option that had been mentioned by the Chair might be a possibility of moving forward in a progressive manner. The Secretariat noted that at the twenty-second session of the SCP, the Committee, as in the revised suggested future work program, could continue discussions on INN. The Secretariat observed that at a certain point, the Committee would be able to address the issues that had been raised by the Delegation of Kenya on behalf of the African Group in which the membership of WIPO shared an interest.

267. The Delegation of Brazil said it wanted to add its voice to the concerns raised by the Delegation of Kenya on behalf of the African Group on the balance of the revised suggested

future work program. The Delegation noted that the revised suggested future work program contained four items under the agenda item on quality of patents, including opposition systems, and there were only two items under the agenda item on patents and health, which was clearly much less. The Delegation sought clarification regarding the revised suggested future work program under the agenda item on exceptions and limitations to patent rights. The Delegation recalled that at the twentieth session of the SCP, the Committee had faced the scenario of only one item on the agenda, which had been exceptions and limitations to patent rights. The Delegation said it had done a great deal to accommodate other requests from all Member States on the quality of patents, including opposition systems, and on the confidentiality of communications between clients and patent advisors. The Delegation understood that similar flexibility should be shown to the requests of developing countries, especially those that had been made by the African Group.

268. The Delegation of Japan, speaking on behalf of Group B, noted that the whole world took the crisis in Africa seriously. The Delegation further noted that, on the basis of an understanding that the revised suggested future work program was a take it or leave it approach, the Group tried to make maximum concessions. The Delegation expressed serious concern that the discussion was deviating from the originally intended last attempt of a take it or leave it approach. The Delegation noted that with regards to the two studies to be presented at the twenty-second session of the SCP, one had been proposed by Group B and the other study had been proposed by another regional group. The Delegation said it would be regrettable if the Committee lost the narrow landing point by failing to agree on the revised suggested future work program, which included a seminar on the relationship between the patent system and availability of medicines, in particular in developing countries and LDCs, which could be discussed from various perspectives. The Delegation considered that Member States should fulfil their responsibility to the Organization. The Delegation called upon the Committee to go along with the revised suggested future work program in order to let the Organization do no more than its usual work in line with its mandate.

269. The Delegation of the United Kingdom expressed its willingness to accept the revised suggested future work program as prepared by the Chair. The Delegation understood that it had been an attempt to find a middle ground solution. The Delegation expressed the need to show flexibility if there was a genuine interest that the work of the Committee continue. The Delegation further encouraged Member States to refrain from counting the number of activities and noted that the work should be valued from its quality and the real impact.

270. The Delegation of India expressed its support to combine a further study on INN along with the Markush claims because document SCP/21/9 acknowledged that Markush claims created impediments and because Markush claims and INN were very much related issues. Further, the Delegation said that document SCP/21/9 acknowledged the tremendous hardship on an examiner or any third party when the compound was typically buried in the Markush formula. The Delegation noted that a particular compound expressed in the Markush formula could be easily identified if it had been supported by a disclosure of INN. Considering the burden on both developing countries and developed countries to search Markush formula to fish out the active pharmaceutical ingredient, the Delegation expressed its support for the concerns raised by the Delegation of Kenya on behalf of the African Group.

271. The Chair offered suggestions regarding a possible way forward.

272. Some Delegations noted they would not be able to go along with the Chair's suggestions regarding a possible way forward. Some Delegations proposed changes to the revised suggested future work program. Some Delegations noted the importance of cost-efficiency with respect to the planning of the twenty-second session of the SCP. Some

Delegations expressed a willingness to work with all Member States in future sessions. Some Delegations expressed concern regarding the Committee's discussions that did not result in a desired conclusion. Some Delegations noted the importance of working together in order to make progress.

273. After some discussions, without prejudice to the mandate of the SCP, the Committee agreed that its work for the next session (SCP/22) be confined to fact-finding and not lead to harmonization at this stage, and the following two studies would be prepared by the Secretariat and submitted to the twenty-second session of the SCP as agreed at its twentieth session:

- (1) a study on inventive step that contains the following elements: the definition of the person skilled in the art, methodologies employed for evaluating an inventive step and the level of the inventive step; and
- (2) a study on sufficiency of disclosure that contains the following elements: the enabling disclosure requirement, support requirement and written description requirement.

AGENDA ITEM 11: SUMMARY BY THE CHAIR

274. The Chair introduced the Summary by the Chair (document SCP/21/11). Some Delegations noted the importance of a factual, neutral, uniform and succinct Summary by the Chair.

275. After some discussions, the Summary by the Chair (document SCP/21/11 Rev.) was noted.

276. 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.

277. The Chair closed the session.

278. In accordance with the procedure previously adopted by the Committee (see paragraph 276 above), Committee members and observers are invited to comment on this draft report, which is being made available on the SCP Electronic Forum. The Committee will be invited to adopt the report at its next session.

[Annex follows]

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